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General practice organ donation intervention: a feasibility study

Submission date
22/09/2017

Recruitment status
No longer recruiting

Registration date
26/09/2017

Overall study status
Completed

Last Edited
13/09/2019

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aims to find out whether UK primary care is a feasible location for an intervention to increase registration to the NHS Organ Donor Register (NHS ODR). Currently, only 35% of the UK population are on the NHS ODR and there is a shortage of donated organs. Previous research in primary care in the USA shows that the setting may be promising for increasing membership to the register by asking patients if they would like to join during consultations. However, there are barriers to the implementation of primary care interventions in the UK, for example increasing workload. This study therefore assesses whether UK primary care is an appropriate setting for an organ donation intervention.

Who can participate?
Patients aged 18 and over at the participating GP practice in Luton (UK)

What does the study involve?
The intervention consists of three elements: training staff in organ donation information, the display of leaflets and posters in the waiting room and asking patients during consultations if they wish to join the register. The intervention runs for a three-month period. To examine the feasibility of the intervention, the training is evaluated through a survey, data on registrations is collected throughout the study, focus groups are carried out with staff and patients, and staff complete an online survey.

What are the possible benefits and risks of participating?
There are few risks to taking part in the study. However, discussions may involve the topic of organ donation and death, which some people might find difficult.

Where is the study run from?
A large GP Practice in Luton, UK

When is the study starting and how long is it expected to run for?
October 2016 to September 2018

Who is funding the study?
1. NHS Blood and Transplant (UK)
2. University of Bedfordshire (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Investigating an organ donation intervention in primary care: a single-practice feasibility study

Acronym
GPOD

Study objectives
To develop and evaluate the feasibility of a GP practice-based intervention designed to increase organ donation rates in ethnically diverse locations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London – Brent, NHS HRA, Research Ethics Committee, 03/11/2017, ref: 17/LO/1361
2. Institute for Health Research, University of Bedfordshire, Ethics Committee, 20/11/2017, ref: IHREC800
3. Confidentiality Advisory Group, HRA, 08/12/2017, ref: 17/CAG/0169
4. Health Research Authority Approval, 11/12/2017

Study design
Single-centre feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format. Only patients at the designated practice can participate.

Health condition(s) or problem(s) studied
Registration as an organ donor on the NHS Organ Donor Register

Interventions
The intervention consists of three elements, training staff in organ donation information, the display of leaflets and posters in the waiting room and asking patients during consultations if they wish to join the register (also called prompted-choice). A single GP practice in Luton, UK has agreed to run the intervention for a three-month period. To examine feasibility, training will be evaluated through paper survey, data on registrations captured throughout the trial period, focus groups with staff and patients and an online staff survey will be used.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of the intervention, assessed using the number of registrations and how often patients are asked the question, collected throughout the intervention period (3 months)

Secondary outcome measures
Due to the mixed methods nature of the study and need to assess feasibility, no secondary outcome measures will be examined

Overall study start date
16/10/2016

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. 18 years of age or above
2. Capacity to consent to the NHS ODR

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
One UK primary care clinic which has already been recruited

Key exclusion criteria
1. Lacks capacity to consent to be a member of the NHS ODR
2. Under 18 years of age

Date of first enrolment
08/01/2018

Date of final enrolment
09/07/2018

Locations

Countries of recruitment
United Kingdom

Study participating centre
A GP Practice
Luton
United Kingdom
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Sponsor information

Organisation
University of Bedfordshire

Sponsor details
University Square
Luton
England
United Kingdom
LU1 3JU

Sponsor type

University/education

Website
https://www.beds.ac.uk/research-ref/ihr

ROR
https://ror.org/0400avk24

Funder(s)

Funder type
University/education

Funder Name
NHS Blood and Transplant

Alternative Name(s)
National Health Service Blood and Transplant, UK National Health Service Blood and Transplant, NHSBT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
University of Bedfordshire

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

There are no plans to share additional documents at this time, due to their use to support a PhD. However, there are plans to publish the protocol within the next year.

The results of this study will be disseminated through planned publication in a high-impact peer review journal approximately one year following trial end date. This study forms part of a PhD thesis which will also be published via Ethos.

Intention to publish date

30/09/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/11/2018		Yes	No
HRA research summary			28/06/2023	No	No