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Eye donation from palliative care and hospice care settings

Submission date
23/09/2019

Recruitment status
No longer recruiting

Registration date
15/10/2019

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
According to the Royal National Institute of Blind people (RNIB) over two million people in the UK are living with sight loss and this number is predicted to double to nearly four million by 2050. Some of the conditions that lead to sight loss and impaired vision can be treated if eye tissue is available, for example, by corneal transplantation and reconstructive surgery, alongside research into a wide variety of eye disease. The problem is that of all organs and tissues that can be donated, eyes are the least donated meaning that NHS Tissue Services (TS) who oversee eye donation (ED) in the UK are not able to supply enough tissue so that the reportedly needed 5000 corneal transplants can be undertaken. In the year 2015-2016 only 2,897 eyes were donated. We know that people hold very strong views about donating their eyes. They are concerned about disfigurement and view eyes as the windows to the soul. We also know people are squeamish about the idea of ED. In addition, health care professionals (HCPs) are reluctant to discuss the option of ED. This reluctance appears to be linked to views about what should/should not be discussed with people during end-of-life care planning (EoLCP). We know that the majority of people who die in the UK could donate their eyes as long as certain criteria is met and yet most people have very little knowledge about the option of ED. What we need to know is whether an increase in eye donation could be achieved by developing new routes of supply by approaching people in specialist palliative care settings (SPCS) and Hospice Care settings (HCS) who have the potential to be eye donors after their death. We also need to know whether patients would be willing to donate their eyes and how they and their family members feel about discussing ED. This information is essential to NHS Tissue Services as they shape future service plans

Who can participate?
Patients under the care of palliative and hospice care services and their nominated carer and health care professionals working in palliative and hospice care settings

What does the study involve?
Participants will be interviewed, take part in focus groups, and answer a questionnaire regarding attitudes, knowledge and preferences concerning eye donation

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of Southampton, UK

When is the study starting and how long is it expected to run for?
November 2019 to December 2021

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS: 41161

Study information

Scientific Title
Eye donation from palliative and hospice care contexts: investigating potential, practice, preference and perceptions

Study objectives
RQ1: Potential - What is the potential for eye donation in SPCS and HCS and what consequences will any increase in eye donation from these settings have for NHS BT-TS (resources, infrastructure and logistics, e.g. numbers of staff needed, storage capacity, etc.)?
RQ2: Practice, Preference, and Perceptions - What system based, attitudinal and educational barriers, facilitators influence the identification and referral of potential eye donors in SPCS and HCS settings and the embedding of eye donation in end of life care (EOLC)?
RQ3: What behaviour change strategies will be effective in increasing eye donation across the community of service providers and service users within SPCS and HCS settings?

Objective I: to scope the size and clinical characteristics of the potential eye donation population from research sites so that NHS BT-TS can consider the impact for their service. For example: Can an increase in eye donation be supported by current retrieval team provision?
Objective II: to map system-based barriers to operationalizing eye donation including: how potential donors are currently identified and referred to NHS BT-TS, and what services, resources, documentation are in place to: raise awareness and embed eye and tissue donation in EOLC planning.
Objective III: identify factors (attitudinal, contextual) that enable or challenge service providers to consider and propose the option of eye donation as part of EOLC planning from a local and national perspective.
Objective IV: identify service users' views regarding the option of eye donation and the propriety (acceptability) of discussing eye donation as part of admission procedures or as part of EOLC planning conversations.
Objective V: develop, pilot, and evaluate an empirically based and theoretically informed intervention designed to change behaviours in relationship to the identification, approach and referral of patients from SPCS and HCS for eye donation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2019, NHS HRA Social Care REC (Ground Floor Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)28 9536 1400; nrescommittee.social-care@nhs.net), ref: 19/IEC08 /0008

Study design
Non-randomised; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Management of Care, Qualitative

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Eye donation

Interventions
The researchers plan to find out how many patients from three SPCS and three HCS across England could have been eye donors, and how many patients were actually approached and referred to TS over a one-year period by reviewing the medical notes of 1200 patients against specific eligibility criteria. They will seek the views of HCPs, patients and their next of kin about the acceptability of discussing ED as part of EoLC via interviews, focus groups and gain a wider understanding
of the challenges this option poses from a national survey of HCPs working in these contexts.

Six clinical sites are involved in this 36-month three-phase study.

Methodology:
The proposed three-year study is structured in line with the six steps in quality intervention development (6SQuID) applying a mix of qualitative and quantitative methodologies, theoretical perspectives and intervention mapping methodologies to deliver three interlinked and developmental work packages that answer the research questions and meet the study objectives.

Phase One: retrospective note review of 1200 deceased patient notes against eye donation criteria. CAG form has been completed in this application.

Potential participants will be approached by clinical partners (PIs) and provided with a recruitment pack including: letter of invitation and participant information sheet outlining the study and providing detailed data protection information in line with recent changes. Posters publicising the research will be displayed in all clinical sites for two weeks before the period of observation and data collection begins.

Potential participants include all patients over the age of 12 receiving care in either a hospice or palliative care service during the period of data collection.

All six sites will participate in a period of 'observation' (five days in each site) where the 'donation culture' will be assessed via observation and informal conversations.

Phase Two:
Participants will either:
1. Agree to undertake a face to face interview (patients N=60)
2. Agree to undertake a face to face interview (health care professionals N=60)
3. Agree to join a focus group (carers N = 120)
4. Agree to join a focus group (health care professionals N = 80)
5. Complete a national survey (health care professionals)
The secondary analysis of two existing datasets will be undertaken in Phase two.

Phase Three:
Transparent Expert Consensus meeting and Delphi rounds to agree a pilot intervention for testing in two clinical sites. Participants will include: research team, PPI representatives, patient and carer representatives, practice and academic experts.

Intervention Type
Other

Primary outcome(s)
Phase 1. Number and characteristics of the potential eye donation population, and current referral rate for each research site established via retrospective note review of 1,200 deceased patient records
Phase 2. Qualitative data from stakeholders to assess their attitudes, knowledge and preferences concerning conversations about eye donation collected from a secondary analysis of existing datasets, and interviews with service users. This data will be used to construct a questionnaire survey that will be sent to 220 service providers in order to explore attitudes, knowledge and preferences concerning eye donation at a national level.
Phase 3. Agreed intervention designed to change behaviours, including pathways for implementation, generation of programme/action logic model, descriptive statistics gathered from Delphi survey rounds indicating level of agreement with the proposed intervention activities and process

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Patients under the care of palliative and hospice care services and their nominated carer
2. Health Care Professionals working in palliative and hospice care settings

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
Patients under the age of 18 years

Date of first enrolment
01/12/2019

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicestershire and Rutland Hospice (LOROS)
Groby Road
Leicester Road
Leicester
United Kingdom
LE3 0QE

Study participating centre
Rowans Hospice
Purbrook Health Road
Waterlooville
United Kingdom
PO7 5RU

Study participating centre
Marie Curie Hospice
Maudsly Street
Bradford
United Kingdom
BD3 9LE

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
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United Kingdom
LS9 7TF

Study participating centre
West Suffolk NHS Foundation Trust
Hardwick Lane
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IP33 2QZ

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
Standing Way
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MK6 5LD

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/49/42

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality

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		01/11/2023	07/11/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes