ISRCTN17256224 https://doi.org/10.1186/ISRCTN17256224

The donor experiences study

Submission date
02/08/2019

Recruitment status
No longer recruiting

Registration date
09/08/2019

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The retention of blood donors is an important challenge for both developed and developing countries. The demand for blood will increase within the next few years due to changes in demographics and ageing populations. The experience of blood donors is particularly important for blood collection services not only because of the duty of care, but because repeat donation is critical for the blood supply. Donor fear is associated with increased risk for procedural issues, donor distress, and some adverse reactions. In turn, these reactions may be disincentives for donor return. Several studies have reported on strategies to assess and possibly address donation related fears, though it remains unclear how these insights can be best incorporated into standard operating procedures. This study aims to examine whether assessing and addressing donor fears may help staff to recommend the most relevant interventions and information in order to increase donor self-efficacy, improve the donation experience, reduce adverse events, and increase subsequent return. Additional study benefits include improving donor health, and improving session flow by avoiding disruptive and costly adverse reactions.

Who can participate?
Any eligible whole blood or plasma donor who has had 3 or less previous completed donations (plasma and/or whole-blood), presenting in participating Red Cross donor centres in Sydney, Australia.

What does the study involve?
Eligible donors are invited to participate while at a donor centre. Participants are randomly allocated to one of four groups. Those in the first group will donate as usual. Those in the second group are asked to complete a fear assessment. Participants in the third group will be offered an instructional brochure in addition to the fear assessment; this brochure includes a summary of a variety of ways to manage fear and stress while donating. Following the fear assessment and receiving the brochure, participants in the fourth group will participate in a brief discussion with the research assistant to review the contents of the brochure. All participants will complete post-donation questionnaires.

What are the possible benefits and risks of participating?
There will be no anticipated risks of participating. We expect some donors to benefit from participation by a reduced risk for adverse events, increased self-efficacy, and an increased desire to return.

Where is the study run from?
The study is being run by Macquarie University in collaboration with the Australian Red Cross Blood Service.

When is the study starting and how long is it expected to run for?
August 2019 to May 2020

Who is funding the study?
Australian Red Cross Blood Service and Macquarie University

Who is the main contact?
Dr. Philippe Gilchrist, philippe.gilchrist@mq.edu.au

Contact information

Type(s)
Public

Contact name
Dr Philippe Gilchrist

ORCID ID
http://orcid.org/0000-0001-5036-3369

Contact details
Macquarie University, Department of Psychology
Macquarie Park
Australia
2109
+61 2 9850 2340
philippe.gilchrist@mq.edu.au

Type(s)
Scientific

Contact name
Dr Philippe Gilchrist

ORCID ID
http://orcid.org/0000-0001-5036-3369

Contact details
Macquarie University, Department of Psychology
Macquarie Park
Australia
2109
+61 2 9850 2340
philippe.gilchrist@mq.edu.au

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Improving donor experiences by assessing and responding to the fears of the individual donor

Acronym
N/A

Study objectives
1. Fear of the blood draw will be significantly positively related to higher anxiety, higher self-reported venipuncture pain, and the self-report and official record of more vasovagal reactions.
2. Assessing fear will not lead to (prime) more donor fear, anxiety, venipuncture pain, self-reported vasovagal reactions, or the official record of more vasovagal reactions.
3. Among fearful donors, providing an instructional brochure will be more effective than no provision of donor information in terms of increasing self-efficacy.
4. Among fearful donors, engaging with a donor to advise relevant strategies, including an instructional brochure following a fear assessment, is expected to result in increased self-efficacy, an improved donation experience, increased donor return, a greater reduction in fear (pre vs. post), and less venipuncture pain, post-donation anxiety, and vasovagal reactions when compared to donation as usual, fear assessment only, or fear assessment combined with an information brochure alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/06/2019, the Australian Red Cross Blood Service Ethics Committee (17 O'Riordan Street
Alexandria, NSW, 2015, Australia; 02 9234 2368; ethics@redcrossblood.org.au), ref: 2019#11.

Study design
Multi-centre, pragmatic, parallel group, individually randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
Condition A: control group. Donation as usual.

Condition B: fear assessment only. Donors will be asked to respond to an e-tablet-based question, prior to donating, relating to their fear of donation.

Condition C: fear assessment and an instructional brochure. Condition C will be identical to Condition B, though the research assistant will also provide all donors with an instructional brochure. This brochure will include a summary of a variety of evidence-based strategies to manage fear and stress-related adverse reactions among donors, including distraction, breathing techniques, and a muscle tensing technique to prevent vasovagal symptoms.

Condition D: fear assessment, with an instructional brochure, and follow-up questions from the Research Assistant. This condition is identical to Condition C, but participants who indicate fear will be asked about the nature of the fear, and the research assistant will discuss and point to appropriate strategies outlined in the accompanying instructional brochure. This condition is designed to demonstrate whether engaging with the donor in follow-up questioning and recommendation of relevant strategies provides additional benefit beyond simply providing information.

Randomisation will include individual randomisation, determined by a computerised randomisation process for each participant following consent.

Intervention Type
Mixed

Primary outcome measure
1. Donor fear is measured using a self-report (France et al., 2013) at pre- and post-donation.
2. Donor anxiety is measured using the Blood Donor Anxiety Scale (Chell, Waller, & Masser, 2016; France et al., 2013) at post-donation.
3. Donor return at 6- and 12-month follow-up is measured using Australian Red Cross Blood Service records.

Secondary outcome measures
1. Self-reported vasovagal symptoms are measured using the Blood Donation Reactions Inventory (France, Ditto, France, & Himawan, 2008; Meade, France, & Peterson, 1996) at post-donation.
2 Staff recorded vasovagal reactions are measured using Australian Red Cross Blood Service

standard procedures at any point at the donation centre.
3. Venipuncture pain is measured using a self-report at post-donation.
4. Donor self-efficacy is measured using a self-efficacy scale (France, Montalva, France & Trost, 2008) at post-donation.
5. Donor experience/satisfaction is measured using a self-report including Positive Support Scale (Brown et al., 2003; Hanson & France, 2009) at post-donation.

Overall study start date
03/12/2018

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Age ≥18 years and fulfilling Blood Service criteria for blood donation
2. 3 or less prior completed donations (plasma and/or whole-blood)
3. Willing and able to provide informed consent
4. Has a plasma or whole blood appointment (appointment made as a walk-in donor or previous appointment)

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,200 participants in total

Total final enrolment
831

Key exclusion criteria
1. Unwilling or unable to provide informed consent.
2. Lack of understanding of the English language necessary to complete questionnaires.
3. Contacted for a research study in the last 6 months as per Blood Service contact policy.
4. Donors with therapeutic, autologous, sample or platelet donation appointments.

Date of first enrolment
14/08/2019

Date of final enrolment

01/11/2019

Locations

Countries of recruitment
Australia

Study participating centre
Australian Red Cross Blood Service Parramatta Donor Centre
22 Oak St, Rosehill NSW 2142
Sydney
Australia
2142

Study participating centre
Australian Red Cross Blood Service Chatswood Donor Centre
62/436 Victoria Ave, Chatswood
Sydney
Australia
2067

Sponsor information

Organisation
Australian Red Cross Blood Service

Sponsor details
417 St Kilda Road
Melbourne
Australia
3004
03 9863 1600
tdavison@redcrossblood.org.au

Sponsor type
Other

Website
https://www.donateblood.com.au/

ROR
https://ror.org/00evjd729

Funder(s)

Funder type
University/education

Funder Name
Australian Red Cross Blood Service

Funder Name
Macquarie University

Alternative Name(s)
Universitas Macquariean, Macquarie University (Sydney, Australia), macquarieuni, Macquarie_Uni, Macquarie University | Sydney NSW, MQ

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

Results and Publications

Publication and dissemination plan
We plan to publish the results of this research in academic journals and Blood Service internal reports by end of year 2020.

Intention to publish date
30/08/2020

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 IP/confidentiality issues.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2021	07/05/2021	Yes	No