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Plasma donation interest among men who have sex with men seeing either a co-developed intervention or "business-as-usual" control materials

Submission date
23/07/2025

Recruitment status
No longer recruiting

Registration date
24/07/2025

Overall study status
Completed

Last Edited
04/12/2025

Condition category
Other

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

Plain English summary of protocol

Backgrounds and study aims
Despite plasma-derived medications being a critical health resource, Canada does not collect enough plasma (the yellow, liquid portion of blood) to meet the needs of our population and consequently must buy most stock from the global market. However, a global shortage of plasma and plasma-derived medications has renewed the push for Canada's self-sufficiency. Furthermore, greater inclusivity in donation criteria reduces marginalization of communities who have been excluded from taking part in this socially valued activity, often considered a civic duty. Until 2022, men (primarily based on sex-designated-at-birth) were not eligible to donate blood or plasma if they had sex with another man within a specified period of time before donation, contributing to marginalization and discrimination of gay, bisexual, and all men who have sex with men. Canadian Blood Services has since moved to sexual behaviour-based eligibility criteria for all donors, which better reflects individual risk assessment rather than group identity. These more equitable eligibility criteria are necessary but also require sensitive, tailored communications to encourage donation consideration among this long-excluded community. The current study aims to test if and how a short video developed to address concerns of men who have sex with men works to support consideration of plasma donation at one of Canada's two national blood collection agencies.

Who can participate?
Members of Leger Marketing Inc.'s Opinion panel who are 18 or older, live in Canada excluding Quebec, and identify as either a cisgender or transgender man AND gay, bisexual, pansexual, queer, Two-Spirit, or questioning within Leger's routinely collected demographic survey will be invited to take part in this study. Participants whose gender identity changes to anything other than a cisgender or transgender man by the point of baseline survey participation will be ineligible to continue. However, participants whose sexual orientation changes to anything other than the above-listed will be eligible to continue.

What does the study involve?
Eligible Leger panelists will be invited to participate in two online surveys posted two months apart. During the first survey, participants will be randomly allocated in a 1:1 ratio to the intervention group or control group. Intervention group participants will see a short video developed to address community-specific concerns. Control group participants will see general social media communications encouraging donation. All participants will be asked a series of questions regarding their experiences, opinions, and feelings related to blood plasma donation in Canada before and after seeing materials according to their assigned group. All participants will be invited to take part in a brief follow-up survey two months after taking part in the first survey.

What are the possible benefits and risks of participating?
Direct benefits are not expected, but participation in this research will benefit society by helping to better understand what supports consideration of plasma donation among communities previously impacted by exclusionary policies. Risks to participants include feeling some discomfort due to the sensitive nature of the topic and possible physical discomfort in response to the sight of donation paraphernalia.

Where is the study run from?
The University of Ottawa in Ontario, Canada.

When is the study starting and how long is it expected to run for?
September 2024 to November 2025

Who is funding the study?
The Canadian Institutes of Health Research through a Canada Graduate Scholarship for Master's Programs (CGS-M).

Who is the main contact?
Amelia Palumbo, apalu035@uottawa.ca

Contact information

Type(s)
Public, Scientific

Contact name
Ms Amelia Palumbo

ORCID ID
https://orcid.org/0000-0003-0098-4540

Contact details
136 Jean-Jacques Lussier, Faculty of Social Sciences,
Vanier Hall
Ottawa
Canada
K1N 6N5
-
apalu035@uottawa.ca

Type(s)
Principal investigator

Contact name
Dr Justin Presseau

ORCID ID
https://orcid.org/0000-0002-2132-0703

Contact details
501 Smyth Rd, Ottawa Hospital Research Institute, Centre for Practice-Changing Research
Ottawa
Canada
K1H 8L6
-
jpresseau@ohri.ca

Type(s)
Principal investigator

Contact name
Dr Elisabeth Vesnaver

ORCID ID
https://orcid.org/0000-0002-0499-8010

Contact details
401 Smyth Rd, BORN Ontario, Children's Hospital of Eastern Ontario Research Institute
Ottawa
Canada
K1H 8L1
-
EVesnaver@bornontario.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol V1.0, 2025/04/30

Study information

Scientific Title
Assessing a co-developed digital intervention supporting men who have sex with men in donating plasma: A randomized controlled trial and process evaluation

Study objectives
The primary hypothesis of this study's outcome evaluation is that gay, bisexual, and other men who have sex with men (gbMSM) in the intervention group will report greater intention to donate plasma immediately after viewing the co-developed short video intervention compared to participants in the "business-as-usual" control group, controlling for baseline intention values.

The secondary hypothesis of the outcome evaluation is that more participants in the intervention group will attempt to donate plasma by 2-month follow-up than participants in the control group, after controlling for baseline intention and history of blood or plasma donation.

Another secondary hypothesis answers the process evaluation research question, which posits that the anticipated underlying mechanisms of action, informed by a theoretical framework, will mediate the effects of the intervention on immediate post-intervention intention, after controlling for baseline mediator and intention values.

The exploratory hypothesis is that gbMSM in the intervention group will report greater intention to donate plasma at 2-month follow-up compared to the control group, controlling for baseline intention values.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/07/2025, University of Ottawa Health Sciences and Science Research Ethics Bureau (REB) (550 Cumberland St, Room 154, Ottawa, ON, K1N 6N5, Canada; +1 613-562-5338; ethics@uottawa.ca), ref: H-05-25-10891

Study design
Single-centre two-arm parallel-group interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Plasma donation among men who have sex with men

Interventions
After completing baseline outcome and process measures and demographics questions, participants will be randomized automatically within the online survey software in a 1:1 ratio to (a) the intervention group or (b) the "business-as-usual" control group.

Participants randomized to the intervention group will receive an approximately 5-minute video. Participants will be unable to move forward in the survey until 30 seconds have passed. This video was collaboratively developed with community partners and tailored to address community-reported barriers and enablers to plasma donation. An intervention logic model

describes the linkage between Theoretical Domains Framework-coded barriers/enablers identified in previous research and specific behaviour change techniques. The intervention was previously found to be feasible and acceptable to community members.

Participants randomized to the business-as-usual control group will be shown an image of a social media infographic post from the national blood collection agency's social media page that addresses a general audience. There will be no minimum required viewing time for control materials before participants may proceed to the next survey page. This serves as a naturalistic comparator exemplifying the type of communications the target population may come across in everyday life.

Intervention Type
Behavioural

Primary outcome(s)
Intention to donate plasma in the upcoming two months measured using the average score of three self-report Likert scale items immediately after exposure to the intervention/control materials

Key secondary outcome(s))
Secondary outcome measure will be assessed at 2-month follow-up:
1. Plasma donation attempted in the past 2 months measured using a single dichotomous self-report item

Exploratory outcome measure will be assessed at 2-month follow-up:
1. Intention to donate plasma in the upcoming two months measured using the average score of three self-report Likert scale items

Process evaluation measures will be assessed immediately after exposure to the intervention /control materials:
1. Positive affect measured using the average score of seven self-report Likert scale items
2. Negative affect measured using the average score of eleven self-report Likert scale items
3. Knowledge measured using the average score of three self-report Likert scale items
4. Social influences measured using the average score of five self-report Likert scale items
5. Beliefs about Consequences measured using the average score of four self-report Likert scale items
6. Memory, Attention & Decision Processes measured using the average score of three self-report Likert scale items
7. Beliefs about Capabilities measured using the average score of three self-report Likert scale items

Completion date
11/11/2025

Eligibility

Key inclusion criteria
1. Validated member of Leger Marketing Inc's proprietary Opinion panel
2. Living anywhere in Canada, except for Quebec
3. English-speaking
4. 18 years of age or older

5. Identifying as a cisgender or transgender man
6. Willing and able to complete an online survey
7. Able to access a computer, phone, or tablet with access to the internet

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
Male

Total final enrolment
219

Key exclusion criteria
1. Members of the Leger Marketing Inc's proprietary Opinion panel who do not meet the inclusion criteria
2. Participants who, since completing the Leger profiling questionnaire, have shifted their self-identified gender to (a) cisgender woman, (b) trans woman, (c) gender creative or non-conforming person, (d) non-binary person, (e) none of the listed gender identity options, or (f) prefer not to answer as identified within the baseline survey

Date of first enrolment
03/09/2025

Date of final enrolment
08/09/2025

Locations

Countries of recruitment
Canada

Study participating centre
Leger Marketing Inc
507 Place d’Armes, Suite 700

Montreal
Canada
H2Y 2W8

Sponsor information

Organisation
University of Ottawa

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in at least one of the following publicly available repositories: Federated Research Data Repository (FRDR; https://www.frdr-dfdr.ca/repo/), uOttawa - Dataverse (Borealis; https://borealisdata.ca/dataverse/ottawa).

Participants' consent will be obtained to store a copy of the dataset with all indirectly identifiable information removed in one or more publicly available data repositories that meet University of Ottawa institutional requirements, such as the two named above, for secondary research use. The complete dataset will be anonymized to the research team, and the research team will further protect marginalized participants' identities by removing sociodemographic data that, together, could indirectly identify someone.

Data will be made permanently available after the student researcher has completed their program. Data will be shared under an Attribution-NonCommercial 4.0 International (CC BY-NC 4.0) copyright license agreement.

IPD sharing plan summary

Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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