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STRIDES: Strategies to improve donor experiences

Submission date 24/10/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/10/2019	**Overall study status** Ongoing	
Last Edited 14/05/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The STRIDES study aims to reduce adverse events related to blood donation by implementing variations on the current interventions. Reducing adverse events is likely to increase donor retention and therefore the number of blood units donated for NHS patients. The study will include changes to the material read prior to donation, the drink consumed prior to donation and the advice given during and after the donation experience. All blood donors in England who attend a blood donation session during the study period will anonymously participate, with the option to opt-out. The results from this study will help inform national policies that should optimise blood collection procedures, minimise donor reactions, improve donor return rates, and improve donor (and staff) well-being and satisfaction. In addition to the main study, up to 250,000 donors will be asked if they wish to join the STRIDES BioResource, part of the NIHR BioResource. The STRIDES BioResource aims to provide additional biological (blood samples) and questionnaire data to address the overall aims of the STRIDES study

Who can participate?
Adults who attend an NHS blood donation clinic in England during the study period

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to future blood donors. The study's results should yield evidence-based policies to reduce adverse events for NHSBT and other blood services; lead to improvements in donor health, experience, and service efficiency (e.g., better retention of donors, who may be more likely to give blood repeatedly). There are no additional risks to participating in the usual blood donation

Where is the study run from?
The STRIDES study is being run by the University of Cambridge and takes place in all NHSBT blood donation clinics across England

When is the study starting and how long is it expected to run for?
November 2019 until November 2029

Who is funding the study?
NHS Blood and Transplant team (NHSBT) (UK)

Who is the main contact?
1. Prof Emanuele Di Angelantonio
ed303@medschl.cam.ac.uk
2. Prof John Danesh
jd292@medschl.cam.ac.uk

Study website
http://www.strides-study.org.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Strategies to Improve Donor Experiences

Acronym
STRIDES

Study objectives
A single intervention or combination of interventions will improve donor experiences by reducing adverse events in and out of the blood donation session

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/11/2018, East of England - Cambridge South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8134; NRESCommittee.EastofEngland-CambridgeSouth@nhs.net), ref: 18/EE/0284

Study design
Cluster randomized crossover/stepped-wedge factorial trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
http://www.strides-study.org.uk/about/pis/

Health condition(s) or problem(s) studied
Blood donor health

Interventions

We will compare four different interventions with current NHSBT practice:
1. Isotonic hydration before donation: 500ml isotonic drink vs. current 500ml plain water
2. Time on donation chair after donation: 3-minutes before standing vs. current 2-minutes
3. Modified applied muscle tension (AMT) exercises: new AMT vs. current practice of AMT
4. Psychosocial intervention: preparatory materials vs. current practice of nothing

The study design is tailored to the specific needs of our study and NHSBT: a cluster-randomised cross-over/stepped-wedge factorial trial involving the whole of NHSBT for 36 months. A minimisation algorithm was used to ensure that, when clusters are randomised to each intervention, balance is maintained in important stratifying factors

Depending on the intervention assigned:
1. In addition to the NHSBT welcome leaflet donors will be given a copy of the 2-sided STRIDES psychosocial leaflet, which will provide guidance of what to expect during and after donation, what to do while donating blood and advice
2. Instead of a 500ml glass of water/squash, donors will be asked to drink a 500ml low-sugar isotonic drink. A poster will be provided about the drink and the contents of the drink will be displayed
3. If donors are eligible to give blood, they will receive modified instructions for Applied Muscle Tension by way of a 1-page study-specific leaflet
4. If a donor is eligible to give blood, a donor's time in the donation chair following blood donation will be increased from 2 to 3 minutes.
In addition, on arrival of a donor at the donation session, a member of the donation team will ask donors whether they would wish to consider participation in the BioResource. If the donor agrees they will be consented and additional blood samples will be taken from the satellite pouch during the donation. Once home, the donor will receive an email like to complete a health and lifestyle questionnaire to help address the main aims of the study. Anonymous data will be provided to the University of Cambridge by NHSBT

Intervention Type
Other

Primary outcome measure
Number of in-session vasovagal reactions (VVRs) with loss of consciousness (i.e. episodes involving loss of consciousness of any duration, with or without additional complications) observed by NHSBT staff

Secondary outcome measures
1. All in-session VVRs (i.e. with and without loss of consciousness)
2. All delayed VVRs (i.e. VVRs with and without loss of consciousness after leaving the donation venue)
3. Delayed VVRs with loss of consciousness; and
4. Any in-session non-VVR adverse events or reactions

Overall study start date
23/04/2018

Completion date
11/03/2029

Eligibility

Key inclusion criteria
All donors attending the donation sites involved in the study

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
1,300,000

Total final enrolment
1381520

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
04/11/2019

Date of final enrolment
04/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Blood and Transplant
NHS Blood and Transplant
Head Office
500 North Bristol Park
Filton
Bristol
United Kingdom
BS34 7QH

Sponsor information

Organisation
NHS Blood and Transplant

Sponsor details
NHS Blood and Transplant
c/o Research Office
500 North Bristol Park
Filton
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England
United Kingdom
BS34 7QH
+44 (0)117 921 7501
research.office@nhsbt.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Hospital/treatment centre

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
NIHR Blood and Transplant Research Unit

Funder Name
NIHR BioResource

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/11/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Anonymous participant level data will be available upon request and approval by the Data Access Committee for the study. Applications can be requested by contacting donorhealth@medschl.cam.ac.uk, 01223 747226. Only relevant information/variables will be provided and the whole data set is unlikely to be released.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 3	01/11/2022	22/12/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol article		10/08/2023	14/08/2023	Yes	No