ISRCTN72521372 https://doi.org/10.1186/ISRCTN72521372

The DECIDA study: Detailed Evaluation of a Childhood Immunisation Decision Aid

Submission date
03/06/2013

Recruitment status
No longer recruiting

Registration date
01/07/2013

Overall study status
Completed

Last Edited
29/10/2013

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
UK parents continue to be concerned about the safety of the combined measles, mumps and rubella (MMR) vaccine. National uptake of the MMR vaccine is below the 95% needed to protect the population. Research shows that parents lack confidence in making an informed decision. Good methods to help parents make informed decisions are needed. We recently conducted a small study with 30 parents that explored their views on an MMR decision aid (web site). The next step was to test this decision aid with more parents. This study aimed to test whether a decision aid (web site) for MMR when compared with an MMR leaflet improved informed parental decision-making and increased uptake of the MMR vaccine. We also explored the financial cost of delivering the MMR decision aid versus the MMR leaflet, and asked parents and health professionals how useful they thought the decision aid and leaflet were.

Who can participate?
The aim was to recruit 576 first-time parents with a child aged 3 to 12 months being offered the first dose of the MMR vaccine. Parents were required to be registered with a participating GP practice in the north of England, have an email address and sufficient English language skills to participate.

What does the study involve?
The GP practices in the study were randomly allocated to one of three groups. Depending on the group their GP practice were put in, parents either received usual care for MMR from their GP practice (group 1) or usual care plus the MMR decision aid web site (group 2) or usual care plus an MMR leaflet (group 3). We measured parents informed decision-making in a questionnaire at the start of the study and then 2 weeks after the study had started. We also recorded the costs of delivering the MMR decision aid and leaflet and interviewed parents and doctors/nurses about their views on the MMR decision aid and leaflet.

What are the possible benefits and risks of participating?
This study helped us to better understand how parents make decisions about whether or not to immunise their child with the MMR vaccine. The MMR decision aid may help participants themselves and other parents in the future to make an informed decision about the MMR vaccine. There were no risks of taking part, just some demands on parents time.

Where is the study run from?
The study was run from the University of Leeds, UK. Other organisations involved in the study were the Health Protection Agency and NHS Leeds.

When is the study starting and how long is it expected to run for?
This study ran from September 2008 to the end of November 2010.

Who is funding the study?
The study was funded by the National Institute for Health Research (NIHR), Research for Patient Benefit Programme, UK.

Who is the main contact?
Dr Cath Jackson
Cath.jackson@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Cath Jackson

Contact details
York Trials Unit
Department of Health Sciences
ARRC Building
University of York
York
United Kingdom
YO10 5DD
01904 32 1869
cath.jackson@york.ac.uk

Additional identifiers

Protocol serial number
08/H1311/23; UKCRN ID 4811

Study information

Scientific Title
Supporting informed parental decision-making for MMR (the combined measles, mumps and rubella vaccine): Evaluation of a web-based decision aid

Acronym
DECIDA

Study objectives

1. Parents receiving the web-based MMR decision aid will exhibit increased informed decision making over time relative to parents receiving an MMR leaflet alone.
2. The rate of vaccine uptake will be greater for parents receiving the web-based MMR decision aid compared to parents receiving an MMR leaflet alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was secured from York Research Ethics Committee on 4 April 2008 (Ref. 08 /H1311/23)

Primary study design
Interventional

Study design
Three-arm cluster randomised controlled trial with qualitative and economic components

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Public health - childhood immunisation

Interventions
The interventions were delivered at the individual parent level.
GROUP 1: Usual practice only (control)
Parents received the usual service provided by their GP practice. In England and Wales, parents of children registered with a GP receive an offer to have their child vaccinated for the first dose MMR at 12 to 13 months. Telephone interviews with participating GP practices indicated that usual practice included an appointment for the first dose MMR vaccination, a leaflet (usually MMR the Facts) and in some GP practices the offer of a consultation if the parent had concerns.
GROUP 2: MMR decision aid plus usual practice
Parents were sent by post the web link for the MMR decision aid with login instructions. They also continued to receive usual practice (described above) from their GP practice. The decision aid was a modified version of the Australian MMR decision aid. It can be accessed at www. leedsmmr.co.uk.
GROUP 3: MMR leaflet plus usual practice
Parents were sent the Health Scotland leaflet MMR your questions answered and also received usual practice.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Decisional conflict . This assessed a parents perception that their decision was informed in accordance with their values and can be acted upon. This 16-item validated scale has five sub-sections: informed, values clarity, support, uncertainty and effective decision. Scores range from

1 (no decisional conflict) to 5 (extremely high decisional conflict). Scores lower than two are associated with implementing informed decisions, higher scores are interpreted as delaying decisions or feeling unsure about their implementation.

Key secondary outcome(s)
1. First dose MMR vaccination uptake data for children of participating parents (provided by GP practices)
2. Knowledge about MMR and the measles disease was measured using 11 multiple choice items.
3. MMR immunisation cognitions: The Theory of Planned Behaviour informed items to assess parents cognitions (attitude, subjective norm, perceived behavioural control) towards having their child immunised with MMR.
4. MMR immunisation trade-off beliefs were measured using a previously modified version of the Beliefs about Flu Vaccination Questionnaire to assess parents trade-off beliefs on vaccine necessity versus vaccine concerns for MMR . A single MMR immunisation trade-off beliefs score was calculated. A positive score indicates that the parent perceives that necessity outweighs the concerns.
5. Anxiety was assessed by the short form State-Trait Anxiety Index.
6. Parents engagement with the decision aid or leaflet: Data were collected in the post-intervention questionnaire. Parents in the decision aid arm were asked Did you use the MMR website? (Yes the whole website /Yes but only some of it /No). The time parents spent working through the decision aid was captured by Google analytics.
7. Parents in the leaflet arm were asked Did you read the MMR leaflet? (Yes the whole leaflet /Yes but only some of it / No).
8. All parents were asked to report how long (minutes) they had spent looking at other information about MMR before or since their child was born.
9. Qualitative component: A sub-sample of parents and health professionals were interviewed about their views on the MMR decision aid or leaflet.
10. Eonomic component: Self-reported intended and actual numbers of parent contacts with health professionals and parent MMR-related expenditure were collected. Costs of delivering the MMR interventions (decision aid and leaflet) were calculated.

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. All 312 GP practices within five Primary Care Trusts in the North of England were eligible.
2. First-time parents with a child aged 3 to 12 months being offered the first dose of the MMR vaccine were eligible.
3. Parents were required to have an email address and sufficient English language skills to participate.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Months

Upper age limit
12 Months

Sex
All

Key exclusion criteria
None

Date of first enrolment
01/09/2008

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
York Trials Unit
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research, Research for Patient Benefit Programme (ref. PB-PG-0107-12048)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/12/2013		Yes	No