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A smartphone app to increase parents' psychological empowerment and knowledge about measles and the MMR vaccination

Submission date
14/04/2016

Recruitment status
No longer recruiting

Registration date
15/04/2016

Overall study status
Completed

Last Edited
09/03/2018

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Vaccinations have substantially contributed to an increase in life expectancy. However, despite scientific studies showing that vaccines are safe and work well, an increasing share of parents now decide not to vaccinate their children in a number of industrialized countries. Italy is currently witnessing a decline in vaccination rates and a rise in the number of people with diseases which are preventable through immunization. Recent data from ECDC and National Institute of Health (ISS) show that, between January and December 2014, Italy had the highest incidence of measles in Europe, with a total of 1,676 cases (28.1 cases per million). Among all paediatric vaccines, the measles vaccination (MMR) deserves special attention. Italy has yet to achieve the recommended target of a 95% coverage for complete MMR vaccination (two doses). In general, parents have positive attitudes towards their children's immunization programs and the MMR vaccine, but there are widespread concerns about the risks and side effects of this vaccination. The refusal to vaccinate seems to arise from several factors including beliefs based on information which are completely or partly incorrect, in addition to a more or less strong sense of autonomy (empowerment) and the subsequent attempts by parents to manage alone the health of their children. This study looks at two types of interventions (or programs) aimed to improve the acceptance of the MMR vaccination by parents. The first intervention aims to increase parents' involvement and knowledge on measles, mumps, rubella and the MMR vaccine through an interactive application for smartphones that includes elements of gamification (a quiz). The second intervention will include two short videos and messages by a young mother aimed at increasing parents' sense of autonomy (making an informed decision) by creating a correspondence between the MMR vaccination and health benefits for their child.

Who can participate?
Parents of a child under 12 months of age or who has not yet received MMR/MMR-V. All participants must be resident in Lombardy, have only one child, and own a smartphone (operating system iOS or Android) with Internet connection.

What does the study involve?
The experiment involves the random assignment of the participants to one of the four

conditions.
Participants in group 1 are assigned to receive intervention 1. They are given access to an interactive application on their smartphone that includes elements of gamification designed to improve their knowledge of the MMR vaccination. Participants in group 2 are assigned to receive intervention 2. They are given the same application, but this time are given access to short videos and messages by a young mother aimed at increasing higher psychological empowerment by linking the vaccination with health benefits for children. Participants in group 3 are given access to interventions 1 and 2 and receive the application and the first video on the first day, eight messages in the following days and the second and last video before the end of intervention 1 (tenth day).

What are the possible benefits and risks of participating?
There are no risks or side effects of the treatments. Possible benefits could be a greaterknowledge about measles and MMR and feeling more a psychologically empowered when making a decision about MMR vaccination.

Where is the study run from?
Institute of Communication and Health of the Università della Svizzera italiana and the Dipartimento di Scienze Biomediche per la Salute of the University of Milan.

When is study starting and how long is it expected to run for?
January 2016 to December 2016

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Development of an app to increase parents' psychological empowerment and knowledge about measles and the MMR vaccination: a randomized controlled 2x2 between subject experiment

Study objectives
The group receiving the two interventions will be more likely to vaccinate against MMR within 1 year from receiving the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Milan Ethical Committee,18/04/2016

Study design
2x2 between-subject randomized factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

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
Receipt of the MMR vaccination

Interventions
This study will employ a 2x2 between-subject factorial design, a valid and reliable method to quantitatively test the single and combined effects of two independent variables on a dependent variable.

The experiment envisages four conditions:
1. Exposure to intervention 1 only
2. Exposure to intervention 2 only
3. Exposure to both interventions 1 and 2
4. No exposure to any intervention (control)

To test the experiment, we will recruit 240 parents of a child under 12 months of age (born after July 1, 2015, so that he/she has not turned one-year-old by 30 June 2016), or who has not yet received MMR/MMR-V. All participants must be resident in Lombardy, have only one child, and own a smartphone (operating system iOS or Android) with Internet connection.

The experiment involves the random assignment of the participants to one of the four conditions (60 participants per condition). Intervention 1 consists of an interactive application on their smartphone that includes elements of gamification that will enhance user involvement in order to improve their knowledge of the MMR vaccination, while intervention 2 will employ, by receiving the same application, short videos and messages by a young mother aimed at increasing higher psychological empowerment by linking the vaccination with the objectives concerning the health of children. In group C, interventions 1 and 2 will be administered simultaneously and have a maximum duration of 10 days. This means that participants of this group will receive the application and the first video on the first day, eight messages in the following days and the second and last video before the end of intervention 1 (tenth day).

Participation in the study involves filling two questionnaires, sent by email 10 days apart, before and after the intervention(s). The first questionnaire will represent the measurement of the variables before the intervention (T0), while the second will be the post-intervention measurement (T1). The questionnaire will contain questions about: knowledge of measles, mumps, rubella and MMR; psychological empowerment of parents (through a scale validated in Study 2 of this project that has already received a positive opinion by the Ethics Committee of the University of Milan); attitudes towards the MMR vaccine; the intention to recommend the MMR vaccination to other parents in the future; the intention to show up for the first dose of MMR; the quality of the relationship with the pediatrician; the level of trust in health institutions; search for information on the MMR vaccination and the sources of information used; the evaluation of the benefits and possible side effects of the MMR vaccine; the perceived risk of contracting measles, mumps or rubella; any unexpected event occurred during the intervention that may have compromised the participation in the experiment. In addition, we will include questions on socio-demographic variables such as age, origin, zip code and education of both parents, the gender of the parent who fills in the questionnaire, and the date of birth of the child.The sample receiving the application, will be further asked the level of playfulness perceived during the interaction with the latter.

Participation in the study is voluntary. Recruitment of the participants will be conducted using a paper invitation and through the involvement of pediatricians, pharmacies and kindergartens operating in the Lombardy region. The invitation to participate will contain all the information regarding the study as well as how to join and participate.

Consensus and informative text on the study will be provided to participants in digital format at the beginning of the compilation of the first online questionnaire, and acceptance of the reading of the document together with consent to participate will be considered indispensable for participation in the experiment.

Intervention Type
Behavioural

Primary outcome measure
Intention to vaccinate one's child against MMR, measured using a single item "Do you intend to have a vaccination for swine flu?" with (1) anchored at "definitely will not" and (5) anchored at "definitely will". A high score will indicate a more positive intention to have a vaccination. Intention will be measured before the intervention (t0), immediately after (t1), and six months after the intervention (t3).

Secondary outcome measures
1. MMR vaccination risk perception, measured using a single item "To what extent are the risks associated with the MMR vaccination higher than the benefits?" with (1) anchored at "Risks are much higher than the benefits" and (5) anchored at "Benefits are much higher than the risks"
2. Attitude towards the MMR vaccination, measured using a single item "What is your opinion about the MMR vaccination?" with (1) anchored at "Absolutely against" and (5) anchored at "Absolutely in favour".
MMR vaccination knowledge, measured using a revised version of the 9-item Vaccination Knowledge Scale
3. Psychological empowerment, measured using a 12-item scale developed by the authors in a previous study

All secondary outcomes will be measured before the intervention (t0) and immediately after (t1)

Overall study start date
01/01/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Mother or father of a child for whom an MMR vaccination decision (1st dose) is still pending (1st child)
2. Italian citizenship or residence in Italy
3. Ability to understand Italian
4. Owning a smartphone with Internet connection

Participant type(s)
Carer

Age group
Adult

Sex
Both

Target number of participants
240

Key exclusion criteria

1. Having more than one child or expecting the second child
2. Lack of Italian citizenship or residence in Italy
3. Inability to understand Italian
4. Not owning a smartphone with Internet connection

Date of first enrolment
18/04/2016

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
Italy

Switzerland

Study participating centre
Institute of Communication and Health - Università della Svizzera italiana
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Study participating centre
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University/education

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Funder(s)

Funder type
Charity

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

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

Location
Switzerland

Results and Publications

Publication and dissemination plan

Intention to publish date
01/09/2016

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?
Results article	results	02/11/2017		Yes	No
Results article	results	07/03/2018		Yes	No