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Helping adherence with glaucoma treatment: a randomised trial

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/09/2014	Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Heidi Cate

Contact details
Norfolk and Norwich University Hospital NHS Trust
Glaucoma Research Unit
Norwich
United Kingdom
NR4 7UY

Additional identifiers

Protocol serial number
6798

Study information

Scientific Title
A single centre randomised interventional trial of additional education and advice about glaucoma verus standard care in improving adherence with topical anti-glaucomatous therapy

Acronym
Adherence study

Study objectives
To determine whether additional education and advice about glaucoma and its management, over and above standard care, is beneficial and cost-effective in improving adherence with topical anti-glaucomatous therapy.

As of 22/12/2010 this record was extensively updated; all changes can be found in the relevant field with the above update date. At this time, the anticipated end date was extended from 22 /11/2010 to 22/11/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved on the 19th February 2008 (ref: 08/H0310/11)

Study design
Single centre randomised interventional process of care trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Topic: Eye, Primary Care Research Network for England; Subtopic: Not Assigned, Eye (all Subtopics); Disease: Ophthalmology, All Diseases

Interventions
The Education and Support intervention will be delivered by four GSAs using motivational interviewing techniques.

Added 22/12/2010:
Duration of follow-up is 8 months. Intervention not disclosed due to masking of physicians working within the department.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Percentage adherence rate compared between control and intervention group.

Added 22/12/2010:
Outcome measures are recorded at 2 months and 8 months post-randomisation.

Key secondary outcome(s))

1. Correlate the level of self-reported adherence with actual adherence and determine associative factors
2. Identify the demand for specific components of the glaucoma support intervention
3. Identify predictors of the level of adherence

Added 22/12/2010:
Outcome measures are recorded at 2 months and 8 months post-randomisation.

Completion date
22/11/2011

Eligibility

Key inclusion criteria
Added 22/12/2010:
1. Newly diagnosed or previously untreated glaucoma patients and ocular hypertension patients prescribed Travoprost
2. Over 18 years old, no upper age limit
3. Male and female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
23/11/2009

Date of final enrolment
22/11/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital NHS Trust
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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	24/03/2014		Yes	No
Protocol article	protocol	22/11/2012		Yes	No