Registry of Efficacy and Effectiveness Studies

Study Title:
Impact Evaluation of a Father Engagement Model in the Home visiting Humanitarian Play Lab (HPL) Program in Rohingya Refugees camps in Cox's Bazar, Bangladesh

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Section I: General Study Information

PI name: Hirokazu Yoshikawa
PI affiliation: New York University

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LEGO Foundation

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Sesame Workshop is the prime; NYU is sub-awardee.

IRB Name:
The Institutional Review Board of the Institute of Health Economics (IHE-IRB), University of Dhaka, Bangladesh

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NA

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-

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-

Study Start Date:
2022-09-25

Study End Date:
2023-08-15

Intervention Start Date:

2022-12-26

Timing of entry:
Prior to implementation of the intervention

Brief Abstract:
Brief Overview: NYU-TIES is evaluating the impact of a BRAC IED-led home-visiting and group-based program that engage both mothers and fathers of 0-2 year old children. The evaluation will focus on the added value of engaging fathers, in addition to only mothers, in caregiver-focused parenting interventions.

Proposed Research Question: What is the added impact of father home visits and groups on father engagement (e.g. activities with their children), perceptions of learning and play, and attitudes and well-being, above and beyond group visits conducted with only mothers?

Intervention: The intervention assessed in this study is an added component to an intervention implemented by BRAC-IED that has been working with mothers of 0-2 year old children to maximize positive outcomes of child development. The new component fathers with children below two years of age. The objectives of this added component are to promote fathers' wellbeing by improving their emotional literacy, encourage fathers to develop relationships with their spouses and children, and encourage responsive caregiving practices among fathers (BRAC & Sesame Workshop, 2022).

Research Design: Randomized controlled trial with embedded qualitative component

Keywords:
early childhood development, parenting, father engagement, humanitarian settings, forced displacement, home-visits, migration, socio-emotional and mental health of parents

Comments:
The study start date here refers to the first day of baseline data collection; the end date refers to the date by which we currently assume endline data collection will be complete.

Section II starts on the next page.

Section II: Description of Study

Type of Intervention:
Parenting intervention through home visits (weekly) and group visits (once every three weeks) for fathers

Topic Area of Intervention:
Early Childhood Education, Caregiver mental health, child development, Parenting

Number of intervention arms:
2

Target school level:
Pre-K

Target school type:
Not Applicable

Location of Implementation:
International : Asia

Further description of location:
Cox's Bazar, Bangladesh

Brief Description of Intervention Condition:
The intervention assessed in this study is an added component to an intervention implemented by BRAC-IED that has been working with mothers of 0-2 year old children to maximize positive outcomes of child development. The new component targets fathers with children below two years old. The objectives of this added component are to promote fathers' wellbeing by improving their emotional literacy, encourage fathers to develop relationships with their spouses and children, and encourage responsive caregiving practices among fathers. Each father will receive the intervention for approximately 6 months, with 3 home sessions and one group visit per month. Each home visit session lasts 30 minutes and covers a variety of topics including, for instance, the importance of father's engagement in child development, building connections with the child, understanding how children respond to stress, and how to comfort them, and the importance of play in children's lives. The group visit consists of similar curriculum in a group setting (45min - 1 hour).

Brief Description of Comparison Condition:
The comparison condition consists of only the mother-focused intervention.

Comparison condition:
Other

Comments:
This study will evaluate the added impact of a home visit program for fathers, conducted by volunteers, above and beyond a group-based mother program. The target population are fathers and mothers of 0-2 year olds. BRAC will be implementing this program across "pockets" or groups of households, across the refugee camps and host community in Cox's Bazar. In both treatment and control conditions, the mother receives a group-based intervention delivered by a mother volunteer. In the treatment condition only, the father receives a home-visit intervention, delivered by a father volunteer. The unit of randomization is the mother volunteer.

Each volunteer's total caseload will cover 4 pockets, and each pocket will have 2 groups. A total of 250 mother

volunteers are included in the study from the refugee community (where we sample 4 pockets, with 2 households each, per volunteer, for a total sample of 1000) and 125 mother volunteers are included from the host community (where we sample 4 pockets, with 4 households each, per volunteer, for a total sample of 2000).

Section III: Research Questions

Confirmatory research questions:

Question 1:

What is the added impact of a parenting intervention consisting of home visits (conducted by male volunteers every week) and group session (conducted by male volunteers every three weeks) to fathers of children aged 0-2 on father engagement with children, in comparison to families who only receive a parenting intervention targeting mothers?

Question 2:

What is the added impact of a parenting intervention consisting of home visits (conducted by male volunteers every week) and group session (conducted by male volunteers every three weeks) to fathers of children aged 0-2 on father well-being, in comparison to families who only receive a parenting intervention targeting mothers?

Question 3:

What is the added impact of a parenting intervention consisting of weekly home visits conducted by male volunteers every week) and group session (conducted by male volunteers every three weeks) to fathers of children aged 0-2 on child development, in comparison to families who only receive a parenting intervention targeting mothers?

Exploratory research questions:

No Questions added yet.

Comments:

Father engagement will be assessed using the following outcomes (pending psychometrics on baseline and endline data): Father and mother reports of perceptions of the Father's Involvement in their Children’s Life, Father's Engaging with Wife about Family, Importance of Fathers’ Activities, and Creation of Stimulating Environment.

Father well-being will be assessed using the PHQ-8 (Depression) scale.

Child development will be assessed using a direct child assessment (the Bayley) provided data collection using direct child assessments proves feasible given conditions; or caregiver-reported child outcomes (specifically, mother-reported CREDI)

Section IV-A: Study Design (Selection)

Study Design:

Randomized Trial (RT)

Comments:

-

Section IV-B: Study Design (Input)

Study Design: Input

Unit of random assignment of intervention:
Volunteer caseloads

Assignment within sites or blocks:
Yes

Define the sites or blocks:
type of population - host & refugee community

Probability of assignment to treatment the same across sites or blocks:
Yes

Probability of assignment to treatment:
0.50

Unit outcome data measured:
parent

Intermediate clusters between unit of random assignment and unit of measurement:
No

Comments:

The data from the two communities (i.e. blocks) have different clustering structures. The refugee sample has 2 levels of data: the household level and the volunteer caseload level; here we only collect data from one of the two groups that the mother volunteer runs. The host sample has 3 levels of data: the household level, the group level, and the volunteer (where we collect data from multiple groups run by a mother volunteer).

Due to an unforeseen reduction in the size of the camp (refugee) community sample, we performed constrained randomization to ensure covariate balance between arms on all potential confounders and potentially improve our power. The host community sample size was not reduced, so we performed simple randomization for that sample.

Constrained randomization involves generating a large number of possible allocation schemes and calculating a balance score that assesses covariate imbalance for each of those schemes. It then limits the randomization space to a pre-specified percentage of candidate allocations before randomly selecting one scheme to implement. For our refugee sample, we used the l2 balance metric, which was first introduced by Raab and Butcher (2001), and constrained the randomization space to the 10% of schemes that provided the best balance.

The covariates that were used included camp number, mother volunteer characteristics (age and tenure at BRAC), caseload characteristics (mother health, education, literacy, and age; father education, literacy, and age; the number of children under 2 in the household; whether the mother is pregnant, and whether the mother suffered a serious injury in the last year) and baseline versions of the outcomes aggregated to the caseload level.

Design Classification

Based on the responses above, this study has been classified as:
RT: Multisite (Blocked) Cluster Randomized Trial

Section V: Sample Characteristics

Approximate number of outcome data units (parent) per randomization unit (Volunteer caseloads): 4

Approximate number of randomization unit (Volunteer caseloads) in the comparision condition within each block (type of population - host & refugee community): 125

Approximate number of randomization unit (Volunteer caseloads) in the intervention condition within each block (type of population - host & refugee community)1: 125

Approximate number of randomization unit (Volunteer caseloads) in the intervention condition within each block (type of population - host & refugee community)2: 63

Number of blocks (type of population - host & refugee community): 2

Were there certain outcome data units (parent) that were targeted for the study?
Yes - Fathers who will be residing with their families for the duration of the intervention period; parents with children

Were there certain outcome data units (parent) that were excluded from the study?
No

Were there certain randomization unit (Volunteer caseloads) that were targeted for the study?
No

Were there certain randomization unit (Volunteer caseloads) that were excluded from the study?
No

Were there certain blocks (type of population - host & refugee community) that were targeted for the study?
Yes - This study was originally planned for the refugee community only; due to restrictions in accessing the refugee community, the study was then expanded to include the host community. The two blocks are therefore host and refugee, with randomization taking place separately within each block.

Were there certain blocks (type of population - host & refugee community) that were excluded from the study?
No

Comments:
Approximate number of outcome data units (parent) per randomization unit (Volunteer caseloads) is 4 in the refugee and 8 in the host community.

The information pre-registered here assumes a sample of 2000 in the host community (8 per 250 mother volunteer) and 1000 in the camp community (4 per 125 mother volunteers). Power analyses indicate that we need a total sample of 2000 to be sufficiently powered (MDES 0.17) to answer our research question.

We are assuming, and report here, an endline that consists of 1000 from the refugee community and 1000 from the host community. However, access to the refugee community for research purposes at endline remains uncertain, which is why we have included a full sample of 2000 from the host community at baseline. In the event that access to the refugee community is not possible at endline, the study will include only the host community.

Section VI: Outcomes (Input)

Confirmatory question 1: Outcome Measure 1

Outcome domain: Other Outcome Domain - Father Engagement
Minimum detectable effect size: 0.173
Outcome measure: Fathers' Perception of their Involvement in their Children's Life
Scale of outcome measure: Continuous
Normed or state test: No
Test-retest reliability: N/A
Internal consistency: N/A
Inter-rater reliability: N/A
Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 1: Outcome Measure 2
Outcome domain: Other Outcome Domain - Father Engagement
Minimum detectable effect size: 0.173
Outcome measure: Fathers' Perceptions of Engaging with Wife about Family
Scale of outcome measure: Continuous
Normed or state test: No
Test-retest reliability: N/A
Internal consistency: N/A
Inter-rater reliability: N/A
Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 1: Outcome Measure 3
Outcome domain: Other Outcome Domain - Father Engagement
Minimum detectable effect size: 0.173
Outcome measure: Father's Perceptions of the Importance of Fathers' Activities
Scale of outcome measure: Continuous
Normed or state test: No
Test-retest reliability: N/A
Internal consistency: N/A
Inter-rater reliability: N/A
Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 1: Outcome Measure 4
Outcome domain: Other Outcome Domain - Father Engagement
Minimum detectable effect size: 0.173
Outcome measure: Mother's Perception of Father's Involvement in Children's Life
Scale of outcome measure: Continuous
Normed or state test: No
Test-retest reliability: N/A
Internal consistency: N/A
Inter-rater reliability: N/A
Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 1: Outcome Measure 5
Outcome domain: Other Outcome Domain - Father Engagement
Minimum detectable effect size: 0.173
Outcome measure: Mother's Perception of Father Engagement with Wife about Family
Scale of outcome measure: Continuous

Normed or state test: No

Test-retest reliability:

Internal consistency:

Inter-rater reliability:

Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 2: Outcome Measure 1

Outcome domain: Other Outcome Domain - Father Well Being

Minimum detectable effect size:

Outcome measure: Depression - PHQ8

Scale of outcome measure: Continuous

Normed or state test: No

Test-retest reliability: N/A

Internal consistency: N/A

Inter-rater reliability: N/A

Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 3: Outcome Measure 1

Outcome domain: Other Outcome Domain - Child Development

Minimum detectable effect size:

Outcome measure: Bayley-4

Scale of outcome measure: Continuous

Normed or state test: No

Test-retest reliability:

Internal consistency:

Inter-rater reliability:

Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 3: Outcome Measure 2

Outcome domain: Other Outcome Domain - Child Development

Minimum detectable effect size:

Outcome measure: Mother-reported CREDI

Scale of outcome measure: Continuous

Normed or state test: No

Test-retest reliability: N/A

Internal consistency: N/A

Inter-rater reliability: N/A

Same outcome measure in treatment and comparison groups: Yes

Section VII: Analysis Plan

Baseline data collected prior to start of intervention:

Yes

Description of baseline data:

We have data from the mother's survey, the father's survey, as well as some basic information on the mother volunteers (number of months working for BRAC, age).

The mother and father surveys have baseline versions of the outcome variables as well as some demographic

information including age, educational level, ability to read. The mother's survey also includes items on overall physical health, illnesses/injuries in the past year, pregnancy status, the gender and date of birth of the focal child, and the number of children under 2 years of age as well as items from the Perceived Refugee Environment Index.

Covariates you plan to include in the model:
-, All non-outcome covariates which were included in the constrained randomization will be included in the analytic model. These include: camp number/location, mother volunteer characteristics (age and tenure at BRAC); mother health, education, literacy, and age; father education, literacy, and age; the number of children under 2 in the household; whether the mother is pregnant, and whether the mother suffered a serious injury in the last year. The analytic model for each outcome will also include the baseline version of that specific outcome.

Covariates you plan to include in the model:

Analytic model:
Our study implements similar (but not identical) interventions in two separate communities: the host community and the refugee community. Caseloads from these two communities were randomized into the treatment arms separately. Thus, while we have balance on potential confounders within community, the levels/magnitudes of covariates (as well as the mechanism through which they might affect the outcomes) could vary significantly across communities. This could threaten the validity of our coefficients. In order to minimize this threat while analyzing the results as a pooled sample, we will use the following procedure:

1. We will pool the data from both communities into one dataset and create an indicator variable that identifies wheth

2. To test whether there are significant differences in how covariates predict outcomes between the two communities

3. We will test the significance of each interaction using a t-test, and deem all interaction coefficients with a p-value

The data from the two communities also has different clustering structures. The camp sample has 2 levels of data: the household level and the group/mother volunteer level since we only collect data from one of the two groups that the mother volunteer runs. The host sample has 3 levels of data: the household, the group, and the mother volunteer (where each volunteer runs two groups). We will use a mixed effects model, estimated through restricted maximum likelihood (REML), to identify the treatment effects for each outcome while applying an extra level of clustering for the sample coming from the host community.

Plan to handle cases with missing outcome data:
Impute missing outcome data

Process description:
We anticipate some item-level missingness as well as potentially attrition from the study. For any baseline missing values or item level missing values at endline we will use multiple imputation (100 datasets) to account for the missing data. We plan on imputing data in one model, but with endline and treatment assignment variables omitted from the runs predicting baseline variables to not allow treatment assignment to influence pre-treatment score estimates. Should this approach require adjustment based on experiences during data collection or in the field, we will update this registry accordingly.

Planned multiple comparisons adjustment, confirmatory question 1 (Other Outcome Domain):
Yes

Number of planned comparisons to adjust, confirmatory question 1 (Other Outcome Domain):

Correction for multiple comparisons, confirmatory question 1 (Other Outcome Domain):
Benjamini-Hochberg correction

Planned multiple comparisons adjustment, confirmatory question 3 :

Comments:
Adjustments for multiple comparisons will be conducted on sets of similar outcomes.

Section VIII: Additional Information

Links:
No links have been added yet.

Files:
No Files have been added yet.

Comments:
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