

Randomised Controlled Trial of Efficacy of Optometric Interventions

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/09/2008	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

Protocol serial number
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

Study type(s)

Not Specified

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(s)

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?

Key secondary outcome(s)

Not provided at time of registration

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 $>0.5^{\wedge}$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

Study participating centre

23 Shenfield Rd

Brentwood

United Kingdom

CM15 8AG

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type
Government

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

Results and Publications

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