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

Submission date
19/10/2021

Recruitment status
No longer recruiting

Registration date
23/11/2021

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Study website
https://www.brainfit-nutrition.de/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2021

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 ≤24
1.2. Mini Mental State Examination score ≥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 ≥60 years
4. Informed consent given

Previous inclusion criteria:
1. Mild cognitive impairment:
1.1. Montreal Cognitive Assessment score ≤24
1.2. Mini Mental State Examination score ≥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 ≥60 years
5. Informed consent given
6. Subjective impairment of short-term memory

Participant type(s)
Patient

Age group
Senior

Lower age limit
60 Years

Sex
Both

Target number of participants
200

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 ≥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
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Study participating centre
Charité - Universitätsmedizin Berlin
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Sponsor information

Organisation
Karl und Veronica Carstens-Stiftung

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Sponsor type
Charity

Website
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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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The researchers plan to submit the study protocol to a journal by the end of 2021.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available because the researchers assure in the participant information sheet that data will not be passed to any third party.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/10/2021	No	Yes
Participant information sheet	in German version 2	17/11/2021	23/11/2021	No	Yes
Protocol article		01/07/2022	04/07/2022	Yes	No
Results article		24/05/2025	27/05/2025	Yes	No