Can adapted motivational interviewing improve uptake of surgical or laser treatment for glaucoma in Nigeria: randomized controlled trial

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ABSTRACT

Purpose: To assess whether adapted motivational interviewing has any impact on the proportion of participants who subsequently underwent surgery or laser treatment for glaucoma.

Methods: A single site randomized controlled trial in Bauchi, Nigeria. Participants were new patients with a confirmed diagnosis of primary open angle glaucoma in one or both eyes, where surgery or laser was recommended. Intervention was a session of motivational interviewing adapted for glaucoma and the local context, using an interview guide based on local qualitative research. Participants were randomly allocated to intervention or usual care. Usual care was routine explanation by an ophthalmologist and an educational pamphlet. After the interview, a 12-item Working Alliance Inventory questionnaire was administered to patient-interviewer pairs to assess the collaborative relationship.

Results: 276 glaucoma patients participated; 70% males. 135 (49%) were assigned to adapted motivational interviewing and 141 to usual care. All received the intervention as allocated. Uptake (i.e., the proportion who underwent treatment) of laser or surgery in the motivational interviewing group was 52% compared with 45% in the usual care group (risk difference 7.2%, 95% confidence interval -4.5-18.9%). Mean Working Alliance Inventory scores were 68.0 for interviewers and 68.5 for participants with a combined reliability coefficient of 93.9% (i.e., high internal consistency and reliability).

Conclusion: We observed only a small increase in the uptake of surgery or laser with motivational interviewing compared with usual care which was not statistically significant. Although only 1 in 2 patients accepted surgery or laser in this trial, this is a much higher proportion than in other studies.

Key words: Glaucoma, Motivational interviewing, Treatment uptake, Africa

INTRODUCTION

Glaucoma is a public health problem in Africa, with the prevalence of blindness due to glaucoma higher than in other regions, with an aggressive course,[1 2] higher rates among young people[3], and late presentation[4] on account of lack of primary eye care and awareness, reduced access to treatment and low awareness of the risk of having primary open angle glaucoma (POAG)[5]. Health facilities are also poorly equipped[6] with inadequate human resources and limited treatment options. Exacerbating these problems is poor acceptance of and adherence to trabeculectomy, the preferred treatment in Africa,[7, 8] as patients experience no immediate visual benefit and are fearful of the procedure.[9] For prevention of blindness in glaucoma there are modifiable factors such as increasing awareness by education,[10,11] and encouraging change in acceptance and adherence to treatment and follow up.

In this study motivational interviewing (MI) was selected as the intervention to enhance uptake of treatment (i.e., they accept and actually undergo treatment). Motivational interviewing has been described as "a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion".[12] Guidance includes giving information whilst honouring patient autonomy. Motivational interviewing was originally developed for addictive behaviours,[13] and a wide range of applications have been developed.[12]

In this study MI was adapted as an approach to counselling for use in patients with glaucoma, and hereafter is referred to as adapted motivational interviewing for glaucoma (AMIG). The purpose of the trial was to assess whether AMIG has an impact on the uptake of surgery or laser treatment by glaucoma patients. The hypothesis tested was that AMIG increases the uptake of treatment (surgery or laser treatment) among glaucoma patients in comparison with enhanced usual care.

Setting

The trial was undertaken in the eye clinic of Abubakar Tafawa Balewa University Teaching Hospital (ATBUTH), Bauchi State, in the North East of Nigeria. More than 80% of the catchment population of approximately four million people live in rural areas or live on less than one United States Dollar

(USD) per day, with low levels of literacy (males 53%, females 13%).[14] All new patients attending the ATBUTH eye clinic are allocated a unique medical record number and are given a green registration card, which includes the dates of clinic attendance, registration and surgical appointments. Surgery is performed twice a week, and if lists are cancelled in advance patients are notified and given another date to attend. It is extremely rare for patients to attend for surgery on any date other than the date given. All operations are recorded in the operating theatre register, giving details of their name, age, sex, hospital record number and surgical procedure. A register of all new glaucoma patients was initiated before the trial started.

METHODS

The definition of POAG used in the trial followed that recommended by Foster in 2002[15] which has been applied to normative data from the Nigeria National Blindness and Low Vision Survey.[16] The values which defined glaucoma were IOP greater than 26mmHg (the 97.5th percentile for IOP from the Nigeria Blindness Survey), and a vertical cup disc ratio (VCDR) of more than 0.7 (the 97.5th percentile for VCDR from the Nigeria Blindness Survey) with visual field loss consistent with glaucoma in one or both eyes.

Trial design

This was a single site effectiveness trial with 1:1 allocation to evaluated intervention or enhanced usual care.[17] No changes were made to the protocol after the trial started. The trial is reported in accordance with the CONSORT statement.[18,19] The full protocol has been published and can be assessed at http://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-15-149. The trial is registered at Controlled-Trials.com, registration number ISRCTN79330571, available at the following URL.

http://www.isrctn.com/ISRCTN79330571?q=abdull&filters=&sort=&offset=1&totalResults=1&page=1&pageSize=10&searchType=basic-search.

Inclusion criteria: New patients (i.e., first attendance at ATBUTH) with a confirmed diagnosis of POAG in one or both eyes, where surgery or laser was recommended as the treatment of choice to

preserve vision. The surgeon decided which eye was most in need of urgent treatment. Other inclusion criteria included aged 17 years or above, ability to understand Hausa or English and lived within 200 km of the clinic.

Exclusion criteria: Patients who had ocular comorbidities or systemic diseases that may contraindicate surgery or laser, communication problems such as profound deafness, previous ocular surgery (except cataract surgery), specific referral for glaucoma surgery, or lack of consent to participate.

Intervention

The intervention was a single session of MI adapted for the local context and language using a draft interview guide generated following a qualitative study.[9] The principal researcher was trained in MI in Europe in two workshops and subsequently coached the two study interviewers. They worked together in pilot interviews until a satisfactory level of competence had been reached. The interviewers conducted all the interviews in a quiet room in the clinic, in the participant's preferred language (Hausa or English). The interviewer engaged the participant by presenting an agenda for discussion which included awareness of glaucoma and the consequences of no treatment, acceptance of surgical treatment options, adherence to prescribed medication and follow up to monitor the eye pressure. Open-ended questions were asked, with active listening including reflections. The interviewers sought to understand the participant's perspective in an empathic fashion and listened for evidence of change talk.

Fidelity to MI (whether delivery adheres closely to the approach) can be assessed using the Motivational Interviewing Treatment Integrity code (MITI).[20] The extent to which a collaborative relationship forms between interviewer and client is assessed using the Working Alliance Inventory (WAI)[21] and high WAI scores given by interviewers and clients indicate greater connection between the two parties. The AMIG sessions sought to follow the spirit of MI, and were recorded. Interview sessions lasted 35 to 60 minutes. After the AMIG interview, the 12-item WAI Short Questionnaire

(WAI-SR) was administered to each participant and interviewer to assess the collaborative relationship.[21]

Outcomes

The primary outcome was the proportion of participants who accepted and underwent surgery or laser treatment (i.e., uptake) within two months of the date given for the procedure.

Sample Size

The sample size was calculated based on the primary outcome using the SAMPSI command in Stata 14 statistical software (Stata/IC14.0; Stata Corp, College Station, TX, USA). Based on the pilot study, we anticipated that 35% of people in the control group would accept and undergo surgery or laser treatment within two months. A sample size of 137 in each arm was required to detect a 50% relative or 17.5% absolute increase in uptake (equivalent to an uptake of 52.5% in the intervention group) (power 0.8, alpha 0.05). The sample size of 137 was rounded up to 150 in each arm to allow for loss to follow-up. No subgroup or interim analyses were planned.

Recruitment

Eligible patients were identified for enrolment by the ophthalmologists who referred them to the Project Manager for recruitment. The Project Manager ensured that potential participants understood the information sheet and signed the consent form. They were given a unique study ID and demographic information, home address and telephone number collected to enable subsequent tracing.

All participants were given a red card with their name, hospital medical record number and their trial ID. They were instructed to present this card to the Project Manager at every attendance at the clinic, and on presentation they were fast tracked through the system. Clinical examination, treatment recommendation, randomization, data collection and entry into the trial database were all undertaken on the same day.

Randomisation

Sequence generation: A statistician, not at the project site, generated the randomization list using the *randbetween* function in Excel (Office 2013, Microsoft inc). Block randomization with variable block sizes was used to ensure balance in the groups over time, as the uptake of laser or surgery may fluctuate over time.

Allocation concealment mechanism: The option of AMIG or no AMIG was printed on headed paper, signed and stamped off-site, in London by persons not involved in the trial. These were placed in sequentially numbered opaque envelopes in accordance with the randomization schedule, which were then sealed and stamped. A second similar procedure was followed to randomize those allocated to AMIG to either interviewer A or interviewer B. These envelopes were kept in a locked cupboard and were only opened when needed.

Implementation: Immediately after recruitment the next envelope in the sequence was opened to see if the patient was allocated to AMIG or not. The interviewers wrote the sequence number on the participant's form and their unique ID number was written on the outside of the envelope and returned to a sealed locked container. The same processes were adopted for allocation to interviewer A or B.

Procedures

During the clinical consultation with the attending ophthalmologist before randomization, an explanation of glaucoma was given to all participants as well as the treatment options and prognosis.[22] After explaining treatment options the ophthalmologist recommended one form of treatment, taking account of the severity of disease and socio-demographic variables. Usual care was enhanced by providing all participants in both groups with written information, in Hausa or English, about glaucoma. This written information was developed and pilot tested following interviews with glaucoma patients. The pamphlet, which was called the "Silent Thief", contained images to represent visual field loss and conveyed simple messages. A copy of the pamphlet was also displayed at the entrance to the clinic.

The date for surgery or laser was determined at the first consultation and name, age, sex, hospital medical record and procedure were entered into the operating list. Patients were informed of

the date orally and it was written on their red card. The date and type of surgery were recorded in the database. A separate tracing database was created containing the agreed date of surgery for each participant and a date two months after this date was generated automatically.

Severity of glaucoma in the study eye was categorized as early, moderate, advanced or end stage, based on VCDR and visual field loss. The former was assessed subjectively by the ophthalmologist using direct or indirect ophthalmoscopy or with fundus photography with a DRS digital fundus camera (CentreVue SpA Padova, Italy). Visual fields were assessed using an Oculus Twinfield Visual field analyser (OCULUS Optikgeräte GmbH). Early glaucoma was defined as VCDR of less than 0.8 with very little to no visual field loss, moderate as a VCDR less than 0.8 with a visual field greater than 10 degrees, advanced as a VCDR of 0.8-0.9 with a visual field of approximately 5-10 degrees and end stage was defined as a VCDR of 1.0, with a visual field of 5 degrees or less, including when no visual field could be recorded.

Ascertainment of the primary outcome

Every operating day the operating list was checked by the Project Manager to ascertain whether trial participants had attended for laser or surgery on the day allocated, by cross checking details in the operating book with those in the trial database. For those attending, the date and type of treatment performed were recorded. Participants who did not attend on the date allocated but who attended within the two month period were identified by presentation of their red cards to the Project Manager.

Masking

Only participants allocated to AMIG and the AMIG interviewers knew who had been allocated to AMIG. Participants were asked by the interviewers not to discuss whether they had had an interview with the Project Manager, ophthalmologists or other patients to avoid contamination and to maintain masking. In particular, the Project Manager, who was responsible for assessing the primary outcome, was masked to the treatment allocation.

Data management

Two databases were created in Epidata (EpiData Odense Denmark, EpiData Association, 2010-. Http://www.epidata.dk) with range and consistency checks. The Project Manager entered data into

the main trial database. Data were entered as soon as possible after recruitment, so that the 'surgery date' and 'tracing date' outputs could be generated. All data entries were double-checked by the lead researcher (MA). The second database, which was maintained by the interviewers, contained the unique ID, allocation status for AMIG and interviewer, and WAI data. The databases were maintained on separate password projected computers in different lockable offices. Random checks of the quality of data entry were regularly performed in Stata (Stata/IC14.0; Stata Corp, College Station, TX, USA).

Data analyses

The randomization code was broken only after analysis of the primary outcome, which was by intention to treat. There were no missing data on the primary outcome. We compared the proportion of people in the intervention and control group achieving the primary outcome (uptake of surgery or laser treatment) using the risk ratio and the risk difference and report these two measures of effect with 95% confidence intervals (calculated using the 'epitab' command in Stata 14). Univariate and multivariable logistic regression analyses were performed to explore factors associated with undergoing surgery or laser treatment such as gender, age group, distance to hospital, education, occupation, mode of presentation, severity of disease, baseline IOP and interviewer. Analysis by interviewer was performed to explore whether the primary outcome varied with the interviewer performing AMIG. Post-hoc analysis of the primary outcome and WAI data was undertaken to compare outcomes and quality of the earlier and later AMIG interviews (first half versus second half).

Working Alliance Inventory questionnaires for participants' and interviewers' ratings of the AMIG sessions were analyzed as total WAI scores and medians. Cronbach's alpha test was applied to participant and interviewer total scores to assess the level of correlation between scores. Data were also analysed to assess whether WAI scores for participants, and for interviewers, were associated with the primary outcome using median split WAI scores using Pearson chi square test.

RESULTS

Recruitment was slower than anticipated due to civil unrest in North Eastern Nigeria (September 2013 to September 2015). Only one eligible patient refused to participate (Figure 1). A total of 276 glaucoma patients participated in the study. 135 (49%) were assigned to the intervention group and 141 to the control group. All received the intervention as allocated. There were no major imbalances between the two groups at baseline (Table 1).

Table 1. Baseline socio-demographic and ocular variables, by allocation arm

In almost all patients (89% of the 276 participants) laser treatment was recommended, in 7% glaucoma surgery alone was recommended and in 4% a combination of cataract surgery with trabeculectomy or laser was recommended. Slightly more of the intervention group (93%) were recommended laser compared with the control group (84%) but this difference was not statistically significant. When participants attended for treatment they were administered the treatment they preferred. All 133 treated patients underwent laser treatment by choice which was the treatment recommended in all but 13.

Figure 1: Participant flow diagram showing enrolment of participants

Outcomes

Primary outcome

Uptake of treatment in the AMIG group was 52% compared with 45% in the usual care group (Table 2). The risk ratio was 1.2 (95% confidence interval (CI) 0.9-1.5) and the risk difference was 7.2% (95% CI 0-18.9%).

Table 2: Results of primary outcome of the trial, uptake of surgery or laser

The number of participants allocated to interviewer A was 68 and 67 to interviewer B. There was no significant difference in the uptake of treatment between interviewer A and interviewer B, being 46% for interviewer A and 54% for interviewer B (Pearson chi2(1): 0.9073; p = 0.34).

In the first 138 patients recruited (of the 276 total) the risk ratio was 1.1 (95% CI 0.8-1.5) and the risk difference was 2.8% (95% CI -13.8-19.5%). In the last 138 recruited the risk ratio was 1.3 (95% CI 0.9-1.8) and the risk difference was 11.3% (95% CI -5.2-27.9%). There were no differences in interviewer and participant median WAI scores during the two time periods (69% and 71% vs 69% and 71% respectively).

In univariate analysis, participants with either graduate/post graduate or informal education were more likely to undergo treatment than and those with no education (Pearson ch^2, 15.16, p = 0.01). There were no other statistically significant predictors of uptake of treatment by socio-demographic or ocular variables in the univariate analyses. Education was also strongly predictive in the multivariable analysis (Table 3).

Table 3: Multivariable regression analysis of factors affecting uptake of surgery or laser

In the adjusted analysis (Table 3) the odds ratio for undergoing treatment was 1.6 (95% CI 0.9-2.8) but this was not statistically significant.

Fidelity testing using MITI for English language sessions was planned, but was not possible because all interviews were conducted in local languages, Hausa or Pidgin English, which prevented formal coding.

Analysis of Working Alliance Inventory scores

Analysis of WAI showed similar scores for participants and interviewers overall and were similar for both interviewers (Table 4).

Table 4: Correlation between participant and interviewer Working Alliance Inventory scores

Analysis of WAI scores gave the same median split for participant and interviewer scores overall (median scores 70 for both). There were no statistically significant differences in the primary outcome by interviewer median split WAI scores.

There were no harmful or unintended effects in either group.

DISCUSSION

Participants in the AMIG arm underwent treatment at a higher rate than the usual care group (a difference of approximately 7%) but this difference could have arisen by chance. This is the first trial to use this counselling intervention for glaucoma in Africa, and the results do not support introduction of adapted MI into routine practice.

The sample size calculation was based on a pilot study of 45 individuals in which there was an absolute difference of 12% between AMIG (47% uptake) and usual care (35% uptake) groups, but a difference of this magnitude may have occurred by chance as the sample size was small.[17] In the main trial the observed risk difference does not exclude the possibility of a 19% difference. There was no difference in uptake of treatment by interviewer, which reflects the similarities in WAI scores.

In this trial all participants underwent laser treatment, which was described as "computer light treatment", probably because this term induces less fear than the term surgery.[4] Laser treatment also does not require an inpatient stay, so reducing patient costs. Indeed, uptake of treatment for glaucoma has improved dramatically since laser treatment became available: six years prior to the trial, when laser was not available, only 8% of 85 glaucoma patients offered surgery as the treatment of choice agreed to the procedure, and less than 2% finally underwent surgery[4]. Participants who underwent laser treatment in the trial may also have discussed their experiences with friends, family and community members, which increased the acceptability of laser treatment amongst those who subsequently attended the clinic, regardless of allocation. Other reasons for the higher than anticipated uptake of laser treatment in the usual care group could reflect improvements in the infrastructure, equipment, skills and motivation of trained staff since the pilot study, and the more informative educational pamphlet given to all participants.

Cultural factors are relevant to the interpretation of these findings. Uptake of treatment was higher among participants with higher levels of education, as has been shown previously.[23] However, uptake was not associated with severity of disease, even amongst those at imminent risk of

blindness. The reason for this finding is not clear, as it is not uncommon for patients with advanced or end stage disease to lose hope, as highlighted in our earlier study.[9] Professionals, despite their higher level of education, had lower uptake of surgery or laser, which may reflect lack or time or a preference for topical treatment, which they can afford.

We have no data on fidelity to MI, which if low, may also explain the lack of effect. Motivational interviewing is complex and may require more and better training and supervision than was possible in this effectiveness trial.[24] The WAI data were not subject to linguistic restrictions, and the results showed encouragingly good concordance, although these self-reported data are subject to information bias.

Follow up of participants for treatment and research purposes continues to be a major challenge in rural Africa where many glaucoma patients never return after the first visit. Low cost approaches such as text message reminders, that have been used to improve follow up in trabeculectomy patients, may be employed.[25]

The findings of this trial may be generalisable to other clinics that treat patients with glaucoma in this area, and potentially also elsewhere in Africa. However, it may not be generalisable to the general population where there will be many more people with undiagnosed, earlier glaucoma who may react differently to AMIG.

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