# STRIDES: Strategies to improve donor experiences

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

#### 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

#### Contact name

Prof Emanuele Di Angelantonio

#### Contact details

Strangeways Research Lab Worts Causeway Cambridge United Kingdom CB1 8RN +44 (0)1223748659 ed303@medschl.cam.ac.uk

#### Type(s)

Scientific

#### Contact name

Dr Amy McMahon

#### Contact details

Strangeways Research Lab Worts Causeway Cambridge United Kingdom CB18RN +44 (0)1223747228 am2663@medschl.cam.ac.uk

## 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 Bristol 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 Protocol article		10/08/2023	28/06/2023 14/08/2023	No Yes	No No