

Evaluation of the Rapid Results Approach to improve childhood nutrition in Nepal

Submission date 26/08/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/06/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study will assess the impact of Sunaula Hazar Din (SHD), a program implemented by the Government of Nepal. SHD uses the Rapid Results Approach (RRA) to improve nutritional indicators of pregnant women and children 0 to 24 months old, as well as family planning of women aged 15-25 years old. The evaluation will measure its effect on nutritional attitudes and outcomes. RRA is a results-focused learning process aimed at jump-starting major change efforts and enhancing implementation capacity. The approach creates motivation and confidence by defining goals and monitoring results in short periods (usually 100 days) and mobilizing communities to act and coordinate.

Who can participate?

Children 0-24 months and their mothers, pregnant women, and women aged 15-25 years old who live in selected Village Development Committees across 15 districts of Nepal.

What does the study involve?

Over a period of 18 months, SHD will be implemented in randomly selected Village Development Committees. Community members can voluntarily participate in the activities organized by SHD in their Village Development Committee. Interviews and anthropometric measurements (such as height and weight) of children will be carried out at the start of the study and 24 months later to find out the impact of SHD on family planning and nutritional indicators.

What are the possible benefits and risks of participating?

Participants who live in a Village Development Committee which has been randomly chosen to receive the programme will benefit from the activities of SHD in their community. We do not anticipate risks related to participation in the study.

Where is the study run from?

The study is run from Village Development Committees across 15 districts of Nepal.

When is the study starting and how long is it expected to run for?
Initial information will be collected in August 2013 and program implementation is expected to start in December 2013. Final data collection is expected to start in August 2015.

Who is funding the study?
The World Bank, USA.

Who is the main contact?
1. Dr Emla Fitzsimons (emla_f@ifs.org.uk)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Nepal01

Study information

Scientific Title
Evaluation of the Rapid Results Approach to improve childhood nutrition in Nepal: a cluster randomized trial

Acronym
RRAN

Study objectives

It is hypothesized that the Rapid Results Approach will improve family planning and nutritional indicators of children and pregnant women in selected districts of Nepal. The null hypothesis is that there will be no difference in donations between treatment groups;

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Nepal Health Research Council, reg. 79/2013
2. UCL Research Ethics Committee, protocol ID 1827/005

Study design

Cluster randomized trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Community interventions to improve nutritional and family planning outcomes

Interventions

The Rapid Results Approach (RRA) will be implemented in randomly selected Village Development Committees. The RRA is a results-focused learning process aimed at jump-starting major change efforts and enhancing implementation capacity. It tackles large-scale medium and long term change efforts through a series of small-scale, results-producing and momentum-building initiatives. The approach creates motivation and confidence by defining goals and monitoring results in short periods (usually 100 days) and mobilizing communities to act and coordinate.

The control group are individuals living in randomly selected Village Development Committees which will not benefit from SHD for a two year period

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Current primary outcome measures as of 15/12/2015:

1. Height for age z-score for children 0-24 months
2. Percentage of children between 0-24 months that suffered from diarrhoea in the 15 days prior to the interview.

Previous primary outcome measures:

1. Percentage of unmet family planning needs among women 15-25 years of age
 2. Percentage of pregnant women taking iron and folic acid supplements for 180 days
 3. Percentage of children 0-6 months age who are exclusively breastfed
 4. Percentage of children 6-24 months age who consume a minimum acceptable diet
- The primary outcomes will be measured using structured questionnaires. They will be measured at baseline to assess the comparability of treatment and control Village Development Committees. They will also be measured 24 months after baseline to assess the impact of the intervention.

Secondary outcome measures

Current secondary outcome measures as of 15/12/2015:

1. Number of instances in which a mother (of children 0-24 months) reports to clean her hands with soap at critical times
2. Percentage of households that report to have human feces in the house, compound, or right outside the compound
3. Percentage of households that report to have animal feces in the house, compound, or right outside the compound
4. Percentage of households using safe sources of water
5. Percentage of children 6-24 months whose mother reported to consume a minimum acceptable diet on the day prior to the interview
6. Percentage of children 6-24 months whose mother reported to consume an animal sourced protein on the day prior to the interview
7. Percentage of pregnant women who report consuming an animal sourced protein on the day prior to the interview
8. Social capital
9. A composite index comprising outcomes related to the goals of SHD

Previous secondary outcome measures:

1. Percentage of children 0-24 months who are stunted (height for age z-score less than -2)
2. Percentage of children 0-24 months who suffer from underweight (weight for age z-score less than -2)
3. Social capital
4. A composite index comprising outcomes related to the 30 goals of SHD

Overall study start date

30/08/2013

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Children aged 0-24 months
2. Pregnant women
3. Women aged between 15 years and 25 years old

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

20586

Key exclusion criteria

Children who are unable to be measured

Date of first enrolment

30/08/2013

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

England

Nepal

United Kingdom

Study participating centre

University College London

London

United Kingdom

WC1E 6BT

Sponsor information

Organisation

The World Bank (USA)

Sponsor details

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Sponsor type

Other

Website

<http://go.worldbank.org/LE9CTYG5M0>

ROR

<https://ror.org/00ae7jd04>

Funder(s)

Funder type

Other

Funder Name

The World Bank (USA)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			19/06/2023	No	No