

Promoting adolescent engagement, knowledge and health evaluation of PAnKH: an adolescent girl intervention in Rajasthan, India

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| Submission date 15/01/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/02/2018 | Overall study status Completed | <input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/06/2023 | Condition category Other | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Adolescence is increasingly recognised as a crucial life stage from both a social and developmental perspective. Decisions made during adolescence – from dropping out from school, to getting married early, to engaging in risky behaviours – can have lifelong implications. At the same time, this is an important period of neurobiological (mental) development, particularly of socio-emotional and non-cognitive skills. In all, these two factors make adolescence a period of heightened vulnerability to adverse environmental factors but also an opportunity for intervention. Adolescent girls in rural India face particular pressures: poverty, highly conservative gender norms and customs around women's marriage, education and role within the household combine to put girls at exceptionally high risk of child marriage, poor sexual and reproductive health, early drop-out from school, poor mental health and poor development of key socio-emotional and non-cognitive skills. The aim of this study is to assess the impact of an integrated community-based programme, PAnKH, on adolescent girls' marriage, education, mental health, gender attitudes and socio-emotional and non-cognitive skills. Through providing information and skills, the programme aims to help girls stay in or return to school, resist child and early marriage practices and make informed decisions about their sexual and reproductive health needs. Through providing a safe and supportive space and specific training around negotiation skills it hopes to improve girls' mental health and non-cognitive skills. Moreover, PAnKH aims to positively transform norms and values relating to girls in their communities.

Who can participate?

Adolescent girls aged between 12-17 (unmarried) or 12-19 (married), their parents and in-laws and other community members

What does the study involve?

Participating villages are randomly allocated to one of three groups. In the first group adolescent girls are directly engaged through group education and weekly sports sessions. In the second group the wider community are also engaged with and mobilised by community campaigns and events targeting similar issues with the wider community. The third group does

not receive any intervention. The study assesses how feasible it is for community-based programmes to alter key outcomes for adolescent girls.

What are the possible benefits and risks of participating?

Possible benefits of participating in the study include access (in allocated villages) to the PANKH program which aims to increase girls' understanding of gender, early marriage, education and sexual and reproductive health as well as build up soft skills and mental health. Possible risks include girls facing adverse community or family reaction due to participating in the program due to its novelty in this context. To mitigate this risk program staff have reached out to community leaders and members at large to discuss the aims of the program and take on board any concerns.

Where is the study run from?

International Centre for Research on Women (India)

When is the study starting and how long is it expected to run for?

March 2015 to May 2018

Who is funding the study?

1. Children's Investment Fund Foundation
2. John D. and Catherine T. MacArthur Foundation
3. Pentland

Who is the main contact?

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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

AEARCTR-0002656

Study information**Scientific Title**

Promoting adolescent engagement, knowledge and health evaluation of PAnKH: an adolescent girl intervention in Rajasthan, India

Study objectives

1. Community-based programmes in rural Rajasthan targeting adolescent girls can have a positive effect on early marriage, education, mental health, socio-emotional and non-cognitive skills and gender attitudes.
2. Integrated programmes that engage with adult members of the community can have a positive effect when compared to intervening with adolescent girls alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. International Center for Research on Women - Institutional Review Board, 03/08/2015, ref: 15-0001
2. Sigma-IRB, India, 27/07/2015, ref: 10005/IRB/D/15-16
3. Social Sciences & Humanities Inter-Divisional Research Ethics Committee, University Of Oxford, 15/12/2015, ref: R43389

Study design

Cluster randomised controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied

Adolescent engagement, knowledge and health

Interventions

This is a cluster randomised controlled trial with 90 clusters (villages or groups of nearby villages) designed to evaluate the effectiveness of two models of PAnKH, a community-based programme targetting the outcomes of adolescent girls in rural Rajasthan, India. As such, 30 clusters were allocated using random numbers generated on STATA to:

1. Control group: The control group does not receive any intervention
2. Girls' only intervention: 40-45 Group Education Activities (GEAs) for adolescent girls as well as weekly sports sessions. The GEAs follow a curriculum designed to address topics related to gender norms, gender-based violence, sexual and reproductive health and education as well as promoting girls socio-emotional and non-cognitive skills and wellbeing
3. Integrated intervention. GEAs were complemented by community campaigns and events targeting similar issues with the wider community

Interventions last for 18 months in total and follow-up data is collected for approximately 24 months after baseline.

Intervention Type

Behavioural

Primary outcome measure

1. Early marriage:
 - 1.1. Proportion of girls ever married (BL, EL)
 - 1.2. Proportion of girls married before each age 13-19 (BL, EL)
2. Education:
 - 2.1. Proportion of girls currently in school (BL, EL)
 - 2.2. Proportion of girls who dropped out of school before each age 13-19 (BL, EL)
3. Mental health:
 - 3.1. Depression, measured using PHQ-9 (EL)
 - 3.2. Anxiety, measured using GAD-7 (EL)
 - 3.3. Rumination, measured using RSS-10 (EL)
4. Socio-emotional and non-cognitive skills:
 - 4.1. Self-efficacy, measured using GSE-10 (BL, EL)

- 4.2. Self-esteem, measured using SDQ-GS (BL, EL)
- 4.3. Peer relations, measured using SDQ-PR (BL, EL)
- 4.4. Resilience, measured using CD-RISC-10 (EL)
- 4.5. Decision making – vigilance, measured using DMQ (EL)
- 4.6. Decision making – buck passing, measured using DMQ (EL)
- 5. Gender attitudes:
 - 5.1. Gender attitudes of girls, measured using adapted GEMS scale (BL, EL)
 - 5.2. Gender attitudes of caregivers, measured using adapted GEMS scales (BL, EL)

(BL=measured at baseline, EL=measured at endline, roughly 24 months after BL)

Secondary outcome measures

- 1. Attitude towards school:
 - 1.1. School attitudes scale – scale devised by authors, details in pre-analysis plan (EL)
- 2. Knowledge of sexual and reproductive health:
 - 2.1. Puberty and menstruation knowledge scale – scale devised by authors (EL)
 - 2.2. Contraception and sexual health knowledge scale – scale devised by authors (EL)
- 3. Attitudes and responses to violence:
 - 3.1. Girls' 'victim blaming' tendencies for violence against women and girls – scale devised by authors (EL)
 - 3.2. Girls' 'perpetrator blaming' tendencies for violence against women and girls– scale devised by authors (EL)
 - 3.3. Girls' 'avoidance behaviours' in response to violence against women and girls– scale devised by authors (EL)
 - 3.4. Girls' 'retaliation behaviours' in response to violence against women and girls– scale devised by authors (EL)
 - 3.5. Girls' 'reporting behaviours' in response to violence against women and girls– scale devised by authors (EL)
 - 3.6. Carers' 'victim blaming' tendencies for violence against women and girls– scale devised by authors (EL)
 - 3.7. Carers' 'perpetrator blaming' tendencies for violence against women and girls– scale devised by authors (EL)
 - 3.8. Carers' 'avoidance behaviours' in response to violence against women and girls– scale devised by authors (EL)
 - 3.9. Carers' 'retaliation behaviours' in response to violence against women and girls– scale devised by authors (EL)
 - 3.10. Carers' 'reporting behaviours' in response to violence against women and girls– scale devised by authors (EL)
- 4. Sports:
 - 4.1. Attitude to and enjoyment of sports – sports attitudes scale – scale devised by authors (EL)
 - 4.2. Participation in sports – time spent playing sport in a typical week (minutes) (EL)
- 5. Restrictions during menstruation:
 - 5.1. Restrictions during menstruation scale– scale devised by authors (BL, EL)

(BL=measured at baseline, EL=measured at endline, roughly 24 months after BL)

Overall study start date

01/03/2015

Completion date

31/05/2018

Eligibility

Key inclusion criteria

Adolescent girls aged between 12-17 (unmarried) or 12-19 (married) at baseline living in the 90 study clusters

Participant type(s)

Other

Age group

Mixed

Lower age limit

12 Years

Upper age limit

19 Years

Sex

Female

Target number of participants

7574 girls at baseline

Total final enrolment

7577

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/11/2015

Date of final enrolment

15/01/2016

Locations

Countries of recruitment

India

Study participating centre

International Centre for Research on Women

C – 59, South Ext, Part II, New Delhi

Delhi

India

110049

Sponsor information

Organisation

Children's Investment Fund Foundation

Sponsor details

7 Clifford Street
London
United Kingdom
W1S 2FT

Sponsor type

Charity

Website

<https://ciff.org/>

ROR

<https://ror.org/00jfgn87>

Organisation

John D. and Catherine T. MacArthur Foundation

Sponsor details

India Habitat Centre
Zone VA, First Floor
Lodhi Road
Delhi
India
110 003

Sponsor type

Research organisation

Website

<https://www.macfound.org/>

ROR

<https://ror.org/00dxczh48>

Funder(s)

Funder type

Charity

Funder Name

Children's Investment Fund Foundation

Alternative Name(s)

CIFF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

John D. and Catherine T. MacArthur Foundation

Alternative Name(s)

MacArthur Foundation, John D. & Catherine T. MacArthur Foundation, JDCTMF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Pentland

Results and Publications

Publication and dissemination plan

The trialists plan to publish results in a mixture of high-impact peer review medical/public health journals and economics journals. They aim to submit for publication within one year of the trial end date.

Intention to publish date

31/05/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---------------------------|--------------|------------|----------------|-----------------|
| Statistical Analysis Plan | statistical analysis plan | 18/01/2018 | | No | No |
| Funder report results | Impact evaluation | 01/12/2018 | 13/08/2021 | No | No |