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Randomised Controlled Trial of Efficacy of Optometric Interventions

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2008	Eye Diseases	

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
M0003074909

Study information

Scientific Title

Study objectives
Optometrists usually prescribe interventions (spectacles, contact lenses or orthoptics) if the intervention improves visual acuity, or if it is believed that it will resolve symptoms. For optometric interventions that are prescribed for symptomatic relief, clinical tests of visual acuity (VA) often do not indicate significant improvement with the intervention.

Visual problems which cause symptoms but do not impair static VA might affect performance on dynamic tasks. Refractive errors and heterophoria are best described as continuous variables and the decision as to when to prescribe an intervention is based on clinical signs whose sensitivity and specificity for detecting symptoms is often, at best, under researched.

The objectively validated Wilkins Rate Of Reading Test will be used to assess the benefit of interventions. This test uses simple words and is relatively independent of reading skill and does not assess linguistic or semantic factors. The results are very dependent on dynamic visual skills and require sustained binocular single vision and clear vision.

The aims of the research
1. In conditions where optical corrections may be prescribed but not improve VA (e.g. decompensated heterophoria): to investigate whether optical corrections influence performance at the Wilkins Rate of Reading test.

2. In conditions where optical corrections may be prescribed and improve VA (e.g. astigmatism): to investigate whether optical corrections influence performance at the Wilkins Rate of Reading test.

3. In both (1) and (2), to investigate the relationship between the severity of the optometric anomalies and the magnitude of any improvement in the Rate of Reading.

4. If the Wilkins Rate of Reading Test does prove to be a useful tool for exploring any benefit from the ¿borderline¿ optometric interventions, to investigate the inter-relationships between the Wilkins Rate of Reading Test result, symptoms and conventional clinical test results.

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
Eye Diseases: Vision disorders

Interventions
Subjects will be invited to return on the research day. They will then be tested four times with the rate of reading test, twice with the appropriate intervention A and twice with the control lens (B). The order of testing will be ABBA or BAAB (randomly) to control for practice effects. The interventions and controls for the five groups identified are summarised.

Hypermetropes will be tested with subjective refractive correction (A) and size lenses to give similar magnification (B)

Astigmats will be tested with subjective cylindrical correction (A) and best vision sphere (B)

Horizontal heterophorias will be tested with aligning prism from Mallett unit (A) and size lenses for exophoria or plano for esophoria as appropriate (B)

Vertical heterophorias will be tested with larger of aligning prism/dissociated heterophoria (A) and plano trial lenses (B)

Early presbyopes will be tested with near refractive correction (A) and size lenses (B).

Clinical data will be obtained using standard testing protocols on all subjects, and a selection from VA, cover test, foveal suppression, dissociated heterophoria, fusional reserves, Randot circles, fixation disparity. Detailed symptom questionnaires designed for each group will be used. Subjects will be assessed from patients routinely attending the practice for eye examinations.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Process measure: does prescribing optometric correction for marginal refractive and orthoptic anomalies benefit patients in terms of improved performance on the Wilkins Rate of Reading test?

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1998

Completion date
31/03/2008

Eligibility

Key inclusion criteria
Subjects meeting the following criteria will be selected, regardless of whether they have any existing refractive correction. All subjects meeting the criteria will be invited to participate.
1. Hypermetropes of age <40years with either retinoscopy or subjective refraction in the better eye in the range +0.75 to +1.50D
2. Patients aged 40-45 years with a subjective near correction in the range +0.50 to +1.50D
3. Astigmats of any age with astigmatism (subjectively) in the better eye in the range 0.50 to 1.50 DC
4. Patients of any age with horizontal heterophoria that may be decompensated
5. Patients of any age with a vertical heterophoria either on the Mallett unit or dissociation test of >0.5^

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
No specific patient exclusion criteria

Date of first enrolment
01/07/1998

Date of final enrolment
31/03/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
23 Shenfield Rd
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Sponsor information

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
City Eye Clinic (EYENET) (UK), NHS R&D Support Funding

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	01/11/2006		Yes	No