Alzheimer Europe

*Making dementia a priority:*
*changing perceptions, practice and policy.*

# CLINICAL TRIALS WATCH

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## MET-FINGER STUDY

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# MET-FINGER study

| 1. Study Information | |
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| **Name of the study** | METformin and FINGER intervention to prevent cognitive impairment and disability in older adults at risk for dementia |
| **Study sponsor** | Imperial College London |
| **Disease** | At risk of developing dementia |
| **Phase** | Phase IIb |

| 2. Information about the intervention that will be tested in the study | |
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| **Name of intervention** | FINGER 2.0 multidomain intervention, combining healthy lifestyle changes and a drug for diabetes (metformin), where appropriate. |
| **Administration** | The multidomain intervention is a lifestyle intervention consisting of four main lifestyle components (diet, physical activity, cognitive training, and cardiovascular/metabolic risk monitoring) as well as a social interaction (through group meetings/sessions). Participants who also have an increased risk for diabetes will additionally take metformin tablets once a day (oral administration). |
| **Is the intervention already on the market for another medical condition?** | Yes - Metformin is used for the treatment of diabetes. |
| **Will all participants receive the same intervention?** | Participants will be selected by chance to receive one of the following options:<br>• Self-guided multidomain lifestyle intervention (participants build their own healthy lifestyle program based on standard healthy lifestyle advice on diet, physical activity, cognitive training and cardiovascular/metabolic risk)<br>• FINGER 2.0 multidomain lifestyle-based intervention (participants will receive a structured intensive lifestyle intervention through individual consultations and group meetings/sessions).<br>Participants in the FINGER 2.0 intervention who have an increased risk of diabetes (but do not have diabetes) will be further selected by chance to receive one of the following treatments:<br>• Metformin 2000mg/day |

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| | • Metformin 1000mg/day<br>• Placebo (also called a dummy treatment; the tablets of placebo are identical in appearance to the tablets containing metformin, but do not contain the active ingredient metformin and, thus, have no therapeutic effect).<br><br>Neither the participant nor the research team will know what metformin/placebo treatment the participants is receiving. |

| **3. Information about participating in the trial** | |
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| **What are the researchers trying to find out?** | • The purpose of the study is to test the FINGER 2.0 multidomain intervention to prevent cognitive impairment in people with modifiable risk factors for dementia. |
| **How long will the treatment last?** | • 24 months (four assessments visits at 0, 6, 12 and 24 months). |
| **What your involvement will entail?** | During the study, participants will be asked to complete:<br><br>• Tests that will assess their cognition including memory, verbal learning, executive functions<br><br>• Tests and questionnaires that will assess their functioning level in daily life (e.g., CDR, scales to assess Activity of Daily Living)<br><br>• Questionnaires to report about their lifestyle and habits, mood, physical and health status<br><br>• Medical check-ups including some laboratory/biological tests (e.g., blood samples, blood pressure)<br><br>• A hearing test.<br><br>Further information on the number of visits can be obtained from the study team. |

## 4. Who can participate in this study?

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| **Who can participate in the study?** | To take part in the study, all participants must:<br>• Be 60 to 79 years old<br>• Have a CAIDE risk score (a validated tool estimating dementia risk) of 6 or above. This would suggest the presence of modifiable risk factors for dementia<br>• Have cognitive performance at the mean level or slightly lower than expected for age according to the Montreal Cognitive Assessment (MoCA) and the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) verbal learning test<br>• Ability to communicate in the local language (English, Finnish or Swedish).<br><br>To be eligible for the metformin/placebo treatment, participants in the FINGER 2.0 intervention must have:<br>• No diagnosed diabetes, no suspected diabetes at the beginning of the trial, and no known contraindications to metformin treatment<br>• Elevated adiposity (accumulation of body fat) or mildly impaired fasting glucose (mild inability to control blood glucose levels). |
| **Who cannot participate in the study?** | Exclusion criteria include:<br>• Dementia, substantial cognitive impairment, or diminished decision-making capacity<br>• Current or previous treatment with medication for Alzheimer's disease (e.g., cholinesterase inhibitors, memantine, aducanumab)<br>• A neurologic disease or conditions that may interfere with the safety, tolerability and/or study assessments (e.g. Parkinson's disease, Huntington's disease, brain tumour, progressive, supranuclear palsy, seizure disorder, subdural hematoma, multiple sclerosis) |

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| | • Any other condition affecting safe engagement in the lifestyle intervention (e.g., current cancer undergoing treatment, major depression, symptomatic cardiovascular disease).<br><br>• Severe loss of vision, hearing, or communicative ability.<br><br>The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study. |

| **5. Where and when will the study be conducted?** | |
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| **European countries involved in the trial** | • UK (Imperial College London, London)<br>• Finland (Finnish Institute of Health and Welfare, Helsinki)<br>• Sweden (FINGERS Brain Health Institute, Stockholm)<br><br>The participants will be primarily recruited from large existing registers/biobanks at each of the trial sites, with already available data (including APOE genotype) that can be used for pre-screening. |
| **Estimated start date of recruitment** | January 2023 |

| **6. Information for your doctor** | | | |
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| **EU CT Number** | 2022-500438-27-01 | **Clinicaltrials.gov identifier** | NCT05109169 |
| **Study contact information** | Imperial College London:<br>metfinger.study@imperial.ac.uk<br><br>THL – The Finnish Institute for Health and Welfare:<br>met-finger@thl.fi<br><br>Karolinska University Hospital:<br>met-finger.karolinska@regionstockholm.se | | |
| **Link to full text** | https://clinicaltrials.gov/ct2/show/NCT05109169<br>https://euclinicaltrials.eu/ctis-public/view/2022-500438-27-01 | | |

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on November 2024.
- ✓ The trial has been reviewed by the academic institution sponsoring the trial. This document has not been reviewed by the pharmaceutical company providing the medication (Metformin) used in this trial.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.