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Will counselling using an adaptation of motivational interviewing method improve the acceptance of surgery and adherence to treatment and follow up in among glaucoma patients in Bauchi

Submission date	**Recruitment status**	[X] Prospectively registered
03/12/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2019	Eye Diseases	

Plain English summary of protocol

Background and study aims

Glaucoma causes irreversible blindness in 4.6 to 6.7 million people worldwide. In Nigeria, the frequency (or prevalence) of blindness in adults 40 years and above is 4.2%, 16.3% due to glaucoma. Glaucoma is a blinding eye disease that has several forms. The commonest form in Africa causes progressive, painless loss of the peripheral field of vision. Eventually central vision is lost too and the eye/person becomes totally blind. The blindness is irreversible. The only current treatment is to lower the pressure of the eye and this can be done by the use of eye drops, surgery or laser treatment. As with all chronic or lifelong diseases, glaucoma needs to be managed and followed up needs to be for life.

There are several reasons why glaucoma control is a major challenge in Africa.

1. The following factors lead to late presentation: a. Earlier age of onset of the disease - aggressive course; b. Lack of early symptoms as loss of vision is painless; c. Lack of a single, simple, valid screening test; d. Lack of awareness; e. Lack of primary eye care
2. The following factors impede optimal management once patients present: a. We are not sure whether topical medication or surgery works better in case of advanced disease; b. Poor uptake of surgical treatment; c. Lack of adherence to medical treatment; d. Lack of adherence to or poor follow up.

Motivational interviewing (MI) is a form of counselling designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the persons own reasons for change within an atmosphere of acceptance and compassion. There is evidence that it can work in psychiatry, substance abuse, HIV care, smoking cessation, healthy life style changes and in other fields of medical and health care. Motivational interview is a skill that can be taught at most levels. Studies have shown that paraprofessionals can be trained in MI with good results. The aim of this study is to assess whether a locally adapted motivational interviewing session about glaucoma and its treatment, has an effect on the management of glaucoma in Bauchi state, Nigeria.

Who can participate?
Glaucoma patients attending the eye clinic at Abubakar Tafawa Balewa University Teaching Hospital in Bauchi, Nigeria. Participants have to live within 200 km of the study site.

What does the study involve?
Participants are randomly allocated to either having a 30-40 minutes interview/discussion or not with one of two interviewers who are also assigned at random.

What are the possible benefits and risks of participating?
The possible benefit of participating is for the patient to get more information about glaucoma that will motivate him/her to make the right decisions regarding treatment to prevent avoidable blindness. There may be emotional pressure on some patients to try to adhere to treatment.

Where is the study run from?
The study is run from the London School of Hygiene and Tropical Medicine, but the principal investigator will be at the study site as the attending ophthalmologist seeing the patients (eye clinic at Abubakar Tafawa Balewa University Teaching Hospital in Bauchi, Nigeria).

When is the study starting and how long is it expected to run for?
September 2013 to December 2015

Who is funding the study?
The British Council for Prevention of Blindness (UK)

Who is the main contact?
Dr Mohammed Mahdi Abdull
mohammed.abdull@lshtm.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Mohammed Mahdi Abdull

Contact details
International Centre for Eye Health
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E7HT
+44 (0)7544706291
mohammed.abdull@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.2

Study information

Scientific Title
Randomised controlled trial of adapted motivational interviewing for acceptance and adherence to treatment in glaucoma patients in Bauchi

Study objectives
Patient counselling delivered using adapted motivational interview by a trained interviewer increases rates of surgery among glaucoma patients where this is the treatment of choice, as well as short term follow up and control of intraocular pressure (IOP).
Also that adapted motivational interview will improve adherence to topical glaucoma therapy and short term follow up and control of IOP among those who reject surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine, 17/07/2013, ref: 6464
2. Abubakar Tafawa Balewa University Teaching Hospital, 22/08/2013, ref: ATBUTH/ADM/42 /VOL1

Study design
Randomised controlled double-blind single-site trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Glaucoma

Interventions
Current interventions as of 16/09/2013:
The intervention is one to two sessions of adapted motivational interview to patients allocated at random. Patients allocated will be interviewed alone or with their carer or household head. The interview will be conducted by one of two trained interviewers also allocated at random. It will not be guided by a manual but the interviewer will have full knowledge of the adapted motivational interview package developed.

Previous interventions:
The intervention is one to three sessions of adapted motivational interview to patients allocated at random. Patients allocated will be interviewed alone or with their carer or household head. The interview will be conducted by one of two trained interviewers also allocated at random. It will not be guided by a manual but the interviewer will have full knowledge of the adapted motivational interview package developed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 16/09/2013:
Proportion of participants who attend for and/or undergo surgery in the study eye, within 2 months of being listed for glaucoma surgery

Previous primary outcome measures:
Proportion of participants who attend for and/or undergo surgery in the study eye, within 4 months of being listed for glaucoma surgery

Secondary outcome measures
Current secondary outcome measures as of 16/09/2013:
1. Accept surgery within 2 months:
1.1. Proportion of participants who report for follow up at 1, 6 and 12 months following surgery
1.2. Proportion of participants whose IOP is controlled at 1, 6 and 12 months (<20 mmHg in the study eye)
2. Refuse surgery after 2 months:
2.1. Proportion of participants who adhere to medical treatments at each follow up
2.2. Proportion of participants whose IOP is controlled at 1, 6 and 12 months (<20 mmHg in the study eye)

Previous secondary outcome measures:
1. Accept surgery within 4 months:
1.1. Proportion of participants who report for follow up at 1, 2, 4 and 6 months following surgery
1.2. Proportion of participants whose IOP is controlled at 1, 2, 4 and 6 months (<20 mmHg in the study eye)
2. Refuse surgery after 4 months:
2.1. Proportion of participants who adhere to medical treatments at each follow up
2.2. Proportion of participants whose IOP is controlled at 1, 2, 4 and 6 months (<20 mmHg in the study eye)

Overall study start date
01/09/2013

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Primary open angle glaucoma in at least one eye, where surgery or LASER is the treatment of choice in one or both eyes
2. Aged 17 years or more (can give consent)
3. Residence within 200km of Bauchi, the study site
4. Understands and speaks Hausa or English
5. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Other forms of treatment other than surgery or LASER more appropriate
2. Other ocular pathology except cataract.
3. Systemic diseases/problems that contraindicate surgery

Date of first enrolment
01/09/2013

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

Nigeria

United Kingdom

Study participating centre
International Centre for Eye Health
London
United Kingdom
WC1E7HT

Sponsor information

Organisation
International Centre for Eye Health (UK)

Sponsor details
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT

Sponsor type
Research organisation

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

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research council

Funder Name
British Council for Prevention of Blindness (UK) ref: ITCR BH 5810

Alternative Name(s)
BCPB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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?
Protocol article	protocol	29/04/2014		Yes	No
Results article	results	29/04/2014	22/01/2019	Yes	No