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The effect of affordable daycare on health and well-being over the life-course

Submission date
12/05/2016

Recruitment status
No longer recruiting

Registration date
16/05/2016

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The provision of affordable and reliable daycare services is a potentially important policy for empowering Indian women. Access to daycare might reduce barriers to labor force entry and generate economic opportunities for women, improve education for girls caring for younger siblings, and promote nutrition and learning among children. However, evidence concerning the effects of daycare programs in low-and-middle-income countries is scarce. The aim of this study is to estimate the effect of a community-based daycare program on health and economic well-being among women and children living in rural Rajasthan, India.

Who can participate?
Households with a child aged 1-6 living in hamlets in the Udaipur District of rural Rajasthan.

What does the study involve?
Participating hamlets are randomly allocated to either the intervention or the control group. A full-time, affordable, community-based daycare program is introduced in the intervention group hamlets. The control group hamlets do not receive any interventions during the study period. We measure social and economic outcomes including women's economic status and economic opportunity, women's empowerment, and children's educational attainment. Primary health outcomes include women's mental health, as well as children's nutritional status.

What are the possible benefits and risks of participating?
Although participants are compensated for their time (with a small gift), there are no direct benefits from study participation. Indirectly, participation may enhance our understanding of the barriers to health and development in the region, as well as potential interventions for improving participants' lives. As all information provided by participants will be kept confidential, participation in the study is not anticipated to adversely affect respondents. However, during the interviews, we discuss topics that are sensitive, such experiences of intimate partner violence. This has the potential to make participants uncomfortable. If they feel distressed, participants are, of course, free to stop the interview at any time. A contact is also provided for participants to discuss any issues that arise from the interview process.

Where is the study run from?
McGill University (Canada)

When is the study starting and how long is it expected to run for?
October 2014 to September 2017

Who is funding the study?
International Development Research Centre (Canada)

Who is the main contact?
1. Dr Arijit Nandi (arijit.nandi@mcgill.ca)
2. Dr Sam Harper (sam.harper@mcgill.ca)
3. Ms Parul Agarwal

Contact information

Type(s)
Scientific

Contact name
Dr Arijit Nandi

ORCID ID
http://orcid.org/0000-0002-3399-0536

Contact details
1130 Pine Avenue West
Montreal
Canada
H3A 1A3
+1 (0)514 398 7849
arijit.nandi@mcgill.ca

Type(s)
Scientific

Contact name
Dr Sam Harper

Contact details
1020 Pine Avenue West
Montreal
Canada
H3A 1A2
+1 (0)514 398 2856
sam.harper@mcgill.ca

Type(s)
Scientific

Contact name

Ms Parul Agarwal

Contact details
2nd Floor
Buhari Towers
No.4, Moores Road
Chennai
India
600 006

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AEARCTR-0000774

Study information

Scientific Title
The effect of an affordable daycare program on health and economic well-being in Rajasthan, India: protocol for a cluster-randomized impact evaluation study

Study objectives
As described below, the primary outcomes were women's mental health, women's empowerment, and women's labor force participation, as well as children's nutritional status.

We hypothesize that the provision of affordable and reliable daycare services is a potentially important lever for improving women's health and economic status. For mothers, access to daycare might reduce barriers to labor force entry and generate economic opportunities for women, which is one of the building blocks for empowerment. Additionally, access to daycare might improve women’s mental health. For example, women report that they perform domestic duties out of compulsion rather than choice. Access to daycare could alleviate “time poverty”, lower stress levels, and improve mental health and subjective well-being by reducing the conflicting demands on women’s time and increasing women’s autonomy.

The provision of daycare may benefit children and adolescents by removing the responsibility of caring for younger children, which limits educational opportunities. Under-nutrition and illiteracy remain challenges in many low- and middle-income countries, especially India, and daycare programs could also improve children’s health and development outcomes through the provision of meals and learning programs.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. The Institutional Review Board of McGill University's Faculty of Medicine, 08/09/2014, FWA 00004545; IRB study number A08-E61-14A
2. The Human Subjects Committee of the Institute for Financial Management and Research in Chennai, India, 22/09/2014, FWA00014616

Study design
Three-year cluster-randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

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
Health conditions included: childhood vaccination coverage; incidence of children's health conditions (e.g., fever, diarrhoea); child nutrition, based on measured height and weight; women's self-rated health and subjective well-being; women's mental distress; intimate partner violence

Interventions
At baseline, household surveys were completed among 3164 mothers with age eligible children living in 160 village hamlets. After the baseline, these hamlets were randomized to the intervention or control groups and respondents will be interviewed on two more occasions.

The intervention is the introduction of full time, affordable daycare centers, called balwadis, in 80 treated hamlets in areas where they are not yet available. The balwadis are being operated by the NGO Seva Mandir, a local non-governmental development organization that operates daycare programs in other areas in the Udaipur district. Each of the balwadis provides childcare, nutritious food and supplements, basic medicines, and preschool education to children one to six years old. The balwadi program also aims to increase immunization coverage of children by maintaining immunization records and following-up with parents and government nurses. Balwadis are operated by local women, called sanchalikas, who are hired and trained by Seva Mandir. Sanchalikas receive approximately 20 days of training each year regarding their roles and responsibilities. The sanchalikas meet with children's families on a quarterly basis to discuss their child's progress. The implementation of daycare programs in treatment villages was accompanied by a household marketing campaign to encourage sustained enrollment. Take-up rates of the intervention will be available after the mid-line survey is fielded.

The control group will not receive any interventions during the study period from October 2014-September 2017.

Intervention Type
Other

Primary outcome measure
The primary outcomes are being measured at three timepoints over the course of the study: a baseline survey, which occurred in early-mid 2015; a first post-intervention, or midline, survey that will be fielded in mid 2016; and a final post-intervention, or endline, survey that will be fielded in mid 2017.

We assessed health, social, and economic outcomes. The primary health outcomes are child nutrition and women's mental health. We measured child length/height and weight using standardized techniques and this information will be used to derive children's length/height-for-age, weight-for-age, weight-for-length/height, and body mass index (BMI)-for-age using the World Health Organization Child Growth Standards. Symptoms of common mental disorders (CMD) are being assessed using the 12-item General Health Questionnaire (GHQ-12). The GHQ-12 produces results that are similar to the longer version of the GHQ and has been found to be a valid screening instrument for CMD in diverse settings. To the best of our knowledge, validation studies have not been conducted among women living in Rajasthan.

The primary social outcome is women's economic empowerment. We adopted a conceptual approach that incorporates both the personal and political dimensions of empowerment, and developed indicators that captured women's sense of selfworth and identity, their willingness to question their own subordinate status, their control over their own lives and their voice and influence within the family. We constructed indicators of empowerment, adapted from the Indian National Family Health Survey whenever possible to facilitate comparability, which encompassed four domains:
1. Decision making within the family and control over income (e.g., who decides how the money you earn will be used: mainly you, mainly your husband, or you and your husband jointly?)
2. Freedom of movement in the public domain (e.g., are you usually permitted to go to the following places—for example, a market within the village—to buy things: on your own, only if someone accompanies you, or not at all?)
3. Participation in community and public life (e.g., are you a member of any type of association, group or club which holds regular meetings?)
4. Views and attitudes on critical gender issues (e.g., please tell me if you agree or disagree with each statement: A married woman should be allowed to work outside the home if she wants to).
We plan to test the reliability of empowerment measures during the second survey wave.

The primary economic endpoint is women's labor force participation. We asked about employment experiences, including whether respondents work, their occupation, the type of work, the quantity of work, whether they are paid for their work in cash or in-kind, and what they do with their children while working.

Secondary outcome measures
The secondary outcomes are being measured at three timepoints over the course of the study: a baseline survey, which occurred in early-mid 2015; a first post-intervention, or midline, survey that will be fielded in mid 2016; and a final post-intervention, or endline, survey that will be fielded in mid 2017.

Secondary outcomes included mechanisms hypothesized to link access to daycare to the primary outcomes described above, including women's time use and economic status.

Use of time was measured using a structured questionnaire that asked respondents whether they spent any time in the past 24 hours on specific activities (e.g., gathering fuel or firewood), how much time they spent on each activity, and whether this amount reflected the usual amount of time spent on the activity. The questionnaire also asks whether respondents were paid in cash or in-kind for the activities they engaged in.

Economic status is measured by household income and wealth. Respondents reported the household income received in the past 12 months from various categories (e.g., agricultural income, business income, rents, remittances, government payments). Household wealth is measured using a series of questions about ownership of specific assets (e.g., telephone, bicycle, radio), environmental conditions (e.g., type of water source, sanitation facilities), and housing characteristics, (e.g., number of rooms, materials used for housing construction). Additionally, respondents are asked about savings accounts held by household members, including for each account the type of account, its purpose, the total value, and whether the respondent can use the account to make purchases.

Overall study start date
01/10/2014

Completion date
30/09/2017

Eligibility

Key inclusion criteria
We selected participants from village hamlets located in Rajasthan, the site of the intervention. 160 hamlets were selected from five blocks (i.e., Badgaon, Girwa, Jhadol, Kherwara, Kotra) in the Udaipur District where Seva Mandir had not previously established balwadis.

These hamlets satisfied five criteria determined a priori, specifically:
1. No readily accessible daycare within 1.5 kilometers to reduce the potential for contamination effects
2. A minimum number of children (≥25) in the appropriate age range in the hamlet to ensure adequate demand
3. An existing structure suitable for a daycare
4. A qualified woman, living in the study hamlet or nearby, to operate the daycare
5. Adequate demand from the village council (Panchayat) for a new daycare

In late 2014, we completed a household census in each of the 160 hamlets to confirm the eligibility of the hamlet, enumerate the population, and identify potential respondents for inclusion. Eligible households were those with at least one mother (biological or guardian) with a child between one and six years of age. At this time, the respondent was considered eligible if they responded to the question “Do you have any children between one to six years of age” with a yes. Based on this, the total number of eligible households was similar to our desired sample size (n=3200). From this list, we randomly selected one eligible respondent from each eligible household to complete a baseline survey.

Participant type(s)
Other

Age group

Adult

Sex
Female

Target number of participants
Based on our power calculations, we aimed to enroll 3200 mothers with age-eligible children from 160 village hamlets (average of 20 participants/cluster)

Total final enrolment
2858

Key exclusion criteria
Households without a mother with an age-eligible child from the 160 study hamlets

Date of first enrolment
14/12/2014

Date of final enrolment
07/04/2015

Locations

Countries of recruitment
India

Study participating centre
Participants are recruited from communities in 5 blocks in the Udaipur district of Rajasthan
India
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Sponsor information

Organisation
McGill University (Canada)

Sponsor details
845 Rue Sherbrooke West
Montreal
Canada
H3A 0G4

Sponsor type
University/education

Website
https://www.mcgill.ca/

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Government

Funder Name
International Development Research Centre

Alternative Name(s)
Centre de recherches pour le développement international, IDRC, CRDI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Publication and dissemination plan
We plan to publish our protocol in mid-2016. Baseline results will be submitted for publication in mid to late 2016. Final results from the trial will be published shortly after the endline survey, at which point all data will also become publicly available.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/06/2016		Yes	No

Results article	13/08/2020	13/08/2021	Yes	No
Results article	08/11/2024	20/11/2024	Yes	No