

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

Submission date 23/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/11/2010	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 than 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

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Sponsor information

Organisation

Medical Research Council (MRC) (UK)

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Sponsor type

Research council

Website

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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