ISRCTN14437015 https://doi.org/10.1186/ISRCTN14437015

Dementia prevention for older people suffering from mild cognitive impairment using computerised cognitive training tools

Submission date
31/01/2020

Recruitment status
No longer recruiting

Registration date
27/02/2020

Overall study status
Completed

Last Edited
17/10/2024

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 pharmacological therapy in primary prevention of dementia. Studies show that everyday motor or cognitive activations can reduce the risk of dementia to a limited extent.

The primary aim is to prove that compared with the standard digital training the MCI specialized digital training will lead to better results in cognitive abilities. The secondary aim is to improve or at least stabilize cognitive performance for a relevant period with a specialized digital cognition training. With this training we attempt to “noticeably” delay the rate of people who shift from MCI to dementia and thus we try to reduce the conversion rate.

Who can participate?
We focus on community-dwelling people with MCI who use a PC, laptop or tablet.

What does the study involve?
The goal is to develop a digital cognitive training that can be used from home with a computer, laptop or tablet. We compare two digital trainings: MCI specialized digital cognitive training and standard cognitive digital training. Participants are randomly allocated to one of these two groups.

What are the possible benefits and risks of participating?
The digital cognitive training might have an impact on existing excessive computer use. However, the cognitive training that we developed is not oriented on motivational or emotional components. The digital training requires cognitive performance which will rather lead to exhaustion.

With the digital cognitive training, we expect to stabilize cognitive performance. In the long run, we expect that it will help older adults with MCI to remain independent. Also, we expect to delay

the rate of people who shift from MCI to dementia. Additionally, we expect positive effects on other non-cognitive aspects and quality of life.

Where is the study run from?
The Center for Health Services Research, University Hospital Erlangen (Germany)

When is the study starting and how long is it expected to run for?
March 2019 to July 2021, with open-ended, yearly follow up

Who is funding the study?
Reinhard Frank-Stiftung (Germany)

Who is the main contact?
Prof. Elmar Graessel
elmar.graessel@uk-erlangen.de

Contact information

Type(s)
Scientific

Contact name
Prof Elmar Graessel

Contact details
Center for Health Services Research
Schwabachanlage 6
91052 Erlangen
Germany
Erlangen
Germany
91054
+49 91318534142
elmar.graessel@uk-erlangen.de

Additional identifiers

Study information

Scientific Title
Individualised computerised cognitive training for community-dwelling people with mild cognitive impairment

Study objectives
Current study hypothesis as of 14/12/2020:
Primary hypothesis: Individualised CCT will lead to statistically significantly greater improvements in cognitive capacities over time in people with MCI as compared with basic CCT.
Exploratory study question: In an open phase of the study we will investigate long-term cognitive status yearly.

———

Previous study hypothesis as of 23/06/2020:
Primary hypothesis: Individualised CCT will lead to statistically significantly greater improvements in cognitive capacities over time in people with MCI as compared with basic CCT.
Secondary hypothesis: With individualised CCT, the rate at which people progress from MCI to dementia will be slowed.

_____

Previous study hypothesis:
Compared with the standard cognitive digital training the MCI specialized digital training will lead to better results in cognitive abilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/03/2020, Friedrich-Alexander-University Erlangen-Nürnberg Ethics Committee (Krankenhausstraße 12, 91054 Erlangen; +49 9131 85-22270; ethikkommission@fau.de), ref: 58-20 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
Current interventions as of 23/06/2020:
The goal is to develop a specialized digital cognitive training for persons with MCI that can be used from home with a computer, laptop or tablet. Study participants can use the digital intervention as often as they wish over the duration of the trial (6 months).

Participants are randomly allocated into one of two groups:
1. Intervention group: Individualised computerised cognitive training, which involves targeted exercises for memory span, information processing, visual-spatial cognition, etc.
2. Control group: basic computerised cognitive training, which involves basic exercises for memory span, information processing, visual-spatial cognition, etc.

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

_____
Previous interventions:

The goal is to develop a specialized digital cognitive training for persons with MCI that can be used from home with a computer, laptop or tablet. Study participants can use the digital intervention as often as they wish over the duration of the trial (6 months).

Participants are randomly allocated into one of two groups:
1. MCI specialized cognitive training, which involves targeted exercises for memory span, information processing, visual-spatial cognition, and etc.
2. standard cognitive training, which involves basic exercises for memory span, information processing, visual-spatial cognition, and etc.

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

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 14/12/2020:
Cognition measured by the Montreal Cognitive Assessment (MoCA) at baseline and after 6 months

_____

Previous primary outcome measure as of 23/06/2020:
Cognition measured by the Montreal Cognitive Assessment (MoCA) at baseline and after 6 and 12 months

_____

Previous primary outcome measure:
Cognition measured by the Montreal Cognitive Assessment (MoCA) and Syndrom-Kurz-Test (SKT) at baseline and after 6 months

Key secondary outcome(s))
Current secondary outcome measures as of 14/12/2020:
1. 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 and by the Mini-Mental Status Examination (MMSE) at baseline and after 6 months

Exploratory outcome measures:
Long-term cognitive status assessed using the Montreal Cognitive Assessment (MoCA) and the Mini-Mental Status Examination (MMSE), yearly in the open phase

_____

Previous secondary outcome measures as of 23/06/2020:
1. 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, Mini-Mental Status Examination (MMSE) at baseline and after 6 months
2. Long term cognitive decline assessed using the Mini-Mental Status Examination (MMSE) to analyse the conversion to dementia up to 3 years

_____

Previous secondary outcome measures as of 25/03/2020:
1. 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, Mini-Mental Status Examination (MMSE) at baseline and after 6 months
2. Functional anatomical changes assessed by medical imaging techniques such as cMRT of the subgroup involved at baseline and 6 months
3. Long term cognitive decline assessed using the Mini-Mental Status Examination (MMSE) to analyze the conversion to dementia at 1, 2, 3, 4 and 5 years

_____

Previous secondary outcome measures as of 18/03/2020:
1. 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, Mini-Mental Status Examination (MMSE) at baseline and after 6 months
2. Non-cognitive symptoms measured by a self-created instrument based on the Neuropsychiatric Inventory and the Mild Behavioral Impairment Checklist
3. Functional anatomical changes assessed by medical imaging techniques such as cMRT of the subgroup involved at baseline and 6 months
4. Long term cognitive decline assessed using the Mini-Mental Status Examination (MMSE) to analyze the conversion to dementia at 1, 2, 3, 4 and 5 years

_____

Previous secondary outcome measures:
1. 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, Mini-Mental Status Examination (MMSE) at baseline and after 6 months
2. Functional anatomical changes assessed by medical imaging techniques such as cMRT of the subgroup involved at baseline and 6 months
3. Long term cognitive decline assessed using the Mini-Mental Status Examination (MMSE) to analyze the conversion to dementia at 1, 2, 3, 4 and 5 years

Completion date
31/03/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/06/2020:
1. Mild cognitive impairment
1.1. Montreal Cognitive Assessment score <24
1.2. Mini Mental State Examination score ≥24
2. Own computer/laptop/tablet and basic skills in their use
3. Age ≥ 60
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. Own computer/laptop/tablet and basic skills in their use
3. Age > 55
4. Informed consent given

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
89

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. Apparent neurological diseases and/or other severe psychiatric diseases

Date of first enrolment
09/06/2020

Date of final enrolment
31/01/2021

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

Sponsor information

Organisation
Reinhard Frank-Stiftung

Funder(s)

Funder type
Charity

Funder Name
Reinhard Frank-Stiftung

Results and Publications

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 we 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?
Results article		15/10/2024	17/10/2024	Yes	No
Protocol article		05/05/2022	06/05/2022	Yes	No
Participant information sheet	version V1	07/02/2020	27/02/2020	No	Yes
Participant information sheet	version V2	10/03/2020	18/03/2020	No	Yes