Question-behavior effect and flu vaccination in the over 65s

Submission date 17/03/2016	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 22/03/2016	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 27/04/2018	Condition category Respiratory	Individual participant data

Plain English summary of protocol

Background and study aims

Asking questions about a behaviour can change that behaviour – called the Question Behaviour Effect (QBE). The aim of this study is to test the QBE as a simple (and potentially cost effective) way to increase influenza vaccination rates among older adults. We will assess whether sending older adults a questionnaire about influenza vaccination increases vaccination rates.

Who can participate?

Patients who are eligible for an influenza vaccination by being age 65 or over at their next birthday

What does the study involve?

Participants are randomly allocated to one of eight groups: either to receive no questionnaire, or to receive a questionnaire measuring:

1. Demographics (i.e., asking whether they had children, their occupation, marital status, and ethnic origin)

2. Demographics plus items about intentions to get vaccinated and attitudes towards vaccination

3. Demographics plus items about intentions to get vaccinated and attitudes towards vaccination plus a post it note requesting questionnaire completion

4. Demographics plus items about anticipated regret about getting vaccinated, intentions to get vaccinated and attitudes towards vaccination

5. Demographics plus items about anticipated regret about getting vaccinated, intentions to get vaccinated and attitudes towards vaccination, plus a post it note requesting questionnaire completion

6. Demographics plus items about benefits of getting vaccinated, intentions to get vaccinated and attitudes towards vaccination

7. Demographics plus items about benefits of getting vaccinated, intentions to get vaccinated and attitudes towards vaccination, plus a post it note requesting questionnaire completion. We tested the effects of these different questions on influenza vaccination rates.

What are the possible benefits and risks of participating?

The benefits of participating were helping inform the development of interventions to improve vaccination uptake. There were no risks of participating.

Where is the study run from? General practices in northern England, Leeds, UK

When is the study starting and how long is it expected to run for? July 2012 to February 2013

Who is funding the study? Economic and Social Research Council (UK)

Who is the main contact? Prof Mark Conner m.t.conner@leeds.ac.uk

Contact information

Type(s) Scientific

Contact name Prof Mark Conner

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Varying cognitive targets and response rates to enhance the question-behavior effect: an eightarm randomized controlled trial on influenza vaccination

Study objectives

Asking questions about a behaviour can change that behaviour - the Question Behaviour Effect (QBE). The present research tested the QBE as a simple (and potentially cost effective) means to increase influenza vaccination rates among older adults. We tested the effects of different questions on influenza vaccination rates.

We also tested the effect of a manipulation (sticky post it note with request for help) designed to increase questionnaire response rates on influenza vaccination rates.

Ethics approval required Old ethics approval format

Ethics approval(s) NRES Committee Yorkshire and Humber - Bradford, 19/07/2011, 11/YH/0229

Study design Interventional randomized controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) GP practice

Study type(s) Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Influenza

Interventions

There are eight arms. Participants in the control 1 (no questionnaire) condition did not receive a questionnaire. Participants in the control 2 (demographics questionnaire) condition received a questionnaire tapping whether they had children, their occupation, marital status, and ethnic origin. Participants in the other six conditions received a questionnaire tapping the same demographic questions plus questions about influenza vaccination. The first (intention + attitude condition) questionnaire contained items tapping intentions and attitudes in relation to influenza vaccination; the second (anticipated regret + intention + attitude condition) questionnaire additionally contained anticipated regret questions; the third (beneficence + intention + attitude condition) questionnaires were the same, but had a sticky note attached to the front that included a message ('Please take a few minutes to complete this for us. Thank you!'). The message was printed in blue on a yellow (72x72mm) sticky note but with the message appearing to be hand written.

Intervention Type

Behavioural

Primary outcome measure

Receiving an influenza vaccination in period 28/07/2012 to 07/02/2013 following invitation as indicated by records

Secondary outcome measures None

Overall study start date 28/07/2012

Completion date 07/02/2013

01/02/2013

Eligibility

Key inclusion criteria

 Participants recruited from General Practices in the northern England, Leeds, UK area who were not taking part in a centralized influenza vaccination invitation scheme in Autumn 2012
 The study population consisted of all patients in each practice eligible for an influenza vaccination that year by being age 65 years or over at their next birthday
 A total of 13,806 patients were individually randomly assigned to one of eight conditions

3. A total of 13,806 patients were individually randomly assigned to one of eight conditions using a random number generator. Subsequently, 354 patients were deemed ineligible for vaccination (i.e., due to having left the General Practice, being deceased, unable to have a vaccination due to a medical condition, or having already received a vaccination) and excluded from the study, leaving 13,452 patients who were included in intention-to-treat analyses 4. A total of 4934 completed questionnaires (43.1%) were returned from 11752 sent out. The sample was 56.2% female with a mean age of 75.5 years (SD = 7.88) and mainly lived in areas of low deprivation (Townsend score M = -1.49, SD = 2.93). The eight different conditions were equivalent on gender and age but significantly different on deprivation

Participant type(s) Patient

Age group

Senior

Sex Both

Target number of participants 13,452

Key exclusion criteria Does not meet inclusion criteria

Date of first enrolment

01/10/2012

Date of final enrolment 29/11/2012

Locations

Countries of recruitment England

United Kingdom

Study participating centre University of Leeds c/o Mark Conner, Professor of Applied Social Psychology, School of Psychology Leeds United Kingdom LS2 9JT

Sponsor information

Organisation University of Leeds (UK)

Sponsor details

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Sponsor type University/education

ROR https://ror.org/024mrxd33

Funder(s)

Funder type

Research council

Funder Name Economic and Social Research Council

Alternative Name(s) ESRC

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Results and Publications

Publication and dissemination plan A paper reporting the details of the study and key findings will be prepared during 2016.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/05/2017		Yes	Νο