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# Impact of patient-held record on knowledge at 1-year follow-up for glaucoma patients: single-center randomized controlled trial

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## ABSTRACT

**Purpose:** To assess whether provision of a personalized patient-held eye health summary (glaucoma personal record) improves patients' knowledge of glaucoma at 1-year follow-up. The National Institute for Clinical Excellence has recommended such an approach to ascertain if this may ultimately help slow disease progression.

**Methods:** Recruited patients, newly diagnosed with glaucoma conditions, were randomly allocated to receive standard clinical care or an additional glaucoma personal record, detailing the current state of each individual's eye condition. Mann-Whitney *U* test was applied for comparison of knowledge scores between groups at 1-year follow-up, using a validated questionnaire. Multiple linear regression analysis was applied to detect any factors significantly associated with a difference in glaucoma knowledge.

**Results:** A total of 122 patients were recruited; 57 controls and 44 intervention patients were tested for their glaucoma knowledge, equating to 83% retention rate. Out of a maximum available 100% converted score, the median scores were 58% and 53% for the control and intervention arm, respectively ( $p = 0.85$ ). Regression analysis showed that age ( $p = 0.015$ ) had a negative association and level of education ( $p = 0.002$ ) had a positive association with glaucoma knowledge.

**Conclusions:** The glaucoma personal record does not impact on a patient's knowledge of glaucoma in either a positive or negative way. Other approaches to improve health literacy among glaucoma patients, particularly for patients who are elderly or have a limited educational background, must be considered to improve patients' awareness and knowledge of their own condition.

**Trial registration:** International Standard Randomized Controlled Trial Number Registry: ISRCTN41306818.

**Keywords:** Health literacy Glaucoma, Glaucoma personal record, Knowledge, Patient

## Introduction

Glaucoma encapsulates a disparate group of eye diseases that are multifactorial and individual to each patient. The common factor is progressive optic nerve fiber loss, which leads to irreversible and disabling visual field defects if it is not diagnosed and treated early. In 2013, the worldwide number of people (age 40-80 years) with glaucoma was esti-

mated to be 64 million, increasing to 76 million in 2020 and 112 million in 2040 (1, 2). Glaucoma patients require lifelong review to monitor their condition and response to eye pressure-lowering treatments. As the population ages, glaucoma will continue to present a significant burden for our current healthcare resources (3). One strategy for an improvement in patient outcomes is to increase patients' knowledge and understanding of their disease, to in turn enhance treatment compliance and reduce disease-related morbidity.

There are various patient-held care records utilized in various UK healthcare services (4-6), but as yet such records have not been available for glaucoma patients. Previous research recognizes that clients who receive emotional support and information at the initial diagnosis of glaucoma benefit by subsequently displaying good compliance and cooperation with their care (7, 8). The NICE Guideline Development Group made recommendations for research into the clinical effectiveness of providing people with glaucoma with a glaucoma personal record (GPR) and for this to be compared to standard treatment (9). Clinical teams may provide numerous

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resources to patients, depending on the individuals' specific needs, yet there is potential to produce a standardized summary that can be tailored to record each individual's current appearance of his or her own glaucoma status. This summary should have the potential to add value to patient care as it would be held by each individual, and be personalized to reflect his or her own condition.

Recent work by Waterman (10) identified the need for patients to be better informed about their glaucoma, to help them understand their condition and the health implications of poor medication adherence. To this effect, Spaeth and Paulus (11) developed a colored glaucoma graph for diagnosed glaucoma patients and glaucoma suspects; it provides both patients and clinicians with visual information concerning current optic disc appearance. Its simple traffic light system was extended to other outcome measures, such as visual field scoring using the Hoddap Classification (12, 13) and intraocular pressure measurement.

This study aims to fulfil the NICE requirement by assessing the clinical effectiveness of providing patients with ocular hypertension (OHT), suspected glaucoma (SG), or chronic open-angle glaucoma (COAG) (henceforth collectively referred to as glaucoma) with an in-house-developed GPR, applying the earlier mentioned visually efficient graphs for clinical parameters, in comparison to current standard best practice. Here we focus on the primary objective of the trial, an evaluation of glaucoma patients' knowledge at 1 year following receipt of a GPR compared to knowledge of patients who receive standard clinical care.

## Methods

### *Trial design and subjects*

This prospective, single-center, parallel-group, randomized, controlled clinical trial recruited 122 adults, newly diagnosed with glaucoma (including OHT, SG, and/or COAG), from a nurse-led ophthalmology outpatient clinic at a medium-sized NHS Trust in the United Kingdom. National ethics approval, reference 12/YH/0471, and local institute approval were obtained prior to commencing the trial. The study is registered with the International Standard Randomized Controlled Trial Number Registry, reference ISRCTN41306818. The degree of standard patient education and information provision within a specialist nurse clinic consists of patients being shown an enlarged model of the eye and ocular anatomy posters, ocular coherence tomography sample scans, and images of healthy and damaged optic nerve heads. Furthermore, the nurse shows examples of normal visual field tests and those showing glaucomatous loss, and patients are offered a generic Trust glaucoma information leaflet to take. The leaflet is based on widely available leaflets, from, e.g., Royal National Institute for the Blind, and covers the definition of glaucoma, its treatment, diagnostic tests, and further contacts. This is the standard clinical practice intervention for the control group, and also for those in the intervention arm, who received the additional GPR booklet with more personal clinical information and further explanations on the impact of certain diagnostic readings.

The main inclusion criteria were English-speaking adults with intact mental capacity who had just received a new

diagnosis of OHT, SG, or COAG or any combination of OHT, SG, COAG, or primary/secondary glaucoma. Patients fulfilling the trial eligibility criteria were recruited and randomized at a baseline clinic visit, to avoid a priming effect.

### *Outcome measures*

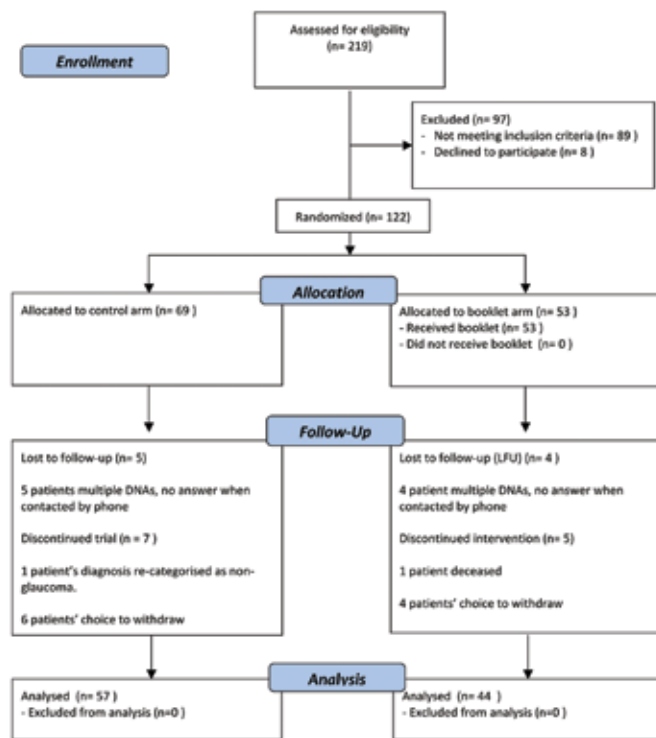
The trial methodology has been described in detail in a previous publication that outlines the protocol (14). In summary, the Health of Patients' Eyes (HOPE) trial is designed to ascertain if a GPR will improve glaucoma patients' knowledge of their condition at 1-year follow-up (primary outcome) and if it will alter clinical outcomes at long-term follow-up appointments at 2 and 3 years (secondary outcome). During the baseline visit and 1-year follow-up visit, clinical parameters were collated: optic disc damage (disc damage likelihood scale), visual field score, and eye pressure. The 25-item National Eye Institute Visual Function Questionnaire (VFQ-25) was also administered to obtain a patient-reported outcome measure of quality of life related to glaucoma (15). During the 1-year follow-up visit, a knowledge assessment was conducted by the chief investigator. This questionnaire was devised and validated by Gray and colleagues (15). Depending on whether a participant is prescribed antihypertensive eyedrops or not, he or she can score a maximum of 17 or 12 points based on 10 or 6 questions, respectively. The questions relate to knowledge concerning the pathology of glaucoma, its effect on vision, means to investigate glaucoma, and, for antihypertensive eyedrop users, the mode of action of the medication and instructions for use. The clinical parameters, and VFQ-25, are planned to be measured again at 2 and 3 years after the first baseline visit as part of the HOPE glaucoma trial.

### *Intervention development and evaluation*

The GPR was devised with the intention to produce an affordable yet functional 16-page A5 booklet containing personalized information concerning a patient's glaucoma condition; the booklet used has been published previously (14). It was refined with advice from a small sample of glaucoma patients and input from the International Glaucoma Association. Traffic light systems are utilized to educate the patient on key clinical parameters: visual field loss, intraocular pressure, disc damage likelihood scale, and disc damage (with explanatory footnotes included). The patient's glaucoma care plan is also summarized in the booklet (11). In addition to the methods described in Forbes and colleagues (14), feedback was sought on the intervention by the development of a 5-question survey, consisting of 4-point Likert answer options, which was posted to all participants randomized to receive the GPR after the year 1 follow-up appointment.

### *Analysis*

Accounting for a 20% dropout rate, the study was designed to have 90% power to detect a 12% difference in patient knowledge of glaucoma between the 2 arms. Differences in distribution (e.g., patient age, sex, level of education) were analyzed by applying 2-sided  $\chi^2$  test or Mann-Whitney *U* test.



**Fig. 1** - CONSORT flow diagram: Health of Patients' Eyes (HOPE) glaucoma. Summary of number of patients involved in different stages of the HOPE trial.

For assessing differences between the control and intervention groups in terms of the level of knowledge demonstrated, 2-sided Mann-Whitney *U* test was applied. Multilinear regression was used to analyze which factors are significantly associated with either reduced or enhanced glaucoma knowledge. Due to the chronic nature of glaucoma, clinical outcome measures cannot be compared between the 2 arms due to the short duration of follow-up (12 months).

## Results

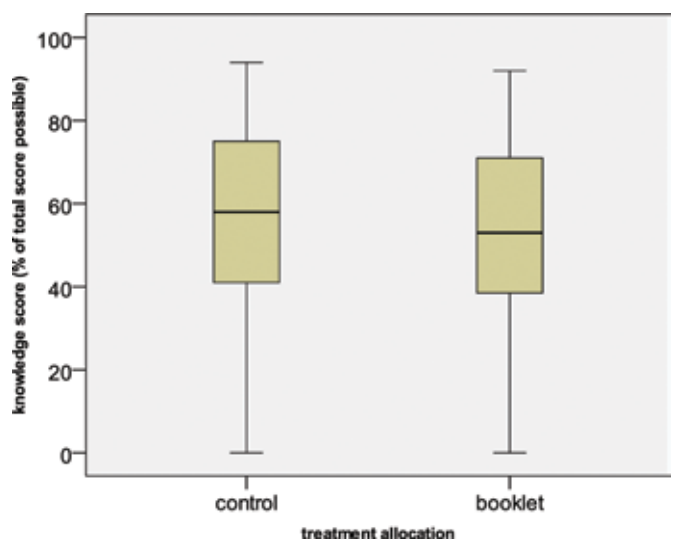
A total of 122 participants were recruited; distribution of patients into the 2 treatment arms was as follows:  $n = 69$  for the control arm and  $n = 53$  for the intervention arm. Patient eligibility, recruitment, and retention through the study are presented in a CONSORT flow diagram (Fig. 1). The 2 trial arms were compared in terms of participant demographics, use of prescribed antihypertensive eyedrops, and the initial diagnosis at presentation. Table 1 shows that there are no pronounced differences in average age, sex distribution, average educational level achieved, or type of diagnosis between the control arm and intervention (GPR) arm.

The primary outcome measure, patients' knowledge of glaucoma, was quantified using a validated researcher-conducted survey at 12 months postrecruitment on average (16). Since the total available score is 12 for those not prescribed antihypertensive drops and 17 for those prescribed eyedrops during the course of the study, the achieved scores were converted into a percentage score with a maximum of 100%. Table 1 and Figure 2 demonstrate that GPR provision

**TABLE 1** - Characteristics of participants in the control and intervention arms

Parameter	Control (n = 57)	Booklet (n = 44)
Median age, y	65	65
Male/female	31/26	25/19
Median education level, y <sup>a</sup>	3: Vocational training	3: Vocational training
Use of prostaglandin analog eyedrops, yes/no, % (n)	17 (10)/83 (47)	25 (11)/75 (33)
Diagnosis, % (n)		
Glaucoma suspect	26 (15)	18 (8)
Open-angle glaucoma	26 (15)	27 (12)
Ocular hypertension	25 (14)	34 (15)
Suspicious discs	2 (1)	5 (2)
Other	2 (1)	0 (0)
Multiple diagnoses	19 (11)	16 (7)
Visual field R, median	-2.14	-2.37
Visual field L, median	-2.31	-2.76
Eye pressure R, median	22.0	22.0
Eye pressure L, median	22.0	22.0
Q1, VFQ-25, median	75	63
Q2, VFQ-25, median	80	80
Q3, VFQ-25, median	75	88
Q10, VFQ-25, median	100	100
Median knowledge score for validated questionnaire, % (see also Fig. 2)	58	53

<sup>a</sup>Options were 0, primary school; 1, O-level/GCSE; 2, A-level; 3, vocational training; 4, college; 5, university.



**Fig. 2** - Glaucoma knowledge scoring. Box-and-whisker plot highlighting the minimum and maximum values (end of whiskers), 25<sup>th</sup> and 75<sup>th</sup> percentile (edge of box), and median for knowledge scores.

does not lead to a statistically significant difference in knowledge when compared to scores achieved by the patients in the control arm.

**TABLE II** - Multiple linear regression for knowledge scoring

Variable	Standardized coefficient	p value
Allocation (control or intervention)	-0.058	0.77
Age	-0.24	0.015 <sup>a</sup>
Level of education	0.32	0.002 <sup>a</sup>
Sex	0.002	0.99
Diagnosis, type of glaucoma	-0.039	0.68
Use of eyedrops	-0.057	0.55
Booklet returned or not	-0.14	0.45
Q1, VFQ-25, baseline (general health)	0.083	0.44
Q2, VFQ-25, baseline (eye health)	0.072	0.50
Q3, VFQ-25, baseline (eye health concern)	-0.023	0.82
Q10, VFQ-25, baseline (peripheral vision)	-0.18	0.068

<sup>a</sup>Statistically significant at  $p < 0.05$

Since knowledge levels may be dependent on various factors, multiple linear regression was applied to determine which factors may contribute to reduced or enhanced knowledge among patients. Table II shows that age is negatively associated with knowledge (i.e., older age is associated with less knowledge). Conversely, a higher level of education is associated with increased knowledge of glaucoma. No other variables were significantly associated with a change in glaucoma health literacy.

A postal survey, sent only to participants in the booklet arm approximately 1 year after they first entered the trial and received the booklet at baseline visit, explored how the participants perceived the GPR intervention. Five questions covered topics around the usefulness and impact of the GPR, or HOPE patient booklet, as it was called in the survey. Table III summarizes the results and shows that the feedback on the GPR was very positive. The response rate for this survey element of the study was 57% (25/44 respondents). Participants were also invited to add free text comments. Twelve of the 15 patients providing such feedback gave positive feedback, e.g., "The feedback was helpful to my optician when checking my eyes" and "The booklet was clear, concise, and easy to understand."

## Discussion

The HOPE glaucoma study constitutes the first effort towards fulfilling NICE recommendations for research into the clinical effectiveness of providing people with COAG with a GPR when compared with standard treatment (9). Three outcomes are deduced from this trial: (1) the GPR used in its present format and with current contents does not enhance a glaucoma patient's knowledge of glaucoma; (2) despite a lack of efficacy in terms of patients' knowledge, the GPR is valued and recommended by those who were allocated the booklet; (3) the key variables that significantly influence a patient's likely (lack of) knowledge of glaucoma are age and level of education.

**TABLE III** - Results of patient satisfaction survey concerning glaucoma personal record

Questions and response options	Participant response		
	Median	Mode	Range
How would you rate the overall usefulness of the personalized HOPE patient booklet? (1 Not at all useful/2 not very useful/3 fairly useful/4 very useful)	4	4	3-4
Do you feel that the overall booklet was fit for its purpose (appropriate number of pages, easy to read, logical layout)? (1 Not at all/2 a little/3 somewhat/4 very much so)	4	4	2-4
Did the personalized HOPE patient booklet help you understand your glaucoma condition better? (1 Not at all/2 a little/3 somewhat/4 very much so)	4	4	1-4
Did the personalized HOPE patient booklet make you look for, or use, other resources (leaflets, websites) to learn more about your glaucoma? (1 Not at all/2 a little/3 somewhat/4 very much so)	3	1	1-4
Would you recommend the personalized HOPE glaucoma booklet to others? (1 Not at all/2 a little/3 somewhat/4 very much so)	4	4	2-4

HOPE = health of patients' eyes.

The content of the GPR was developed using validated tools published previously, and a balanced approach was taken to include visual information and text. Extended use of text was avoided to minimize the size of the booklet and to make the booklet as inclusive as possible for those patients who are less health literate. One could question whether too little in-depth information about glaucoma was included in the GPR, and if this therefore diminished the potential educational impact of the intervention. There is a possibility that the current standard education received by newly diagnosed glaucoma patients in a specialist nurse clinic is already extensive, and that this may therefore limit any impact that the GPR may have on a patient's knowledge of the condition. However, contrary to the one-off education received by patients when newly diagnosed with glaucoma, the GPR features in the follow-up visits, and therefore may have a more long-term positive impact not measured in the 1-year follow-up visit. Longer-term follow-up of the HOPE glaucoma trial patients at 2 and 3 years will further assess this in terms of clinical outcomes. The trial included the use of a control group, random allocation of the GPR, allocation concealment to minimize selection bias, and the use of validated questionnaires to capture knowledge outcome data. Upon analysis of the data, we can conclude that on average the patients in the 2 trial arms had similar baseline characteristics, with no marked differences detected in levels of education, age, sex, type of glaucoma, or degree of prescription of prostaglandin analogs. The sample size was such that the trial was adequately powered to detect a small (12%) difference in knowledge between the 2 arms. Against these strengths, the trial

was conducted in one center only in a rural location, covering a highly homologous white British population. Furthermore, blinding of the assessor was not possible due to the trial design and this may introduce detection bias. The benefit of a single center meant that only one investigator delivered the invention and knowledge test, diminishing the risk of inter-rater variability.

The results of our trial participant survey of those in receipt of a GPR indicate that overall the intervention is welcomed by glaucoma patients. However, despite participants' opinion that the GPR helped them understand their glaucoma better, this did not translate into higher knowledge scores compared to standard care patients. This may to some extent be explained because GPR patients did not go beyond reading the booklet, such as exploring the Internet for sources of information. Potential issues with the survey are that nonresponders may have a less positive opinion, or be less interested in the concept of a GPR, but this is not recorded. Even among the survey responders, 10% of the patients who received the GPR mentioned that they did not recall receiving it. A small sample was canvassed in the survey and there is potential for an unquantified bias to be introduced due to a response rate of only just over 50%. One factor that may mask the knowledge influence by the GPR is that both groups were still exposed to educational resources and materials presented at diagnosis as part of standard clinical practice, as summarized in Methods. In terms of potential for optimization of GPR delivery, this trial already offered and delivered support and education to patients at the time of diagnosis, the most opportune moment (7). However, there may have been scope for reinforcement of the educational message; for example, 3 months after the baseline visit, via a telephone conversation, or through closer collaboration with community opticians and other ophthalmic clinical staff. The core aim of this trial was to improve health literacy among glaucoma patients through the provision of printed (personal) health information, as suggested by NICE. Numerous different health literacy education options are available (17, 18). When compared to other types of educational interventions, the anticipated positive effect of GPR is not expected to be as high as one-to-one or group interventions (19), although the former is mostly likely the most economical to deliver.

In this trial, GPR did not significantly improve glaucoma knowledge. A patient's level of achieved education did correlate positively with an increased level of knowledge on glaucoma, and this has been observed previously by others (19, 20). Since the trial arms were well-balanced in terms of average level of education achieved, this is unlikely to have confounded our results. The negative correlation of age with glaucoma knowledge pinpoints the need for more tailored health education in glaucoma management. In line with observations from other studies, a more intense support program is required for elderly patients and those with a low socioeconomic status to optimize individuals' adherence to glaucoma treatment (20, 21). More long-term follow-up of participants in this HOPE trial will determine if glaucoma knowledge—known to improve medical adherence (22)—or other factors identified here such as patient level of education may impact on glaucoma progression.

## Conclusion

The use of a GPR, in the format used in this trial, is not an effective additional source of information to enhance patients' knowledge of glaucoma. The GPR does not impact on a patient's knowledge of glaucoma in either a positive or negative way. Age-specific interventions and support programs, and educational support aimed at those glaucoma patients who are less health literate, need to be considered to optimize their effectiveness.

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## Disclosures

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Conflict of interest: None of the authors has conflict of interest with this submission.

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