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The medical Risk Assessment and Health Education in Older people (RAHEO) study: Feasibility and performance of a health risk appraisal questionnaire combined with health education in Romania

Submission date	Recruitment status	[_] Prospectively registered
17/06/2014	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
25/06/2014	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
19/10/2017	Other	

Plain English summary of protocol

Background and study aims

This study aims to improve preventive care and medical education in older people. The main objective of this study is to evaluate health risks of people 65 years of age and older, and the potential benefits of using the Health Risk Appraisal for Older People (HRA-O) standardized questionnaire in clinical practice in developing counselling sessions tailored to individual health and lifestyle needs to improve their general health and wellbeing.

Who can participate?

People 65 years of age and older and who meet the following criteria are eligible for this study: live in Bucharest or within 2 to 4 hours travel time, speak/understand Romanian language, do not live in a nursing home, do not have severe dementia, do not have severe disability, do not have a terminal illness, and have not had major surgery in the last 3 months.

What does the study involve?

The study takes place over a period of 8 months. Participants are randomly allocated into one of two groups. Group 1 (intervention group) receive monthly specialised counselling guided by individual Health Reports. Group 2 (control group) receive their usual care. In addition, everyone is asked to complete a Brief Questionnaire answering questions about health measurements, medical history and functioning. They are also asked to complete a complementary HRA-O questionnaire, answering questions, for example, about their diet habits, physical activity, social network at the start of the study and then 6 months later. Data on subjects name, sex, contact details, education level, living arrangements, marital status, income, body weight, height, blood pressure and current medication is also recorded. At the end of the study, people in the intervention group are asked to complete a feedback questionnaire, answering questions about their experience being part of this study.

What are the possible benefits and risks of participating?
There is no relevant benefit or risk related to taking part in the study for participants.

Where is the study run from?
This research project takes place at the National Institute of Gerontology and Geriatrics Ana Aslan, Bucharest, Romania. The study takes place in both hospital and out-patient clinic settings.

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

Who is funding the study?
University of Geriatrics, Berne, Switzerland

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The medical risk assessment and health education in older people (RAHEO) study: A randomized controlled study to evaluate the feasibility and intermediate effects of a preventive intervention (health risk appraisal questionnaire with follow-up counselling) compared to usual care in older patients in Romania

Acronym
RAHEO

Study objectives
The main hypotheses that are tested in this randomized controlled study are:
1. Is it feasible to implement a preventive intervention consisting of a standardized health risk appraisal questionnaire (HRA-O) with follow-up counselling in a Romanian setting (e.g. acceptance by older patients)?
2. Does this preventive intervention, over a period of six months, improve intermediate outcomes (e.g. adherence to favorable health behaviors, use of recommended preventive services) among older persons?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the National Institute of Gerontology and Geriatrics Ana Aslan, Bucharest, Romania, 28/01/2014, ref. 972

Study design
Interventional single-blinded randomized controlled clinical trial. Trial is single-center, conducted at two sites of this center (one site: inpatient, one site: outpatient)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Health and well being/prevention/older people/geriatrics

Interventions
Test group - Individualized, specialized medical counselling guided by health reports generated based on the Health Risk Appraisal for Older people (HRA-O) standardized questionnaire
Control group no counselling

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Outcome measures for evaluating the feasibility (based on abstraction of recruitment phase, and feed-back in intervention group):
1. Number of patients excluded due to inability or unwillingness to complete the self-administered questionnaires or unwillingness to give informed consent
2. Structured feed-back from participating older persons at start and at end of intervention period
3. Base-line prevalence of identified risks

Outcomes (based on comparisons between persons in intervention and control groups, and pre-post comparisons in intervention group):
1. Adherence to recommended health behaviors (self-report) at six-month follow-up
2. Intention to change health behavior (self-report) at six-month follow-up
3. Health status and status of preventive care (self-report, and objective clinical data) in surviving older persons at six-month follow-up

Secondary outcome measures
1. Survival
2. Detailed analysis of preventive care process (e.g., blood pressure control, medication use)

Overall study start date
20/05/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
Site 1: Subjects 65 years of age and older, both male and female admitted to ambulatory geriatric care of the National Institute of Gerontology and Geriatrics Ana Aslan, Bucharest, Romania, during the study recruitment period
Site 2: Subjects 65 years of age and older, both male and female admitted to inpatient geriatric care of the National Institute of Gerontology and Geriatrics Ana Aslan, Bucharest Romania, during the study recruitment period

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
The target total recruitment number of participants is 400 (approximately 200 per site).

Key exclusion criteria
1. Moderate to severe dementia
2. Severe disability - needs human help in one or more basic activities of daily living
3. Has terminal illness
4. Has had major surgery within the last 3 months
5. Does not live in catchment area - Bucharest and within 2 to 4 hours travel time
6. Lives in nursing home
7. Does not speak/understand Romanian language
8. Inability or unwillingness to complete the self-administered questionnaires
9. Person unwilling to give informed consent

Date of first enrolment
20/05/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Romania

Study participating centre
National Institute of Geriatrics and Gerontology "Ana Aslan"
Bucharest
Romania
011241

Sponsor information

Organisation
Forschungsfonds Geriatrie (Switzerland)

Sponsor details
Bern University Hospital
Department of Geriatrics
Inselspital
Freiburgstr. 3
Postfach 20
Bern
Switzerland
CH-3010

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
Universität Bern

Alternative Name(s)
Universität Bern, Université de Berne, Universitas Bernensis, UniBE, , Бернскі ўніверсітэт, Бернски университет, Universitat de Berna, Bernská univerzita, Πανεπιστήμιο της Βέρνης, Universitato de Berno, Universidad de Berna, Berni Ülikool, Bernako Unibertsitatea, , Bernin yliopisto, Univèrsitât de Bèrna, Universidade de Berna, , Università di Berna, , Берн университеті, , Berno universitetas, Universiteit van Bern, Universitetet i Bern, Бернский университет, Bern Üniversitesi, Берн университеты, Бернський університет, , UB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

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?
Results article	results	20/07/2017		Yes	No