ISRCTN84560580 https://doi.org/10.1186/ISRCTN84560580

The role of information in the uptake of preventative healthcare

Submission date 10/02/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [X] Individual participant data
Registration date 17/02/2015	**Overall study status** Completed	
Last Edited 06/03/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Many families in low- and middle-income countries do not use preventative health services. One potential reason is that they underestimate the health benefits of such services. We will examine whether giving families information designed to improve household perceptions of the benefits of healthcare increases service uptake. The general principle will be tested using the example of the vaccine for diphtheria, pertussis, and tetanus (DPT) for which there is universally accepted evidence on its health benefits. The study takes place in Uttar Pradesh, India.

Who can participate?
Families with a child aged 0-36 months who has not received the recommended three doses of the DPT vaccine.

What does the study involve?
One group of families will receive information that describes the symptoms of tetanus, the possible health consequences, the benefits of getting their child vaccinated against tetanus in terms of mortality and morbidity gains, wider community benefits associated with herd immunity (spillovers), and where the family can get the child vaccinated at what cost and up until what age. A second group of families will receive similar information except that the benefits of vaccination will be framed in negative terms. A third group of families will receive no information and thus act as a control. At least nine months later the vaccination rates of children will be compared across the three groups.

What are the possible benefits and risks of participating?
By taking part in this study there are no risks of physical injury or harm since the research involves no invasive procedures or examinations. Knowledge generated by the study may benefit the health of children in future.

Where is the study run from?
The study has been set up by the London School of Hygiene and Tropical Medicine (UK), working in collaboration with Sambodhi Research and Communications (India).

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in April 2015. The final data will be collected in April 2016.

Who is funding the study?
Merck Sharp & Dohme Corp (USA) through MSD for Mothers

Who is the main contact?
Dr Timothy Powell-Jackson
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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
Nil known

Study information

Scientific Title
Information and the demand for preventative healthcare: a randomised controlled trial of improving household perceptions on the efficacy of DPT immunisation in Uttar Pradesh, India

Study objectives

1. Providing households with accurate information on the health benefits of the DPT vaccine will increase uptake of the vaccine.
2. Framing the information as a loss (incurred by not vaccinating the child) will increase uptake of the DPT vaccine more than when the information is framed as a gain (incurred by vaccinating the child).
3. The effect of information is greater amongst those who initially have lower perceptions of the efficacy of DPT vaccine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Intervention Research Ethics Committee of the London School of Hygiene and Tropical Medicine in London, 16/12/2014, ref: 8778
2. The institutional review board of the Public HealthCare Society in New Delhi, 18/08/2014
3. The Intervention Research Ethics Committee of the London School of Hygiene and Tropical Medicine in London, amendment 13/11/2017, ref: 8778-1
4. The institutional review board of the Public HealthCare Society in New Delhi, amendment 24 /09/2017

Study design
Randomized controlled trial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
The role of information in influencing household decisions to get their child vaccinated against tetanus

Interventions
Families will be individually randomised into three study arms. Mothers in the first treatment group will be given information on tetanus and benefits of vaccination framed in positive terms. The information script will describe the symptoms of tetanus, possible health consequences, the individual benefit of the combination vaccine in terms of mortality and morbidity gains, wider community benefits associated with herd immunity, and where the family can get the child

vaccinated at what cost and up until what age. A second treatment group will provide essentially the same information on efficacy but framed in negative terms. The third arm acts as a control group with no information given to the mother.

Added 08/03/2018:
The trialists are doing a longer term follow-up study of the same study participants. A household survey will be administered at 30 months follow-up.

Intervention Type
Behavioural

Primary outcome measure
Proportion of study children with three doses of DPT vaccine at endline as verified by the vaccination card or reported by the mother

Added 08/03/2018:
1. Proportion of (index) children with three doses of DPT vaccine at 30 months follow-up as verified by vaccination card or reported by the mother
2. Proportion of other children in the household under five years with three doses of DPT vaccine at 30 months follow-up as verified by vaccination card or reported by the mother

Secondary outcome measures
1. The proportion of children fully vaccinated (against tuberculosis, diphtheria, pertussis, tetanus, polio and measles)
2. An index of the mother's knowledge of tetanus symptoms
3. An index of the mother's perception of the efficacy of tetanus vaccination

Added 08/03/2018:
1. Proportion of children fully vaccinated at 30 months follow-up (against tuberculosis, diphtheria, pertussis, tetanus, and measles)
2. Proportion of other children in the household under five years fully vaccinated at 30 months follow-up (against tuberculosis, diphtheria, pertussis, tetanus, and measles)
3. Proportion of children vaccinated with measles vaccine at 30 months follow-up
4. Proportion of other children in the household under five years vaccinated with measles vaccine at 30 months follow-up
5. Proportion of children with suspected diarrhoea in the last four weeks at 30 months follow-up
6. Proportion of children with suspected pneumonia in the last four weeks at 30 months follow-up
7. Proportion of children with suspected diarrhoea in the last four weeks and correctly treated at 30 months follow-up
8. Proportion of children with suspected pneumonia in the last four weeks and correctly treated at 30 months follow-up
9. Mother's knowledge of any symptom of tetanus at 30 months follow-up
10. Mother's knowledge of any cause of tetanus at 30 months follow-up
11. Mother's knowledge of any tetanus prevention method at 30 months follow-up
12. Mother's perception of the efficacy of tetanus vaccination at 30 months follow-up

Overall study start date
01/10/2014

Completion date

15/05/2018

Eligibility

Key inclusion criteria
1. Mother with a child aged 0-36 months living in the same household
2. Child has not received three doses of DPT vaccine
3. Mother gives consent to participate in the study
4. Mother intends to remain in the study area for the six months

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
900

Total final enrolment
722

Key exclusion criteria
1. Child of mother is not aged 0-36 months
2. Child of mother is not living in the same household
3. Child has received three doses of DPT vaccine
4. Mother does not give consent to participate in the study
5. Mother due to emigrate from the study area in the six months

Date of first enrolment
10/07/2015

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
India

Study participating centre
Sambodhi Research and Communications Limited
O-2, 2nd Floor
Lajpat Nagar-II
New Delhi

India
110024

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine

Sponsor details
Keppel Street
London
United Kingdom
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Sponsor type
Research organisation

Website
http://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme Corp (USA) through MSD for Mothers

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal around 1 year after the trial end date

Intention to publish date
15/05/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in the LSHTM repository (DataCompass). The data used in the analysis (not the raw complete dataset) are available off the PLOS Med website alongside the paper.

IPD sharing plan summary

Published as a supplement to the results publication, Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/03/2018		Yes	No
Protocol file			24/08/2022	No	No
Dataset		06/03/2018	06/03/2024	No	No