

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/10/2024	Condition category 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 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

See additional files (in German)

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2019

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

Age group

Senior

Sex

Both

Target number of participants

100

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

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Sponsor information

Organisation

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Sponsor type

Charity

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Funder(s)

Funder type

Charity

Funder Name

Reinhard Frank-Stiftung

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2022

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?
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
Protocol article		05/05/2022	06/05/2022	Yes	No
Results article		15/10/2024	17/10/2024	Yes	No