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Understanding and using self-generated validity to promote behaviour change: increasing uptake of the seasonal flu jab for the over 65s

Submission date	Recruitment status	[X] Prospectively registered
17/08/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/03/2017	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10736

Study information

Scientific Title
Understanding and using self-generated validity to promote behaviour change: a randomised trial on increasing uptake of the seasonal flu jab for the over 65s

Study objectives
To further our understanding of a phenomena called Self-Generated Validity (SGV) or the Mere Measurement Effect, and use it to promote attendance for the flu jab amongst the over 65s. The SGV refers to the fact that when people are asked to report their intentions to perform a behaviour, they are subsequently more likely to perform the actual behaviour than if they didn't report their intentions. This study investigates the optimum conditions needed to produce the strongest effect. These can then be incorporated into future campaigns.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bradford REC, 27/07/2011, ref: 11/YH/0229

Study design
Randomised; Interventional; Design type: Prevention

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
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
The interventions relate to patients being assigned to one of eight conditions and receiving one set of the following:
Group 1: standard invite materials only (control 1)
Group 2: short questionnaire to tap demographics (age, ethnicity, social class) (control 2)
Group 3: intention and attitude items (experimental 1) plus demographics
Group 4: as Group 3 but with post-it (intervention to increase return rate) (experimental 2) plus demographics. Post-it refers to the sticky notes which will be attached to some of the

questionnaires to see if there is a difference in return rates between those questionnaires which have them and those which do not.
Group 5: regret, intention and attitude items (experimental 3) plus demographics
Group 6: regret, intention and attitude items with post-it (experimental 4) plus demographics
Group 7: beneficence, intention and attitude items (experimental 5) plus demographics
Group 8: beneficence, intention and attitude items with post-it (experimental 6) plus demographics

It is predicted that there will a 'dose response' effectiveness of SGV as detailed below:-
1. Conditions 3-8 will be more effective than conditions 1-2
2. Condition 5 will more effective than condition 3 (adding anticipated regret)
3. Condition 6 will more effective than condition 5 (use of post-it will promote return rate and therefore the engagement with the questionnaire necessary for the optimum effect)
4. Condition 4 will be more effective than condition 3 (as above)
5. Condition 8 will be more effective than condition 7 (as above)
6. Condition 7 will be more effective than condition 3 (adding beneficence)
7. SGV effect will not vary depending on socio-economic status

The research hopes to identify the best way to maximise uptake of the flu jab using SGV.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
Uptake of flu jab for over 65s; timepoint(s): between September 2010 and March 2011

Secondary outcome measures
Duration from invite to uptake in days. Differences in attendance rates by condition, social class and their interaction will also be analysed, as well as the impacts on time delay to uptake. Given that SGV effects may only operate in those completing questionnaires, secondary analysis will examine differences in condition among those who returned completed questionnaires. Analysis will also examine the impact of questionnaire responses on attendance rates within conditions (e.g., is attendance higher among those with stronger intentions to attend).

Overall study start date
12/09/2011

Completion date
30/03/2012

Eligibility

Key inclusion criteria
All patients over 65 registered with participating general practitioners (GPs) who are being sent their annual flu jab invite

Target Gender: Male & Female; Lower Age Limit 65 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 15000; UK Sample Size: 15000; Description: Patients who are over 65 from participating GPs

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
12/09/2011

Date of final enrolment
30/03/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
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Sponsor information

Organisation
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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 (ESRC) (UK) Grant Codes: RES 062 23 2220

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration