

The first human research in the world that analyzes the correlation between *matcha* (powdered green tea) and amyloid β levels in the brain

Clinical Trial to Evaluate the Dementia Prevention Effects of *Matcha*

ITO EN, Ltd. (President: Daisuke Honjo; headquartered in Shibuya-ku, Tokyo), Shimadzu Corporation (President & Chief Executive Officer: Teruhisa Ueda; headquartered in Kyoto City, Kyoto) and MCBI Inc. (Chief Executive Officer: Kazuhiko Uchida; headquartered in Tsukuba City, Ibaraki Prefecture), a start-up company originated from University of Tsukuba, have announced that these three parties have reached an agreement to jointly conduct a **clinical trial to assess *matcha's* inhibitory effects on the decline of cognitive function** targeting subjects with mild cognitive impairment (MCI), the pre-dementia stage, with a point of view to contribute to the prevention of dementia, which has become a social problem worldwide, by determining whether consumption of *matcha* exerts inhibitory effects on decline of cognitive function.

A report published by the Ministry of Health, Labor and Welfare reveals that the number of elderly people aged over 65 with dementia is expected to approach 7 million by 2025 (one in five persons), making the prevention of dementia an urgent social challenge.

Matcha is a beverage that has been enjoyed by Japanese people a long time. One of its components, theanine, has been reported to have stress-buffering as well as sleep-improving effects. Another component, tea catechins, has been reported to have an antioxidant effect and exert inhibitory effects on the decline of cognitive function.

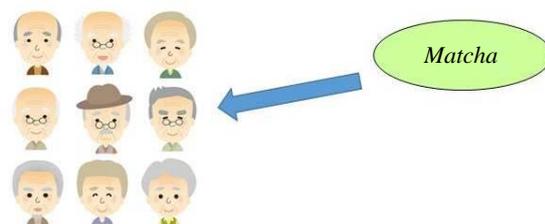
This clinical trial attempts to evaluate whether the consumption of *matcha* improves cognitive function by targeting subjects with mild cognitive impairment (MCI), the pre-dementia stage, or those in the pre-MCI stage (pre-MCI) with a view to create opportunities prevention of dementia through lifestyle improvement, such as diet, including beverages. It will be conducted over a one-year period. Approximately 200 million yen has been earmarked for the total budget. This is globally unprecedented research that will attempt to analyze the overall effects of the consumption of *matcha*. This clinical trial will analyze the results of a variety of cognitive function by several cognitive function tests with sleep evaluation, blood-based biomarkers, neuroimaging (fNIRS and amyloid PET) before and after the intervention.

In addition to the aforementioned three parties, Sochi-kai (Chief Director: Takashi Asada), a medical institution, and university hospital will participate in this clinical trial, as well as Hachiro Sugimoto, a visiting professor from Doshisha University who developed Aricept, the first therapeutic agent for Alzheimer type dementia in the world, and medical statistics experts as advisors.

Joint research between ITO EN, Shimadzu and MCBI

Research objective: Evaluate the *matcha's* dementia prevention effects

Subjects
 Sochi-kai, medical institute, and university hospital



- [Research group]
- ITO EN, Ltd.
 - Shimadzu, Corp.
 - MCBI, Inc.
 - A medical institute Sochi-kai (Chief Director: Takashi Asada)
 - Hachiro Sugimoto, a visiting professor (Doshisha University)
 - University hospital



Evaluations of blood-based biomarkers with kinetic analyses, amyloid PET, fNIRS, and various cognitive examinations

For inquiries concerning this clinical trial, contact Public Relations, Public Relations Department of ITO EN, Ltd.
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Descriptions of terms

Theanine

Theanine is a type of amino acid in tea leaves and is an ingredient in tea flavor. There is an abundant amount of theanine (2 to 4 times more than in regular green tea) particularly in tea leaves grown in shade (such as *matcha* and *gyokuro*, or refined green tea). Recent clinical studies have confirmed that theanine has physiological effects including an anti-stress effect, sleep improving effect, relaxation effect, and neuroprotective effect.

Tea catechins

Tea catechins are a type of polyphenol in tea leaves and a primary ingredient that produces the bitter taste of tea. Studies have confirmed that tea catechins have physiological effects, including an antioxidant effect, antiviral action, action of lowering cholesterol and action to suppress the elevation of blood glucose.

Mild cognitive impairment (MCI)

MCI is a precursor state of dementia, such as Alzheimer's disease. Those with MCI forget things frequently but do not have trouble carrying out daily activities. It is believed that 40% of those with MCI will develop dementia, such as Alzheimer's disease, after four years.

Pre-MCI

Pre-MCI is considered to be the earliest stage of dementia based on pathology and biomarkers, although the development of Alzheimer's disease and mild cognitive impairment (MCI) are not confirmed. While those with MCI do not exhibit clinical symptoms and their cognitive functions are normal, amyloid β deposition has already started.

fNIRS (functional Near-Infrared Spectroscopy)

fNIRS is a brain function imaging apparatus that shows changes in blood flow measured at multiple points, using near infrared light, which is mostly transparent in living bodies. fNIRS stands out from other technologies designed for the visualization of brain functions because it facilitates the measurement of brain activity in a somewhat natural, safe environment.

Amyloid PET

Amyloid PET imaging is an imaging diagnosis method based on positron emission tomography (PET) imaging of amyloid that enables the visualization of amyloid β accumulated in the brain.

Amyloid β

Amyloid β deposition (senile plaques) indicates the pathological lesions induced by Alzheimer's disease. Amyloid β also indicates neurotoxicity. The abnormal production and accumulation of Amyloid β is believed to be closely associated with the development of Alzheimer's disease.