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# A randomized controlled trial of a web-based patient decision aid for COVID-19 vaccination among adults in Canada

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| **Submission date**<br>15/12/2025 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>16/12/2025 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>16/12/2025 | **Condition category**<br>Other | |

## Plain English summary of protocol

Background and study aims

The COVID-19 pandemic required many people in Canada to face complex decisions about vaccination. Trustworthy health information is often available on government websites, but it can be difficult to find, understand, or navigate, or it may not answer people's questions about details of why vaccines are recommended. This can lead to confusion or stress about what to do. This study, part of a PhD at Université Laval, will test VaxDA-C19, a bilingual web-based decision aid on COVID-19 vaccination. It provides clear, current information on the potential benefits and potential harms of the COVID-19 vaccines available in Canada in 2025–2026, and helps users consider their vaccination priorities. The study aims to determine whether VaxDA-C19 users have clearer COVID-19 vaccination intentions, feel more confident, and make more informed decisions than those receiving standard information from the Public Health Agency of Canada (PHAC) or neutral health information unrelated to COVID-19. It will also assess whether or not people end up getting a vaccine and whether they feel regret about their decision.

Who can participate?

We are seeking 1,050 adults aged 18+ years in Canada who still need to decide on COVID-19 vaccination in the 2025-2026 season.

Participants must be able to read and understand English or French, have internet access on a computer, tablet, or smartphone, and be able to give informed consent.

People are ineligible if they've completed their COVID-19 vaccination schedule, have no decision to make, can't complete questionnaires in English or French, or aren't facing a vaccination decision. Each person can only participate once. The questionnaires may ask about recent vaccination (within 3 months) and eligibility for free vaccination in some provinces (e.g., Quebec or Alberta).

What does the study involve?

The study is conducted entirely online and has two parts.

Part 1 (baseline – about 20 minutes)

Participants are recruited via online survey panels. After an eligibility screening and online consent, they complete an initial questionnaire about their background. There is also a brief item

asking them to commit to providing thoughtful answers to ensure high-quality data.
Participants are then randomly assigned by computer to one of three groups:
Group 1 (VaxDA-C19 tool): participants use an interactive decision aid that explains COVID-19 vaccines, their benefits and risks, and recommendations in clear, neutral language, with visuals and frequently-asked questions.
Group 2 (standard info): participants visit Canadian public health websites about COVID-19 vaccination.
Group 3 (neutral control): participants view a Health Canada webpage on safe disposal of prescription drugs, unrelated to COVID-19 but requiring similar attention and reading time, serving as an attention control.
The external website opens in a new window; the survey remains open. After reviewing the material, participants return to the survey to answer a brief question about their website reading, then complete questions on vaccination intentions, knowledge, emotions, and conflict. The first part takes about 20 minutes. Panel members may receive a small incentive, while the research team receives only anonymous data.
Part 2 (follow-up – about 2 to 5 minutes)
At the end of the first questionnaire, participants are asked if they agree to be contacted for a brief follow-up survey in 3 to 4 months. Those who agree provide an email address, which is securely stored and used only for the follow-up invitation and gift-card draw.
About 3–4 months later, participants who consented to follow-up receive an email with a link to the second questionnaire (2–5 minutes). It asks if they received the COVID-19 vaccine or booster, whether their intentions or decisions have changed, and their current feelings and any regret. Completers are entered into a random draw for two $200 cash gift cards (odds 1 in 250). Incentives from survey panels follow their usual procedures.

What are the possible benefits and risks of participating?
Benefits:
Participation may offer no direct personal benefit, but some may find value in clear information and reflecting on options. This study helps public health experts improve vaccine messaging and decision support in Canada. Participants completing the follow-up survey can win a gift card.
Risks:
Answering questions about COVID-19, illness, or vaccination may cause temporary discomfort, worry, or frustration for some participants. There are no medical risks involved in participation, as no vaccines or treatments are provided as part of the study.

Mitigation and data protection:
Participants can skip questions and stop at any time without explanation. The materials include links to health resources and advise talking to a healthcare professional if needed.
Survey answers are collected anonymously. For those who consent to follow-up, email addresses are stored separately, used only for re-contact and the gift-card draw, and deleted after the follow-up survey and draw are complete, no later than June 2026. Anonymized survey data, including sociodemographic information and website usage data (for example, which pages were visited and how long was spent on them), will later be deposited in Université Laval's Dataverse public repository with no identifying information. Other electronic research data not shared in the repository will be destroyed seven years after the end of data collection, in December 2032.

Where is the study run from?
The study by Université Laval's Faculty of Medicine in Québec City is stored securely on Canadian servers, in accordance with its data protection and research ethics policies.
When is the study starting, and how long is it expected to run for?
Study start (protocol development): September 2020

Planned recruitment start (first participant enrolled): December 2025
Planned end of data collection (last follow-up): March 2026

Who is funding the study?
The project is funded by the Canadian Institutes of Health Research (CIHR) and is conducted in collaboration with the Canadian Immunization Research Network (CIRN), with institutional support from Université Laval.

Who is the main contact?
Principal Investigator / Scientific contact:
Professor Holly O. Witteman, Faculty of Medicine, Université Laval

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Prof Holly Witteman

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# Additional identifiers

# Study information

### Scientific Title
Three-arm randomized controlled trial of a bilingual web-based patient decision aid for adults in Canada making COVID-19 vaccination decisions

### Study objectives
The primary aim of this randomized controlled trial (RCT) is to assess the impact of VaxDA-C19, a web-based vaccine (Vax) patient decision aid (DA) designed to support COVID-19 (-C19) vaccination decisions in Canada, in comparison with an active control (public health website) and a neutral attention control on adults in Canada.
The objectives are:
To determine if VaxDA-C19 increases participants' intentions to receive a COVID-19 vaccine or booster immediately after the intervention, compared to both control groups.
To assess whether VaxDA-C19 enhances decision quality by reducing participants' decisional

conflict (Decisional Conflict Scale) and boosting knowledge retention (Knowledge Score) immediately after the intervention, relative to both control groups.
To evaluate if VaxDA-C19 leads to higher self-reported COVID-19 vaccination rates and decreases decision regret (Decision Regret Scale) at a 3- to 4-month follow-up, compared to both control groups.
To examine the effect of VaxDA-C19 on emotions immediately post-intervention, versus both control groups.
To explore whether the effects or lack of effects of VaxDA-C19 depend on participant traits (e.g., health literacy, numeracy, and individualism vs. collectivism orientation) and the degree of intervention exposure (e.g., time spent on the page and fidelity to the intervention protocol).

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 02/12/2025, Comités d'éthique de la recherche avec des êtres humains de l'Université Laval – Comité d'éthique de la recherche en sciences de la santé (Research Ethics Board for Health Sciences, Université Laval) (Research Ethics Boards (CÉRUL) Pavillon Alphonse-Desjardins 2325, rue de l'Université, local 3435, Québec (Québec), G1V 0A6, Canada; +1-418-656-2131; cerul.sante@vrr.ulaval.ca), ref: 2022-498 A-2 R-2 / 02-12-2025

## Primary study design
Interventional

## Allocation
Randomized controlled trial

## Masking
Open (masking not used)

## Control
Active

## Assignment
Parallel

## Purpose
Treatment

## Study type(s)

## Health condition(s) or problem(s) studied
COVID-19 vaccination decision-making

## Interventions
The study is a Randomized Controlled Trial (RCT) with three parallel arms. Participants are allocated 1:1:1 to one of the three arms via electronic simple randomization concealed within Qualtrics.
Arms & treatment duration:
Arm 1 (VaxDA-C19 patient decisional aid - experimental): to a bilingual (English/French) web-based patient decision aid about COVID-19 vaccination. The patient decision aid provides up-to-

date, evidence-based information about SARS-CoV-2, COVID-19, vaccine benefits and risks, and options for primary and booster doses for adults and children. It includes frequently asked questions, neutral risk communication formats, and decision support elements designed to help users clarify their values without pressuring them toward a particular choice.
Arm 2 (Active comparator - PHAC/ASPC): participants are exposed to the Public Health Agency of Canada (PHAC/ASPC) COVID-19 vaccination web pages for the relevant demographic.
Arm 3 (Attention control - sham comparator): Participants are exposed to neutral health content (e.g., Safe disposal of prescription drugs) for an equivalent, minimal duration (target: 2–3 minutes) to control for time-on-task bias.
Follow-up: All arms complete a baseline questionnaire immediately post-intervention (T0), followed by a second survey three to four months later (T1) to measure decision regret and self-reported vaccination behaviour.
Blinding: This is a single-blinded study; participants are aware of their assignment, but data analysts will be blinded to the identity of the study arms during statistical analysis.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Self-reported intention to receive a COVID-19 vaccination measured using a Likert scale (from “definitely no” to “definitely yes”) in the online questionnaire at T0 (immediately post-intervention, at the end of the initial online survey session)

### Key secondary outcome(s))
1. Knowledge score measured using a composite score derived from 16 True/False/“I don’t know” items, assessing factual knowledge about COVID-19, COVID-19 vaccines, and the public health context at T0 (immediately post-intervention) and T1 (follow-up 3–4 months)

2. Decisional conflict measured using the Decisional Conflict Scale. The primary analysis will focus on the total score, with subscale scores analyzed exploratory at T0 (immediately post-intervention) and T1 (follow-up 3–4 months)

3. Emotion score measured using five 7-point Likert items assessing worry about infection (self and community) and anticipated guilt related to the vaccination decision and potential infection risk at T0 (immediately post-intervention) and T1 (follow-up 3–4 months)

4. Self-reported vaccination behaviour measured using binary self-report (“Yes” or “No”) of receiving the target COVID-19 vaccine or booster dose since T0 at T1 (follow-up 3–4 months)

5. Decision Regret measured using the 5-item Decision Regret Scale, administered to participants who have made a vaccination decision since T0 at T1 (follow-up 3–4 months)

### Completion date
01/06/2026

## Eligibility

### Key inclusion criteria
1. Adults (≥18 years) living in Canada
2. Able to provide free and informed consent
3. Able to read and understand French or English

4. Able to use a computer, tablet, or smartphone with internet access
5. Eligible for a COVID-19 vaccination booster dose

### Participant type(s)
All

### Healthy volunteers allowed
Yes

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
99 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Younger than 18 years of age
2. Unable to provide free and informed consent
3. Difficulty understanding or answering questions in English or French
4. Difficulty using a computer, tablet, or smartphone with internet access
5. No remaining decisions to make about COVID-19 vaccination; previous participation in this study

### Date of first enrolment
16/12/2025

### Date of final enrolment
31/03/2026

## Locations

### Countries of recruitment
Canada

### Study participating centre
**Université Laval**
Faculté de Médecine, 1050 avenue de la Médecine
Québec City, QC
Canada
G1V 0A6

# Sponsor information

**Organisation**
Université Laval

**ROR**
https://ror.org/04sjchr03

# Funder(s)

**Funder type**
Not defined

**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

**Funder Name**
Canadian Immunization Research Network

**Alternative Name(s)**
CIRN

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

### Location
Canada

## Results and Publications

### Individual participant data (IPD) sharing plan
Anonymized individual participant data (IPD) from this trial will be shared via Université Laval's public repository (borealisdata.ca) after the main trial results are published. The dataset will include survey responses (e.g., sociodemographic variables and questionnaire scores) and website usage data (e.g., which pages were visited, and the time spent on each page), but it will not contain any direct identifiers or contact information.

Email addresses collected from participants who consent to be contacted for the follow-up survey will not be shared. They will be stored separately from the survey data, used solely to send the follow-up invitation and manage the gift card draw, and will be deleted after the follow-up survey and draw are completed, no later than June 2026.

Before deposit, the IPD will be checked and, if necessary, further aggregated or masked to minimize any residual risk of re-identification. The Borealis repository will also host accompanying documentation, including the trial protocol, data dictionary, and statistical analysis code used for the main analyses. Anonymized IPD and accompanying documentation will be made openly available for secondary use by other researchers without project-specific approval, subject to the standard terms of use of Université Laval's Borealis repository. Other electronic research data not shared in the repository will be destroyed seven years after the end of data collection, in December 2032.

### IPD sharing plan summary
Stored in publicly available repository