ISRCTN58518971 https://doi.org/10.1186/ISRCTN58518971

Effect of educative reminder telephone calls on human papillomavirus immunization rate

Submission date
08/06/2020

Recruitment status
No longer recruiting

Registration date
27/07/2020

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Accounting for 569,847 new cases and 311,000 deaths in 2018, cervical cancer is classified as the fourth most frequent female cancer worldwide. Human papillomavirus, a sexually transmitted disease, is identified as the source of 99.7% of cervical cancers. Being the cause of essentially all cervical cancer, HPV is also related to vulva, vaginal, oropharyngeal, penis and anal cancers as well as genital warts. Available for more than a decade, HPV immunization is a very safe and effective primary prevention measure. The third and last available HPV vaccine launched in 2014 has been approved for females aged 9 to 45 and males aged 9 to 26. Unfortunately, despite being a largely preventable disease, wild variation in HPV coverage is observed among women depending on their race, incomes, geography and education level. To date, there is no research evaluating the use of educational phone calls to increase the HPV vaccination rate, particularly in a high-risk population. The aim of this study is to measure the effect of educative reminder telephone calls on HPV immunization rate.

Who can participate?
Women who agree to get a prescription of HPV vaccination and understand French

What does the study involve?
Participants will be randomly allocated to receive one (control group) or three (intervention group) phone calls to inform them about the HPV vaccination and also to answer their questions. The rate of HPV vaccination is measured after 6 months.

What are the possible benefits and risks of participating?
The only drawbacks for patients are having one (control group) or a few (intervention group) phone follow-ups. No visit is planned. Participants will receive $15 in compensation at the end of the study.

Where is the study run from?
Sherbrooke University Hospital Center (Canada)

Where is the study starting and how long is it expected to run for?
July 2019 to June 2020

Who is funding the study?
1. Sherbrooke University (Canada)
2. Merck Company Foundation (USA)

Who is the main contact?
Dr Jessica Ruel-Laliberté
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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
2020-3319

Study information

Scientific Title
Effect of educative reminder telephone calls on human papillomavirus immunization rate: a randomised controlled trial

Study objectives
Reminder educative phone calls increase the human papillomavirus (HPV) vaccination rate in adult women age 18 to 45 with risk factors of cervical cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/09/2019, Sherbrooke Research Ethics Committee (3001, 12e avenue Nord, Sherbrooke, Canada; +1 (0)819 346-1110 #12856; ethique.recherche.ciussse-chus@ssss.gouv.qc.ca), ref: 2020-3319

Study design
Interventional single-blnid randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Prevention of cervical cancer

Interventions
The randomization schedule will be done in blocks of 6 in a 50:50 ratio. Allocation will only occur once the consent will be obtained. A secured order list made by a computer generator will determine the group allocation of each patient. Only the two principal authors will have access

to the secured computer list for the reminder educative telephone calls. Given the nature of the intervention, study investigators and research coordinators will not be blinded to treatment allocation.

All eligible participants will be given an initial recruitment questionnaire where risk factors of cervical cancer and immunization status are assessed. The risk factors identified are based upon a clinical gynecology oncology reference book (L. Stewart Massad, 2018). They will receive a file containing a three-dose HVP vaccine prescription, vaccination clinic contact list and an HPV virus information brochure from the Canadian Obstetric Gynaecology Society.

If a participant is assigned to the intervention group, she will receive a total of three standardised phone calls made by either the same author or one of the two research medical student involved at 1, 3 and 6 months after randomisation. During the first two interventions, callers will need to follow the instruction of an educative script and at each intervention call, participants will verbally inform research team if they got vaccinated and if not, investigators will ask what barriers they faced. If barriers identified concern lack of patient knowledge, the research team will provide a specific answer to any questions and calm any doubts or fear. If it concerns a logistical issue such as a loss of a prescription or not knowing where to get vaccinated, a new prescription will directly be made at the pharmacy and the vaccination clinic contact list will be provided by email or discussed by phone.

The control group will receive a phone call at 6 months to assess HPV immunization status and barriers to vaccination.

When patients do not answer phone calls, a total of two callbacks will be made and an email will be sent with the script and the two questions. Patients who will complete the study will receive a check by mail of 15 Canadian dollars each as a reward for their participation.

Intervention Type
Behavioural

Primary outcome measure
Rate of HPV vaccination at 6 months after randomisation

Secondary outcome measures
1. Rates of vaccination measured using phone call at 6 months for high-risk patients in intervention and control groups. High-risk patients are categorized as presenting one or more of these risk factors: smoker or past smoker, more than two sexual partners in the past 12 months, low education status (high school or college), history of abnormal pap smear or had their last pap smear more than 3 years ago
2. Type and frequency of barriers to vaccination in intervention and control groups mentioned by non-vaccinated patients in a phone call at 6 months
3. Type and frequency of barriers to vaccination in intervention group mentioned in phone calls at 1 and 3 months which were overcome by recall calls

Overall study start date
01/07/2019

Completion date
01/06/2020

Eligibility

Key inclusion criteria
Women are eligible for study enrollment if:
1. They agree to get a prescription of HPV vaccination
2. Understand French

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
142

Total final enrolment
130

Key exclusion criteria
Women who:
1. Do not know their HPV immunization status
2. Refuse vaccination

Date of first enrolment
01/10/2019

Date of final enrolment
10/10/2019

Locations

Countries of recruitment
Canada

Study participating centre
Centre Hospitalier Universitaire de Sherbrooke
3001, 12e Avenue Nord
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.chus.qc.ca/en/

ROR
https://ror.org/020r51985

Funder(s)

Funder type
Industry

Funder Name
Merck Company Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Université de Sherbrooke

Alternative Name(s)

University of Sherbrooke, UdeS, UDS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

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

Intention to publish date
01/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jessica Ruel-Laliberté (jessica.ruel-laliberte@usherbrooke.ca).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2021	30/03/2021	Yes	No
Protocol file	in French version 1	17/07/2019	10/10/2022	No	No