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Examining the assumptions, accuracy and acceptance of an electronic monitoring device for adherence to eye drops

Submission date	**Recruitment status**	[X] Prospectively registered
25/02/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/03/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/08/2022	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Glaucoma treatment is only effective if patients instil eye drops on time daily. However, research has demonstrated that many patients find this problematic such that poor adherence places them at risk of sight loss. One of the difficulties for nurses, other healthcare workers (HCWs), and researchers is the lack of a 'gold standard' to quantify adherence. Clinically, the lack of an objective measure presents a nursing challenge in directing resources to support patients' and leads to difficulties with personalising the provision of educational interventions.

To address this, researchers have developed a prototype tool to measure adherence called the EASY label which records when patients squeeze an eye drop bottle. This new tool is a significant advance clinically and for research because it measures the timepoint at which the drop is instilled on the assumption that this enters the eye (acknowledged as the best possible approximation of adherence).

The present study will have patients and healthcare workers perform usability testing on the EASY label prototype before it enters mass production. The researchers will ask participants to instil eye drops into a plastic model head so as to measure: 1) whether the label functions reliably; 2) if it registers each eye drop instilled accurately in that there are no over or under registrations as each drop is instilled and if the users use the label as instructed; 3) whether patients with different diagnoses respond similarly and if it affects normal adherence behaviour. A key part of the study will explore user acceptance by interviewing patients and HCWs about the usefulness, practicalities and ethics of the label. By involving patients and HCWs at this early stage, the researchers will ensure the relevance and ownership of the label in the real world making it a viable option to support patient-centred research into adherence.

Who can participate?

1. Patients aged 18 or older with primary open angle glaucoma, ocular hypertension, normal tension glaucoma or pseudo-exfoliative glaucoma, who have been prescribed glaucoma eye drops
2. Doctors, optometrists, nurses or healthcare workers working routinely with patients with glaucoma, who regularly instil, or teach patients to instil, eye drops

What does the study involve?
Initially, participants will be requested to instil an eye drop to the eye of a plastic model head 28 times (given one eye drop bottle and thereby one label lasts for 28 days). The study will test two distinct manufacturers' bottles as it is thought that different bottles may affect the use of the label, meaning two sets of 28 instillations per participant. The patients and HCWs will use both bottles during the test with random ordering set-up by an independent researcher to avoid any bias arising due to ordering effects. Researchers will use an observation checklist to monitor key aspects of drop instillation such as picking up the bottle, taking the lid off and whether the participant successfully expressed each of the required drops. Researchers will tally each successful drop into the model head's eye, noting any unsuccessful or questionable instillations and why they occurred.
Once the drop instillation is complete, each bottle with a label will be sequentially numbered to aid data entry and analysis. At the end of the period of drop instillation each HCW and patient will be interviewed and audiotaped. This will involve a modified 'think aloud' technique immediately after the performance of the task in which participants will be invited to share what they thought about while they were instilling the drop and how they felt. Then they will be asked for their views on how easy the label was to use and whether they thought it would influence the adherence behaviour of patients in the future. To minimise the risk of social desirability bias in the reporting of their responses, all participants will be reassured that there are no right or wrong answers and that everyone's views are important.
The final part of the interview will be qualitative and semi-structured with open-ended questions. HCWs will be asked to explore how the environment (lighting, noise, heat) might affect the use of the label, if they can think of any user characteristics which may interfere with proper use of the label and, if so, why. For the HCWs, enquiries will be made around how they feel about sharing the adherence data with patients, what drawbacks or benefits it would bring and any other practicalities which need to be taken into account, especially regarding its potential use in routine glaucoma clinics. Additionally, the patients will also be invited to discuss how they feel about being monitored for adherence at home, whether and how they would like to see the results of the monitoring data in the context of learning about glaucoma and its treatment/prognosis, whether they would like online applications so they can monitor their own adherence at home, in what circumstances the label should be used, and how they feel about giving consent for the label to be used.

What are the possible benefits and risks of participating?
Taking part in the EASY label observations and interviews will mean participants giving up around 90 minutes of their time. That said, the researchers will do their best to arrange this at a time that is convenient and are happy to cover travel expenses for any journeys that are needed. The study may not help participants personally but the information we gather will help us to understand whether the EASY label works as hoped, and how best to use the EASY label going forwards to benefit patients and healthcare workers.

Where is the study run from?
The study is organised by Cardiff University's School of Healthcare Sciences and is intended to recruit from Cardiff and Vale University Health Board (UK)

When is the study starting and how long is it expected to run for?
May 2020 to June 2021

Who is funding the study?
Glaucoma UK

Who is the main contact?
Prof. Heather Waterman
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number

517125

Study information

Scientific Title
Examining the AssumptionS, accuracY and acceptance of an electronic monitoring device for adherence to eye drops: the EASY label study

Acronym
EASY Label Study

Study objectives
This is a prospective cohort study performing usability testing of a prototype label, or flexible sensor, that measures adherence to glaucoma medication by recording the time an eye drop bottle is sufficiently squeezed to express a drop.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/03/2020, East of Scotland Research Ethics Service (c/o Mrs Lorraine Reilly, Tayside Medical Science Centre, Residency Block 3, George Pine Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; +44 (0)1382 383878; eosres.tayside@nhs.net), ref: 20/ES/0041

Study design
Prospective cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Glaucoma/ocular hypertension

Interventions
The present study will have patients and healthcare workers perform usability testing on the EASY label prototype before it enters mass production. Patients and healthcare professionals will be asked to instil an eye drop to the eye of a plastic model head 28 times each for two distinct eye drop bottles. Researchers will observe this procedure. This will be done in the glaucoma clinic or research laboratory.

The researchers will measure:
1. Whether the label functions reliably
2. If it registers each eye drop instilled accurately in that there are no over or under registrations as each drop is instilled and if the users use the label as instructed
3. Whether patients with different diagnoses respond similarly and if it affects normal adherence behaviour

A key part of the study will explore user acceptance by interviewing patients and HCWs about the usefulness, practicalities and ethics of the label. By involving patients and HCWs at this early stage, the researchers will ensure the relevance and ownership of the label in the real world making it a viable option to support patient-centred research into adherence.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Accuracy of instilling eye drops and frequency of malfunctions of the label, assessed by comparing the actual number of drop instillations into a plastic model's head, as observed in real time by researchers, with digital registrations of label use, at visit 1

Key secondary outcome(s))
Participant acceptance towards the EASY label assessed using qualitative interviewing and thematic data analysis, as well as a brief survey on how simple the label was for participants to use, at visit 1

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Have primary open-angle glaucoma, ocular hypertension, normal tension glaucoma or pseudo-exfoliative glaucoma
2. Aged years 18 or older
3. Can understand English or have an interpreter
4. Have the mental capacity to participate, in line with the Mental Capacity Act
5. Prescribed glaucoma eye drops

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Aged less than 18 years old
2. Not having eye conditions listed in inclusion criteria
3. Unable to understand English (or no access to an interpreter)
4. Lacking the mental capacity to participate
5. Not prescribed glaucoma eye drops

Date of first enrolment
01/12/2020

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff and Vale University Health Board
UHB Headquarters
Woodlands House
2nd Floor
Maes y Coed Rd
Heath Park
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CF14 4HH

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
International Glaucoma Association

Alternative Name(s)
IGA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Heather Waterman (watermanh1@cardiff.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No