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Cost-effectiveness of nutritional supplementation and exercise programme among older people in Santiago, Chile

Submission date 25/01/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/07/2005	**Overall study status** Completed	
Last Edited 31/07/2017	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
This study aims to evaluate the cost-effectiveness of a national nutrition supplementation programme and a specially designed physical exercise intervention for older people. The aim is to find out whether the nutritional supplement decreases the incidence of pneumonia and whether the exercise increases walking capacity (i.e., the distance they are able to walk in six minutes).

Who can participate?
Adults aged 65 - 67.9 years, living in low to middle socioeconomic circumstances, and attending the participating health centres.

What does the study involve?
Participating health centres are randomly allocated to one of four groups, to deliver to their patients either the daily nutritional supplement, two 1-hour physical activity classes per week, both interventions or neither for 24 months. The researchers assess the incidence of pneumonia and walking capacity. The researchers also use administrative records and interviews with staff and patients to estimate the cost-effectiveness of the interventions.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The Chilean Ministry of Health (Chile)

When is the study starting and how long is it expected to run for?
August 2005 to November 2007

Who is funding the study?
1. The Wellcome Trust (UK)
2. Chilean Ministry of Health (Chile)

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
075219

Study information

Scientific Title
Cost-Effectiveness of Nutritional supplementation and EXercise programme among older people in Santiago, Chile

Acronym
CENEX-Chile

Study objectives
This project aims to evaluate the cost-effectiveness of a national nutrition supplementation programme, and a specially designed physical exercise intervention for older people. The study has been conceptualised as a public health programme effectiveness study and has been designed as a full-factorial cluster-randomised trial.

The two study hypotheses are:
1. Provision at health centres of a fortified nutritional supplement for two years to adults aged

65.0 to 67.9 years at baseline will decrease the incidence of pneumonia among individuals to whom the programme is provided
2. Provision of a community-based, twice-weekly resistance training exercise programme for two years to adults aged 65.0 to 67.9 years at baseline will increase walking capacity among individuals to whom the programme is provided

The main outcomes are incidence of pneumonia and change in walking capacity. Costing data (user and provider), collected at all levels, will enable the determination of the cost-effectiveness of the two interventions individually and in combination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institute of Nutrition and Food Technology (Instituto de Nutrición y Tecnología de los Alimentos [INTA[), University of Chile, 08/08/2005, ref: 3040
2. Ministry of Health, Chile
3. The London School of Hyiene and Tropical Medicine (LSHTM), University of London, 08/08 /2005, ref: Acta de Aprobación No.9/2005

Study design
Factorial cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

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
Pneumonia and physical functional decline

Interventions
The study has been designed as a full-factorial cluster-randomised trial. There will be 28 clusters which are defined as health centre catchment areas, and 100 individuals will be randomly selected from each cluster. The total study sample size will be 2800 individuals.

20 of the clusters will be randomly assigned to one of the four study arms; the remaining eight clusters will be randomly assigned to either the nutritional supplement or the control arm. The four study interventions are:
1. Provision at the local health centre of monthly supplies of micronutrient fortified nutritional

supplements (powdered vegetable and legume mix, and powdered milk drink) for 24 months
2. Provision of two one hour-long exercise classes a week for 24 months at local community centres
3. Both one and two above
4. Neither one nor two above

Intervention Type
Mixed

Primary outcome measure
Current information as of 22/09/2010:
1. For nutrition intervention:
The incidence of pneumonia over the 24 months after the initiation of the intervention.
2. For exercise intervention:
Walking capacity (distance walked in six minutes) 24 months after initiation of the intervention.

Initial information at time of registration:
1. Incidence of pneumonia over 24 months of intervention and subsequent six months
2. Change in walking capacity over 24 months of intervention
3. Change in body mass index over 24 months of intervention

Secondary outcome measures
Added 22/09/2010
1. Body mass index
2. Incidence of acute respiratory infection
3. Self-reported health status (Short-Form 36)
4. Depression, assessed bt Geriatric Depression Scale (GDS-15)
5. Self-reported incidence of chronic diseases
6. Physical and functional limitations
7. Self reported productive activity
8. Self-reported incidence of falls
9. Self-reported incidence of fracture
10. Blood pressure
11. Anthropometry
12. Timed up-and-go assessment
13. Blood indicators of cardiovascular disease risk and insulin resistance (in a sub-sample)

Overall study start date
01/08/2005

Completion date
01/11/2007

Eligibility

Key inclusion criteria
1. Aged 65.0 to 67.9 at baseline
2. Living in the catchment area of one of 28 selected health centres of low/medium socio-economic status in Santiago, Chile

Participant type(s)

Patient

Age group
Senior

Sex
Both

Target number of participants
2800

Key exclusion criteria
1. Non-ambulatory
2. Recent un-explained weight loss (more than 3 kg in past three months)
3. Possible clinical dementia (as assessed via mini-mental state examination)

Date of first enrolment
01/08/2005

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
Chile

England

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine
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Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

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Sponsor type
University/education

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ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Ministry of Health (Chile) (in kind contribution)

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	05/07/2007		Yes	No
Protocol article	protocol	27/05/2009		Yes	No
Results article	results	01/04/2011		Yes	No
Results article	results	01/04/2013		Yes	No
Other publications	secondary outcome analysis	09/09/2013		Yes	No
Results article	results	24/07/2017		Yes	No