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Feasibility RCT: In-MINDD Profiler & Supportive Environment

Submission date
23/04/2014

Recruitment status
No longer recruiting

Registration date
07/05/2014

Overall study status
Completed

Last Edited
25/02/2019

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 aim
Dementia is a serious loss of cognitive ability beyond what might be expected from normal ageing. Whilst dementia is incurable, we know that there are factors that protect against cognitive decline and we know that there are factors which contribute to cognitive decline. Some of these factors such as hypertension, obesity, smoking, physical and psychosocial activity are amenable to early preventive activity long before dementia may develop. The aim of the In-MINDD study is to reach potential future patients when they are in mid-life and help them adopt lifestyle changes that may reduce their risk of developing dementia, or delay its onset.

Who can participate?
Adults registered with a doctor and presenting one or more risks factors (for example depression, diabetes, hypertension, smoking etc) with access to the internet.

What does the study involve ?
This study compares one type of care with another type of care in order to find out if one is more effective than the other. Participants in this study will be randomly allocated to one of two groups in the study.
Those allocated to group A will meet with a researcher who will explain the study and ask the participant to fill in a consent form. The researcher will introduce the participant to the In-MINDD online system and show them how to enter information in the system. Participants will be allocated a personal user name and password for the In-MINDD system. The researcher will enter details from participants medical records into the In-MINDD system. Participants will discuss their personal dementia risk score and strategies for reducing their dementia risk score with a health professional. Participants will carry out activities suggested by the In-MINDD system for a period of six months. Examples of activities that might be suggested include making changes to diet to aid weight reduction or increasing the amount of physical activity done. Participants will be able to access advice and support about these activities from the In-MINDD online system. After six months participants will meet with the researcher and update their information on the In-MINDD system in order to generate a final dementia risk reduction score.
Group B is the control arm of the study. If participants are allocated to group B they will be asked to fill in consent form and a questionnaire with the study researcher. The researcher will

then enter details from their medical records into the In-MINDD system. After this they will not be asked to do anything until six months later when they will meet with the researcher and update their information on the In-MINDD system. At this point they will be given access to the In-MINDD system so that they can undertake activities which may reduce their risk of developing dementia.

What are the possible benefits and risks of participating?
The aim of the In-MINDD study is to reach potential future patients when they are in mid-life and help them adopt lifestyle changes that may reduce their risk of developing dementia, or delay its onset. It is therefore possible that participants may prevent or delay the onset of dementia in later life. Participants who take part in the study will be talking about the risk of developing dementia in the future. Some people worry about the possibility of developing dementia and these discussions may bring such concerns to the fore.

Where is the study run from?
This is a European FP7 programme study and is based at Dublin City University (Ireland), University of Glasgow (UK), Maastricht University (The Netherlands) and Université de Nice Sophia Antipolis (France).

When is the study starting and how long is it expected to run for?
July 2014 to November 2015

Who is funding the study?
European Union

Who is the main contact?
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Study website
http://www.inmindd.eu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V4

Study information

Scientific Title
Innovative Midlife Intervention for Dementia Deterrence (In-MINDD) feasibility randomised controlled trial in four European primary care settings

Acronym
In-MINDD

Study objectives
This trial will test whether or not giving patients a dementia risk score and access to online support materials helps them change their health-related behaviour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application for ethical approval is made separately in the four European countries.
1. Dublin City University Research Ethics Committee (Ireland)
2. Irish College of General Practitioners Research Ethics Committee (Ireland)
3. Maastricht University Ethics Committee (Netherlands)
4. Université Nice Sophia Antipolis (France): Commettee for human research protection (Comité de Protection des Personnes)
5. Agency for the Safety of Health Products (France) [Agence National de sécurité du medicaments (ANSM)]
6. Advisory committee on data processing in the domain of research on health (France) [Comité consultatif sur le traitement de linformation en matière de recherche dans le domaine de la santé (CCITRS)]
7. University of Glasgow (UK): Integrated Research Application System (IRAS)
8. National committee for informatics and freedom (France) [Comité National Informatique et Liberté (CNIL)]

Study design
Multi-centre primary care-based investigator-blinded randomised 6-month feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dementia

Interventions
In-MINDD arm of trial.
Participants in the In-MINDD arm will receive a letter telling them that they have been allocated to the In-MINDD arm of the trial and they should contact their GP or practice nurse and arrange an appointment, in order to discuss their dementia risk score and personalised plan. Participants dementia risk will be presented as an overall risk score, in visual form, as well as a breakdown of which risk factors contribute most to their overall risk score, e.g. smoking and lack of physical activity. This letter will also give them a link to the In-MINDD on-line support environment. Participants will then be free to access and use information held in the In-MINDD online support environment. Examples of activities that might be suggested include making changes to diet to aid weight reduction, or increasing the amount of physical activity done; or taking up a new activity, such as learning a language. Participants will be able to access advice and support about these activities from the In-MINDD online system. At three months, participants will be asked to complete an online questionnaire about risk factor(s) they have selected and the steps and actions they have taken, if any, to reduce that or those risk factors. This questionnaire will address risk factors they selected, what they have learned about reducing that risk factor, what steps/actions they took to follow the advice given, how they have accessed those activities and how often and whether they are still participating in those activities. They will also be asked if they would be willing to be interviewed about their experience so far in In-MINDD. In addition, use of the In-MINDD support environment will be monitored remotely, e.g. how often they access the systems; for how long; and what sites they visit. After six months participants will meet with the researcher or practice nurse again and update their information on the In-MINDD system in order to generate a final dementia risk score.

Control arm of the trial.
Participants in the control arm will receive a letter from the researcher telling them they are in the control arm; in addition, they will receive generic health information material e.g. on smoking cessation, increasing physical activity. Participants in the control arm will be asked to complete an online questionnaire at three months. (In order to maximise follow up rates participants who dont complete the online questionnaire will be offered a telephone alternative.) They will be informed that we will contact them towards the end of the trial period, to identify anyone who may wish to be interviewed. At the end of the trial period they will meet again with the researcher and complete the profiler. They will receive a copy of their dementia risk score, with supporting information, and will be given access to the In-MINDD on-line support environment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Global risk score, calculated on the basis of a basket of individual risk factors identified from work package 1 of In-MINDD. These will include physical and cognitive activity; presence of depression, diabetes and/or cardiovascular disease; high cholesterol; smoking status; hypertension; and obesity.

dementia risk score will be measured by a dementia risk questionnaire. The questionnaire will be completed at baseline and at study completion (six months) and will be comprised of information on participants' mood, physical activity, cognitive activity and diet via four validated instruments which have been carefully selected and adapted where necessary.

Secondary outcome measures
Changes in individual risk factors

Overall study start date
01/07/2014

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. Registered with a participating practice
2. Age 40 60 on date of consent
3. Presence of any one (or more) of the following risk factors
3.1. Depression previous history OR active episode of minor depression as recorded on medical record IF GP deems patient fit to participate
3.2. Diabetes (diagnosis e.g. on a diabetes disease register)
3.3. Hypertension (as per national guidelines)
3.4. Obesity (BMI of 30.0 or above)
3.5. Current smoker
3.6. High cholesterol (as per national guidelines)
3.7. Coronary heart disease (diagnosis e.g. on a CHD disease register)
3.8. Self reported sedentary lifestyle
3.9. Self reported lack of cognitive stimulation
4. Medically stable
5. Literate in language of the partner country where patient is recruited (English/Dutch/French as appropriate).
6. Access to the internet in order to communicate by email and access information online

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
4 countries x 25 patients - 600 total

Key exclusion criteria
1. Active episode of major depression, if GP deems patient too severely ill to participate, recorded in medical record or assessed using a validated assessment score e.g. HADS
2. People who are unable to give informed consent
3. People who have dementia

Date of first enrolment
01/07/2014

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
France

Ireland

Netherlands

Scotland

United Kingdom

Study participating centre
General Practice and Primary Care
Glasgow
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
European Communitys Framework Programme Seven (FP7); ref. #304979

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2015		Yes	No
Funder report results	results summary	05/04/2016		No	No