

# BrainFit-Nutrition: Intervention study for people with mild cognitive impairment using computerised cognitive training tools and a nutrition intervention

<b>Submission date</b> 19/10/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/12/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

With increasing life expectancy, the number of older people suffering from cognitive impairments increases. Mild cognitive impairment (MCI) often results in dementia (about 15% of people with MCI will eventually have dementia). Currently, there is no drug treatment for the primary prevention of dementia.

Studies show that cognitive training can improve the cognitive abilities of people with MCI. Computerized cognitive training (CCT) offers several advantages over traditional paper-and-pencil cognitive training and has the potential to be more individualized by matching task difficulty with individual performance. Recent reviews have reported promising effects of CCT on improving the cognitive capacities of people with MCI.

Several studies have indicated positive effects of predominantly whole food, plant-based diets on cognitive functions. A current analysis of a study of the German Center for Neurodegenerative Diseases confirmed a Mediterranean diet as protective against cognitive impairment and dementia. In addition, plant-based diets have been shown to be successful in the treatment of chronic diseases associated with a higher prevalence of dementia.

This study investigates the effects of CCT and nutrition on cognition. There are two CCT groups: an 'individualized' CCT (iCCT) specialized for people with MCI that automatically matches task difficulty with individual performance, and a 'basic' CCT (bCCT). There are two nutrition intervention groups: an anti-inflammatory, neuroprotective, whole-food, plant-based diet and a diet recommended by the DGE (German Nutrition Society). The primary aim is to prove that the MCI-specialized CCT combined with a whole-food, plant-based diet will lead to better results in cognitive abilities than the other conditions. The secondary aims are to prove that a) compared with the basic CCT the MCI-specialized CCT will lead to better cognitive abilities and b) compared to the DGE-recommended diet the whole food, plant-based diet, will lead to better cognitive abilities.

### Who can participate?

Community-dwelling people aged 60 years and above with MCI

What does the study involve?

This study compares two CCTs, MCI-specialized CCT and basic CCT, and two nutrition interventions, a whole-food, plant-based diet and a diet recommended by the DGE (German Nutrition Society). Participants are randomly allocated to one of these four groups. Both CCTs can be used from home with a computer, laptop or tablet. Participants can use the digital intervention as often as they wish over the duration of the study (6 months). Both nutritional intervention groups receive ongoing online group counselling every 14 days over the duration of the study, either on a whole-food, plant-based diet or according to the recommendations of the DGE, respectively.

What are the possible benefits and risks of participating?

The CCT might have an impact on existing excessive computer use. However, the cognitive training is not oriented on motivational or emotional components. The digital training requires cognitive performance which will lead to exhaustion. The negative effects of nutrition interventions are rare and relatively small. The following unwanted effects can occur: a feeling of heat, different mouth and/or body odour, constipation, diarrhea, flatulence, stomach cramps, nausea and vomiting

With the CCT, the researchers expect to stabilize cognitive performance. In the long run, it is expected that it will help older adults with MCI to remain independent. Also, it may delay the shift from MCI to dementia. Additionally, the researchers expect positive effects on other non-cognitive aspects and quality of life. Participants of both of the nutrition intervention groups receive a potentially effective and equivalent intervention. Therefore, there is a predictable possible benefit of participating in the study.

Where is the study run from?

1. Center for Health Services Research, University Hospital Erlangen (Germany)
2. Complementary and Integrative Medicine Group of the Institute of Social Medicine, Epidemiology and Health Economics, Charité - Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?

June 2021 to May 2024

Who is funding the study?

Karl und Veronica CarstensStiftung (Germany)

Who is the main contact?

1. Prof. Elmar Graessel  
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2. PD Dr. Christian Kessler  
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## Contact information

**Type(s)**

Scientific

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Protocol serial number**

21-318\_1-B

## **Study information**

### **Scientific Title**

Computerised cognitive training tools and online nutritional group counselling for people with mild cognitive impairment: Study protocol of a completely digital, randomised, controlled trial

### **Acronym**

BrainFit-Nutrition

### **Study objectives**

Current hypothesis as of 29/12/2021:

Primary hypothesis I:

Individualised CCT will lead to statistically significantly greater improvements in cognitive capacities during the intervention period of six months compared with basic CCT.

Primary hypothesis II:

Online nutritional group counselling focusing on a WFPB diet will lead to statistically

significantly greater improvements in cognitive capacities during the intervention period of 6 months compared with online nutritional group counselling focusing on a healthy diet recommended by the German Nutrition Society.

Secondary hypothesis:

Individualised CCT in combination with online nutritional group counselling focusing on a WFPB diet will have a positive interaction effect. The group with iCCT in combination with online nutritional group counselling focusing on a WFPB diet will show more cognitive improvements than all other groups during the intervention period of six months in people with MCI.

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Previous hypothesis:

Primary hypothesis: Individualized computerized cognitive training (CCT) and a whole-food, plant-based diet have a positive interaction effect. The group with individualized CCT and a plant-based diet show more cognitive improvements than all other groups.

Secondary hypothesis: Individualized CCT will lead to statistically significantly greater improvements in cognitive capacities during the intervention period of 6 months in people with mild cognitive impairment (MCI) as compared with basic CCT.

Tertiary hypothesis: A whole-food, plant-based diet will lead to statistically significantly greater improvements in cognitive capacities during the intervention period of 6 months in people with MCI as compared to the DGE (German Nutrition Society)-recommended diet.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 21/09/2021, Friedrich-Alexander-University Erlangen-Nürnberg Ethics Committee (Krankenhausstraße 12, 91054 Erlangen; +49 (0)9131 85-22270; ethikkommission@fau.de), ref: 21-318\_1-B

### **Study design**

Prospective double-blind randomized controlled intervention study

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Mild cognitive impairment (MCI)

### **Interventions**

An external department will create randomization lists (Institute of Medical Informatics, Biometry, and Epidemiology, Friedrich-Alexander University Erlangen-Nürnberg, Waldstraße 6, 91054 Erlangen).

Participants are randomly allocated into one of four groups with two intervention variables (BrainFit and Nutrition):

1. BrainFit: two versions of computerized cognitive training: individualized (iCCT), which involves targeted exercises for memory span, information processing, visual-spatial cognition, etc, and basic (bCCT), which involves basic exercises for memory span, information processing, visual-spatial cognition, etc
2. Nutrition: two types of nutritional intervention: an anti-inflammatory, neuroprotective, whole-food, plant-based diet and a diet recommended by the DGE (German Nutrition Society)

Both CCTs (iCCT and bCCT) can be used from home with a computer, laptop or tablet. Participants can use the digital intervention as often as they wish over the duration of the trial (6 months). Both nutritional intervention groups receive ongoing online group counselling every 14 days over the duration of the trial, either on a whole-food, plant-based diet or according to the recommendations of the DGE, respectively.

### **Intervention Type**

Mixed

### **Primary outcome(s)**

Current primary outcome measure as of 26/01/2024:

1. Cognition measured by the Montreal Cognitive Assessment (MoCA) at baseline and after 6 and 12 months

Previous primary outcome measures from 06/12/2021 to 26/01/2024:

1. Cognition measured by the Montreal Cognitive Assessment (MoCA) at baseline and after 6 months
2. Cognition measured by the computerised cognitive test battery (ccTB) integrated in the digital software at baseline and after 6 and 12 months

Original primary outcome measure:

Cognition measured by the Montreal Cognitive Assessment (MoCA) at baseline and after 6 months

### **Key secondary outcome(s)**

Current secondary outcome measures as of 26/01/2024:

1. Cognitive function measured by the Mini-Mental State Examination (MMSE) at baseline and after 6 and 12 months
2. Cognition measured by reaction time and logical thinking assessments delivered and collected by the digital software (cctb) at baseline and after 1, 2, 3, 4, 5 and 6 months
3. Depression measured by the Patient Health Questionnaire 9 (PHQ-9) at baseline and after 6 and 12 months
4. Activities of daily living measured by the Bayer Activities of Daily Living Scale (B-ADL) at baseline and after 6 and 12 months

Previous secondary outcome measures from 06/12/2021 to 26/01/2024:

1. Cognitive function measured by the Mini-Mental State Examination (MMSE) at baseline and after 6 and 12 months
2. Depression measured by the Patient Health Questionnaire 9 (PHQ-9) at baseline and after 6 and 12 months
3. Activities of daily living measured by the Bayer Activities of Daily Living Scale (B-ADL) at baseline and after 6 and 12 months

Previous secondary outcome measures from 24/11/2021 to 06/12/2021:

1. Cognition measured by the Mini-Mental Status Examination (MMSE) at baseline and after 6 and 12 months
2. Cognition measured by reaction time and logical thinking assessments delivered and collected by the digital software at baseline and after 1, 2, 3, 4, 5 and 6 months

Original secondary outcome measures:

Cognition measured by the Mini-Mental Status Examination (MMSE) at baseline and after 6 and 12 months to detect the conversion rate to dementia

### **Completion date**

31/05/2024

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 24/11/2021:

1. Mild cognitive impairment:
  - 1.1. Montreal Cognitive Assessment score  $\leq 24$
  - 1.2. Mini Mental State Examination score  $\geq 24$
2. The digital applications and examinations require a PC with a microphone and camera (Windows/Linux/macOS), laptop or an Android tablet and basic skills in their use and access to the internet
3. Age  $\geq 60$  years
4. Informed consent given

Previous inclusion criteria:

1. Mild cognitive impairment:
  - 1.1. Montreal Cognitive Assessment score  $\leq 24$
  - 1.2. Mini Mental State Examination score  $\geq 24$
2. No depression (Patient Health Questionnaire [PHQ]-9  $< 12$ )
3. The digital applications and examinations require a PC with a microphone and camera (Windows/Linux/macOS), laptop or an Android tablet and basic skills in their use
4. Age  $\geq 60$  years
5. Informed consent given
6. Subjective impairment of short-term memory

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

60 years

### **Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

271

**Key exclusion criteria**

1. Completely blind or deaf
2. No personal computer, laptop or tablet
3. Normal cognition, Montreal Cognitive Assessment score >24
4. Dementia, Mini Mental Status Examination score <24
5. Depression, Patient Health Questionnaire 9 score  $\geq 12$
6. Diagnosis of another disease that causes cognitive impairment:
  - 6.1. Psychosis (schizophrenia, mania, bipolar psychosis)
  - 6.2. Parkinson's disease
  - 6.3. Multiple sclerosis
  - 6.4. Multiple strokes
  - 6.5. Alcohol abuse/drug consumption (addiction)
  - 6.6. Severe brain disease (tumor, injury, hydrocephalus)
  - 6.7. Severe vitamin B deficiency

**Date of first enrolment**

03/01/2022

**Date of final enrolment**

30/09/2022

**Locations****Countries of recruitment**

Germany

**Study participating centre****University Hospital Erlangen**

Department of Psychiatry and Psychotherapy  
Center for Health Services Research in Medicine  
Friedrich-Alexander-University Erlangen-Nürnberg  
Schwabachanlage 10  
Erlangen  
Germany  
91054

**Study participating centre****Charité - Universitätsmedizin Berlin**

Institute of Social Medicine, Epidemiology and Health Economics  
Complementary and Integrative Medicine Group

Königstraße 63  
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14109

## Sponsor information

### Organisation

Karl und Veronica Carstens-Stiftung

### ROR

<https://ror.org/00w6s5b11>

## Funder(s)

### Funder type

Charity

### Funder Name

Karl und Veronica Carstens-Stiftung

### Alternative Name(s)

Carstens-Stiftung

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Germany

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not expected to be made available

### Study outputs

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>		24/05/2025	27/05/2025	Yes	No
<a href="#">Protocol article</a>		01/07/2022	04/07/2022	Yes	No
<a href="#">Other publications</a>	User experience	10/12/2025	30/12/2025	Yes	No
<a href="#">Participant information sheet</a>			25/10/2021	No	Yes
<a href="#">Participant information sheet</a>	in German version 2	17/11/2021	23/11/2021	No	Yes
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes