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Screening the elderly for impaired vision: a nested trial within the MRC elderly trial

Submission date 23/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/10/2000	**Overall study status** Completed	
Last Edited 24/11/2010	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Liam Smeeth

Contact details
Epidemiology Unit
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
liam.smeeth@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9900232

Study information

Scientific Title

Study objectives
To determine the effectiveness of mass screening for visual impairment in unselected elderly people (aged 75 and over) in a community setting as part of a multidimensional screening programme.
To assess barriers to treatment of visual impairment among elderly people.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Primary care

Interventions
In the MRC Elderly Screening Study, practices were randomly allocated as follows:
1. Brief assessment by questionnaire followed by a detailed assessment, including visual acuity, only if indicated (the control group for this study) - the targeted screening group
2. Brief assessment by questionnaire followed by a detailed assessment including visual acuity for all patients (the intervention group for this study) - the universal screening group.

In the brief assessment, as one of the 35 questions about their health, participants were asked the following question on vision: 'Do you have difficulty seeing newsprint, even if you are wearing glasses?'
In arm A, criteria for triggering to the detailed assessment were three or more problems identified from the brief assessment or any one of four 'serious' symptoms (unexpected weight loss, frequent falls in previous month, vomiting blood, coughing blood).

In arm B all participants had a detailed assessment. In the detailed assessment, the participants' distance visual acuity was measured using a logarithm of the minimum
angle of resolution (logMAR) chart. Anyone with a pinhole corrected acuity of 0.5 or more (equivalent to Snellen acuity less than 6/18) was referred to an ophthalmologist. If the visual impairment was corrected by use of a pinhole, the participant was referred to an optometrist for refractive error correction.

The patient assessments described above began in 1995 and were completed at the end of 1998. All participants are being followed up for mortality and hospital admissions but are not being re-examined as part of the MRC Elderly Screening Trial. We are proposing to conduct a nested trial within the MRC trial, specifically to examine the effectiveness of the visual acuity screening component of the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
These were changed prior to outcome data collection following the pilot study and with the agreement of the trial steering committee. The Primary outcomes are now:
1. Visual acuity less then 6/18 in either eye.
2. Visual function: the composite score on the national eye Institute Visual Function Questionnaire 25 Version.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2000

Completion date
12/06/2002

Eligibility

Key inclusion criteria
The trial is being conducted in practices involved in the MRC Trial of Assessment and Management of Elderly People in the Community (The Elderly Screening Trial), who were recruited through the MRCGP framework. The patient population included all patients aged 75 years and over registered with study practices at the start of the main trial (1995-1997). We propose to re-examine 2000 participants from 20 practices within the main trial (100 in each practice). We will randomly select 10 practices from the two arms of the main trial. Within each practice, we will then randomly sample 150 people from the list of people who were originally eligible for inclusion in the main Elderly Screening Trial. We will ascertain those participants who have died or moved away. The remaining participants will be invited to an assessment.

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
2000

Key exclusion criteria
Anyone in long-term care or with terminal disease.

Date of first enrolment
01/02/2000

Date of final enrolment
12/06/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Epidemiology Unit
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/07/2002		Yes	No
Results article	results	01/03/2004		Yes	No