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Prevention of dementia using mobile phone applications

Submission date	Recruitment status	[X] Prospectively registered
19/06/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
24/06/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/07/2025	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

The projected steep rise in global dementia prevalence from an estimated 40 million today to around 100 million by 2050 will largely occur in low and middle income countries and vulnerable populations in high income countries. Up to 30% of all dementia is attributable to potentially modifiable risk factors. This offers a large window of opportunity for dementia prevention. By encouraging self-management of risk factors populations can be empowered to create a feeling of ownership over their own health. This empowerment increases adherence to preventive interventions, including healthy behaviours, without the necessity of frequent doctor visits. The rapidly increasing global penetrance of internet access via mobile devices such as smartphones brings preventive health care, within reach for large groups of people who are otherwise deprived of preventive medical care. In addition to its scalability, mobile Health platforms facilitate the delivery of truly personalized medicine, taking individual wishes and needs into account. We have previously shown that dementia may be prevented through risk factor modification, and that people who are at risk of dementia are willing and able to use an internet intervention to reduce their risk of cognitive decline and dementia. In PRODEMOS we will further investigate how to adapt, implement and upscale self-management of risk factors to prevent dementia and particularly how to make prevention of dementia accessible on a global scale using mobile Health. To reach this aim we will build on the existing Healthy Ageing Through Internet Counselling in the Elderly (HATICE) intervention which is based on self-management of dementia risk factors such as hypertension, high cholesterol, diabetes mellitus, unhealthy diet, smoking and physical inactivity using an interactive Internet approach. Using an implementation study design in the EU and China we will assess acceptability, feasibility, adoption, costs, sustainability and effectiveness of delivery of this dementia prevention strategy via mobile health.

Who can participate?

Adults aged 55-75 years, at increased risk of dementia operationalised as the presence of at least two cardiovascular risk factors

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are able to use an interactive mHealth application that helps and encourages them to make changes to their

lifestyle and manage their own risk factors supported by a coach. Those in group 2 are given their usual care and also access to a static app similar in appearance to that used by group 1 participants, but only providing general information on a healthy lifestyle, without the interactive features. Each participant's BMI, blood pressure and blood cholesterol levels are measured before the start of the trial and 18 months later. They are also asked to fill out questionnaires on disability, depression, physical activity, diet, quality of life and self-management. Dementia, cardiovascular disease and mortality are also assessed.
(added 26/11/2020): Delays caused by the COVID-19 pandemic necessitated adaptation of the original recruitment timeframe. The original study duration was intended to be 18 months, with a recruitment period of 12 months. This means 30 months in total would be required for complete recruitment and complete follow-up. Due to the delays this is not feasible anymore. We therefore introduce a flexible design in which people recruited later into the trial, may have a shorter follow-up, with a minimum of 12 months. This flexible design will allow for achieving a maximum number of person months in the study, given the COVID-restrictions now and in the future. This will not impact the implementation outcomes of our study. In fact, it will provide additional information on sustainability of the intervention.

What are the possible benefits and risks of participating?
Participating in the study may lead to a healthier lifestyle, which on the long term may lead to health benefits. There are no serious risks involved in participating in the study. A potential risk is learning about an increased risk of dementia, which for some participants may be unpleasant to know. However, the study is about reducing the risk of dementia, and it will be clearly described in the PIS that people will learn about their risk factors for dementia.

Where is the study run from?
1. The University of Cambridge, UK
2. Capital Medical University, China

When is the study starting and how long is it expected to run for?
January 2020 to April 2023

Who is funding the study?
European Commission

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1.0

Study information

Scientific Title
Prevention of dementia using mobile phone applications: a randomised controlled trial

Acronym
PRODEMOS

Study objectives
In PRODEMOS we will investigate the effectiveness and successful implementation of an innovative mHealth intervention to optimize self-management of dementia risk factors in individuals aged between 55 and 75 years, of low socioeconomic status (SES) in the UK and from the general population in Beijing at increased risk of dementia, with the aim to reduce overall dementia risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 23/04/2019, The Ethics Committee of Capital Medical University (10 Youanmen Xitoutiao, Beijing 100069, China; 0086 10 8391 6535; ankui@ccmu.edu.cn), ref: Z2019SY015
2. Approved 09/10/2019, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; hra.approval@nhs.net), ref: 19/LO /0934

Study design
Multi-national multi-centre prospective open-label blinded endpoint (PROBE) randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Elderly persons at risk of dementia

Interventions
Intervention group: coach-supported mobile health platform
Participants randomised to the intervention arm of the study will have access to an interactive mHealth platform that facilitates self-management of dementia risk factors in order to reduce dementia risk, with remote counselling by a coach. After secure login, the mHealth platform shows the participants' own dementia risk profile, created through baseline measurements. At the platform, a participant can prioritise his or her risk factors. Within one or more of the prioritised risk factors, a participant can set goals for lifestyle change and monitor these goals by entering data of (self-) measurements. During the intervention, participants can edit goals, reach goals, remove goals, set new goals and adjust prioritisation of risk factors. Participants will receive automated reminders in case of inactivity (low log-in frequency, few goals set, or few measurements entered) in a frequency that is in line with their own preferences. Furthermore, the platform facilitates an environment with evidence-based education modules (both static and interactive), peer videos which will be developed within the project and news items that are arranged according to personal risk factors and goals and will be offered in a step-by-step manner, tailored to the individual participant by the coach.
The intervention platform use is supported by a remote coach, since evidence from a comprehensive systematic review suggests more pronounced effects of intervention studies with blended care (platform with human support) than platform-only studies.

Control group
Participants randomised to the control arm of the study have access to a portal, which is similar in layout to the intervention portal. The platform contains static, evidence-based, written education material about a healthy lifestyle. The control platform does not facilitate prioritisation of risk factors, goal setting, coach support, or dynamic education material.

For both the control and the intervention group, the treatment and follow-up are 18 months. Participants will be randomised 1:1, stratified by country and within the UK stratified for the Cambridge and Sussex regions.

Intervention Type
Other

Primary outcome(s)
1. Effectiveness of the mHealth intervention measured by the difference in dementia risk as measured with the CAIDE risk score between baseline and follow-up.
2. Implementation of the mHealth application.
2.1 Acceptability: through qualitative research analysing the perceptions of different stakeholders (i.e. end-users, professionals, insurance companies and policy makers) whether the mHealth intervention is agreeable. Factors related to acceptability are user-friendliness and credibility.
2.2 Adoption: quantitative analysis of the utilisation, usage and uptake of the mHealth intervention
2.3 Appropriateness: qualitative analysis of the perceived fit or relevance of the mHealth intervention in the target population

2.4 Feasibility: qualitative analysis to what extent the mHealth application can be carried out in a low socio-economic setting and a middle-income setting.
2.5 Fidelity: qualitative evaluation of the degree to which the mHealth application is implemented compared to the original design
2.6 Implementation cost: analysis of the implementation costs will be part of the health economic analysis
2.7 Coverage: quantitative analysis of the degree to which the population with low socio-economic status and the population in a middle-income setting actually receives the mHealth application.
2.8 Sustainability: quantitative evaluation of the extent to which the mHealth application is being used during 18 months of the implementation trial and whether the dementia risk is sustainably reduced after this period.

Key secondary outcome(s))
At baseline and follow-up:
1. Individual modifiable components of the CAIDE risk score
1.1 Blood pressure
1.2 BMI
1.3 Total cholesterol
1.4 Physical activity (Questionnaire: International Physical Activity Questionnaire (IPAQ short))
2. Estimated 10-year cardiovascular disease risk (estimated from a validated prediction score)
3. LIfestyle for BRAin health (LIBRA) score (estimated)
4. Number of uncontrolled risk factors
5. Incident dementia (obtained from questionnaires and validated)
6. Incident cardiovascular disease (stroke, TIA, myocardial infarction, angina pectoris) (obtained from questionnaires and verified from medical records)
7. Mortality (obtained from questionnaires and validated)
8. Diet (Questionnaire: Cleghorn short form food frequency questionnaire)
9. Disability (Questionnaire: WHO Disability Assessment Schedule 2.0 (WHODAS 2.0, 12-item))
10. Anxiety (Questionnaire: Hospital Anxiety and Depression Scale (HADS, anxiety only))
11. Self-management (Questionnaire: Partners In Health (PIH))
12. Depressive symptoms (Questionnaire: Geriatric Depression Scale 15-item (GDS-15))
13. Cost-effectiveness (questionnaire EQ5D)

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Age ≥ 55 years - 75 years
2. Good proficiency of the national language (English in UK, Mandarin in China)
3. Possession of a smartphone
4. Persons who currently don’t have good access to preventive health care, including Low SES in the UK (Sussex and Greater Cambridge areas), operationalised as living in a postal code area ranked as equal to or less than the 3rd decile of the index of multiple deprivation (IMD) OR inhabitant of the Greater Beijing area irrespective of SES.
5. ≥ two dementia risk factors defined as:
5.1. Manifest cardiovascular disease, as diagnosed by specialist or general practitioner
5.2. Lack of physical exercise (self-reported), defined as below the World Health Organization (WHO) norm (five times a week 30 minutes or a total of 150 minutes per week of intermediate

exercise)
5.3. Active smoking (self-reported use of any sort of tobacco in any quantity)
5.4. Hypertension, defined by any of the following:
5.4.1. Diagnosis by specialist or general practitioner.
5.4.2. Currently on anti-hypertensive drugs.
5.4.3. Baseline blood pressure: ≥ 140/90 mmHg;
5.5. Overweight, defined by any of the following:
5.5.1. Body mass index (BMI) ≥ 30 (UK) or 28 (China)
5.5.2. Waist circumference men ≥ 102 cm (UK) or 90 cm (China), women ≥ 88 cm or 85 cm (China)
5.6. Diabetes mellitus, defined by any of the following:
5.6.1. Diagnosis by specialist or general practitioner
5.6.2. Use of insulin or other blood glucose-lowering medication
5.7. Depression
5.7.1. Currently on anti-depressive medication or receiving psychotherapy
5.7.2. History of treatment (i.e. drug therapy, psychotherapy etc.) for depression
5.8. Dyslipidaemia, defined by any of the following:
5.8.1. Diagnosis by specialist or general practitioner
5.8.2. Use of lipid-lowering drugs
5.8.3. Baseline low density lipoprotein (LDL-C) ≥ 3.0 mmol/L and/or total cholesterol ≥ 5.0 mmol /L.

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Previously diagnosed with dementia by a specialist or general practitioner
2. Mini Mental State Examination (MMSE) < 24
3. Any condition expected to limit 18-months compliance and follow-up, including metastasised malignancy or other terminal illness
4. Smartphone illiteracy, defined as not able to send a message from a smartphone
5. Visual impairment interfering with operation of a smartphone
6. Participating in another RCT
7. Present alcohol or illicit drug abuse; binge drinking is not an exclusion criterion – this is a potential target for behaviour change

Date of first enrolment
01/01/2021

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
United Kingdom

England

China

Study participating centre
University of Cambridge
Cambridge
United Kingdom
CB2 1TN

Study participating centre
Capital Medical University
Beijing
China
100069

Sponsor information

Organisation
AMC

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request as pseudonomised individual participant data, after publication of the main results.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2024	20/05/2024	Yes	No
Results article	Qualitative results	28/03/2025	22/07/2025	Yes	No
Protocol article		09/06/2021	13/08/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative pre-results	22/11/2022	28/11/2022	Yes	No
Other publications	Attitudes and views on healthy lifestyle interventions for the prevention of dementia and cardiovascular disease among older people with low socioeconomic status: a qualitative study in the Netherlands	28/02/2022	22/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		24/09/2020	01/12/2020	No	No
Statistical Analysis Plan		23/11/2020	01/12/2020	No	No
Statistical Analysis Plan		22/03/2023	23/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes