The Effect of Maternal Beliefs, Mental Health, and Economic Resources on Human Capital Accumulation in Early Life

SHORT STUDY TITLE: Maternal Resources and Children's Health

CONFIDENTIAL

STATEMENT OF COMPLIANCE FOR NON DRUG OR DEVICE CLINICAL TRIALS

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (as updated) and the Handbook for Good Clinical Research Practice (GCP). The Therapeutic Goods Act has adopted ICH Guideline for Good Clinical Practice.

Contents

1. GENERAL INFORMATION

Protocol for "The Effect of Maternal Beliefs, Mental Health, and Economic Resources on Human Capital Accumulation in Early Life," November 2022.

This study is being funded by J-PAL/EPoD SPI, Research Grant, Massachusetts Institute of Technology, USA.

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This trial will be registered at the American Association's registry for randomized controlled trials (https://www.socialscienceregistry.org) and at the Australian New Zealand Clinical Trials Registry (ANZCTR) (http://www.anzctr.org.au)

2. SYNOPSIS

Using a novel locally grown health service delivery model in rural Bangladesh that tracks the universe of newly married couples and connects them to local health services, we aim to study whether targeting mothers early in pregnancy with three complementary interventions -- individually or in combination -- can improve their own wellbeing as well as their children's developmental outcomes. The three interventions that we plan to pilot in a randomized controlled trial are: (1) information on the importance of early life conditions on future outcomes; (2) information and enrolment support to relevant government programs (including health services, cash- and food-transfers); and (3) psychological counselling. Our outcomes of interest include women's empowerment, parental inputs, physical and mental health, and children's health and development. Our partnership with the relevant government ministry in Bangladesh and an NGO offers a unique opportunity to implement evidence-based policy at scale.

TITLE	*The Effect of Maternal Beliefs, Mental Health, and Economic Resources on Human Capital Accumulation in Early Life*
OBJECTIVES	*1) Explore what are pregnant women's views about the idea of a "healthy pregnancy" and how these perceptions translate to health behaviours and investments in children.* *2) Investigate if providing targeted interventions (health services, cash- and food-transfers, and psychological*

	counselling) to women early in pregnancy offer cost-effective ways to enhance children's physical health, and maternal wellbeing and their physical and mental health.
PRIMARY HYPOTHESIS	Our study has four main hypotheses, each of which will be tested by a different intervention: *1)* According to government data, programs aimed for women with children are often undersubscribed, which may be largely explained by the fact that many poor women are not aware of the existence of these programs, their potential eligibility, or how to navigate the system to get enrolled. In fact, among the relatively few mothers that do get enrolled, they are often enrolled too late into (or even after) their pregnancy, missing critical windows for fetal development. Given this, we hypothesis that providing information on government programs and enrolment support will improve program take-up and women and children's outcomes. *2)* While knowledge on the signature importance of the "fetal origins" and early childhood periods (Barker, 1990, Almond and Currie 2011) is widespread among clinicians and social scientists, the full range of effects may be less known to disadvantaged groups such as women in remote areas in low- and middle-income countries. Thus, to the extent that expectant mothers' beliefs underestimate the returns of prenatal investments on children's future outcomes, or misperceive the malleability of fetal health, we hypothesise that interventions that target maternal beliefs starting in early in pregnancy will be effective at promoting children's future potentials. *3)* Research has shown that while psychological interventions conferred substantial benefit to mothers, they have not been effective in improving outcomes for children (Baranov et al. 2020, Angelucci and Bennett 2021). A likely cause is that interventions typically start too late (in the third trimester of pregnancy), and we hypothesis that a early start of psychological interventions will result in substantial benefits to mothers' and children's outcomes.

	4) In low-income settings agents are often faced with numerous challenges that may interact in ways that prevent information or psychological interventions alone from generating significant or sustained improvements, and even more so to other agents within the household. Indeed, recent work suggests that poverty and low psychological well-being mutually reinforce each other in a vicious cycle (Ridley et al. 2020). We hypothesis that relaxing multiple constraints, namely through information provision, economic transfers (cash, food, services), and psychological counselling will be complementary, reinforcing each other (Haushofer et al. 2020, Angelucci and Bennett 2021).
DESIGN	This is a 3x2 factorial RCT of 2,640 participants across two sub-districts in rural Bangladesh. The two information interventions will be cross-randomized with the one mental health intervention.
BLINDING/MASKING	Participants will be able to know if they have been assigned to the treatment group as they will receive either information, services, counselling, or all three.
OUTCOMES	We will measure women's empowerment, parental investment, mother's physical and mental health, and child's physical health and cognitive and socio-emotional development. We list the specific outcome variables below. Maternal outcomes: Women's empowerment (women's agency in fertility planning, personal expenditures and expenditures on children, children and household investment decisions, savings accounts, and participation in social programs and local leaderships); Women's beliefs (about importance of early life conditions, self-efficacy in parenting, beliefs about modifiability of child skills); Parental Investment (time, monetary, and warmth); Physical health (self-reported physical health, body-mass index, and mid-upper arm circumference (MUAC)); Mental health (PHQ-9 a screener for depression, GAD-7 a screener for anxiety); intimate partner violence (IPV); and Stress (Cohen Stress Scale, Biomarkers of stress using hair samples[1]).

[1] We plan to collect biomarkers of stress from mothers and their infants. Using hair samples, we can extract HPA axis hormones such as cortisol. Hair-derived biomarker measurement indicates HPA axis activity over the course of months (analytes in each centimeter of hair approximate hormone secretion over one month), and thus more

	Child outcomes: Health at birth (birth weight and low birth weight); Developmental outcomes (Bayley Scales of Infant and Toddler Development that captures children's cognitive, language, motor, adaptive); Health (weight-for-length, length-for-age, acute respiratory illnesses); Stress (Biomarkers of stress from hair samples).
STUDY DURATION	The estimated time (in months) from when the study opens to enrolment until completion of data analyses is 14 months.
INTERVENTION/S	We will provide three interventions through the Kapasia Model of Maternal and Child Health (henceforth, Kapasia Model): 1) Information about women's eligibility to health services and other safety net programs (cash transfers, food transfers) offered by the government, and assist them with the enrolment process. 2) Information to pregnant mothers and their families on the importance of the early-life environment, and especially the 9-month in utero period, in laying the foundations for a child's lifelong success. 3) Psychological counselling to pregnant women starting *early* in pregnancy.
NUMBER OF PARTICIPANTS	A total of 2,640 women from 120 villages (22 women per village) from two sub-districts of Gazipur district will take part in this study. The information interventions will be randomized at the village level, with 40 villages receiving information and enrolment support for government programs, 40 villages receiving additional information on the importance of early life conditions, and 40 control (no information) villages. The psychological counselling intervention will be randomized at the Union Health and Family Welfare Centre (UHFWC) level (there are 20 total UHFWCs across the 2 subdistricts), stratified by sub-district, and allocated at a 1:1 ratio.

accurately reflect chronic hormone secretion (see Baranov et al. 2022 for a discussion and an example of successful hair cortisol measurement with mother and child dyads in Pakistan). Hair sample collection was funded with this proposal, and further funding will be sought for laboratory extraction of analysis. Hair samples are easily storable and stable for 1-2 years.

POPULATION	Our population includes newly married women, pregnant women, and mothers with young children aged 6 months or younger located in two subdistricts of Gazipur district in Bangladesh. According to the Demography and Health Surveys of 2014, women in Bangladesh tend to marry early. By age 18, 50% are married and their first child arrives 1.5 years later, which means that many women become mothers as teens. Moreover, 98.6% get married and nearly all have at least one child. As a result, there is virtually no selection into fertility in this setting. Two thirds of women deliver their child at home, have between one and two antenatal visits. Half have primary education or less, and less than 35% work outside home (half of which are employed in agriculture). Husbands are on average 10 years older, have similar levels of education, and the vast majority work in agriculture or in the informal sector. Moreover, Bangladesh has one of the highest rates of malnutrition in the world. 20% of children born in the country every year are born either "small" or "very small" (Demography and Health Survey, DHS 2014), 41% of those below the age of 5 are stunted, and about five million children are out of school (World Bank, 2015).
SELECTION AND ENROLMENT	Eligibility criteria for inclusion: 1. Listed in the digital database of Kapasia Model 2. Permanent residence of any of the two subdistricts of Gazipur district in Bangladesh 3. Newly married women 4. Pregnant women 5. Mothers with young children aged 6 months or younger To be eligible, women must fulfill the first and the second criteria, any of the criteria from 3 to 5 must be fulfilled.

3. RATIONALE / BACKGROUND

In low- and middle-income countries (LMICs), over 250 million children under age five are not achieving their developmental potential due to adverse living environments (Black et al 2017). In Bangladesh, maternal and child deprivation is alarmingly high. The country has one of the highest rates of malnutrition in the world and about five million children are out of school (World Bank, 2015). Mothers in rural areas also face important economic and psychological challenges. During (and after) pregnancy, women experience a loss of status in the household

due to a reduced ability to supply labour. Further compounding stress from economic pressures, during this period women often experience an increase in Intimate Partner Violence (IPV) (Mojahed et al. (2021)). These factors combine to create an adverse intrauterine and early life environment that can have profound negative effects that propagate throughout the life course for the next generation (Almond and Currie 2011; Almond et al. 2018; Heckman 2016). While research has shown that well-designed interventions targeted at key developmental stages can help break the intergenerational cycle of disadvantage (Aizer and Currie 2014), most of this evidence comes from high- and middle-income settings. Yet there is an urgent need to understand whether and how welfare enhancing early-life interventions can be implemented at-scale and in cost effective ways in low-income countries.

We aim to investigate whether providing targeted interventions to women *early in pregnancy* offers cost-effective ways to enhance maternal wellbeing and children's physical and mental development in rural Bangladesh. To do so, we will leverage a locally grown health service delivery model known as the *Kapasia Model*, that identifies hard-to-reach disadvantaged women as soon as they get married and tracks them on a digital database with the purpose of connecting them to health services and other safety net programs. The *Kapasia Model*, located in the sub-district of Kapasia, has been highlighted as a best practice on maternal and child care by the United Nations Population Fund and the Bangladesh Ministry of Health and Family Welfare has recently decided to scale it up.

Our project will be a collaborative effort with two ministries of Bangladesh, the Ministry of Health and Family Welfare (MHFW) and the Ministry of Women and Children Affairs (MWCA). The MHFW has already agreed to support our research, and we are in contact with the MWCA to collaborate on two of their *key* programs: the Maternity Allowance Program (targeting women in rural areas) and the Lactating Mother Program (targeting women in urban areas). Both programs provide unconditional cash transfers to pregnant and lactating women of Taka 800 (about $25 in PPP) per month per woman for a duration of three years. These two welfare programs constitute the largest transfers of its kind for the MWCA. However, based on our discussions with key personnel within these Ministries these initiatives are often undersubscribed, which may be largely explained by the fact that many poor women are not aware of the existence of these programs, their potential eligibility, or how to navigate the system to get enrolled. In fact, among the relatively few mothers that do get enrolled, they are often enrolled too late into (or even after) their pregnancy, missing critical windows for fetal development.

We will introduce three interventions through the *Kapasia Model*. The first intervention would deliver information about women's eligibility to health services and other safety net programs and assist them with the enrolment process. The second would deliver information to pregnant mothers and their families on the importance of the early-life environment, and especially the 9-month in utero period, in laying the foundations for a child's lifelong success. While knowledge on the signature importance of the "fetal origins" and early childhood periods (Barker, 1990, Almond and Currie 2011) is widespread among clinicians and social scientists, the full range of effects may be less known to disadvantaged groups such as women in remote areas in LMICs. The third would introduce psychological counselling to pregnant women

starting *early* in pregnancy. Research has shown that while psychological interventions conferred substantial benefit to mothers, they have not been effective in improving outcomes for children (Baranov et al. 2020, Angelucci and Bennett 2021). A leading explanation is that interventions typically start too late (in the third trimester of pregnancy). The psychological counselling will be provided by our local collaborator, *Moner Bondhu* ("Friend of your mind", https://www.monerbondhu.org/) – a local organization that provides care for mental health and well-being services. The organization has been very successful in reaching out to a large populace and has received numerous accolades from national and international organizations. We will investigate the role of maternal beliefs about the idea of a "healthy pregnancy" and its relationship with their children's future health and economic outcomes. We will survey a sample of pregnant mothers to learn about their perceptions regarding the returns of different health-related behaviours in utero on their child's outcomes in adulthood. To the extent that expectant mothers' beliefs underestimate the returns of prenatal investments on children's future outcomes, or misperceive the malleability of fetal health, the results of this paper could suggest that interventions that target maternal beliefs starting in early in pregnancy may be effective at promoting children's potential.

This proposal contributes to the growing literature on the "psychological poverty trap." We ask the question: is providing women with information more likely to lead to action when psychological constraints (like depression) and income constraints are relaxed? Research has shown that interventions aimed at reducing depression, like psychotherapy (Baranov et al. 2020, Vlassopoulos et al. 2021), can improve both mental health and economic decision-making. However, in low-income settings agents are often faced with numerous challenges that may interact in ways that prevent information or psychological interventions alone from generating significant or sustained improvements, and even more so to other agents within the household. Indeed, recent work suggests that poverty and low psychological well-being mutually reinforce each other in a vicious cycle (Ridley et al. 2020). Relaxing multiple constraints *simultaneously* may be necessary to break that cycle. Our study will test whether information provision, economic (cash, food, services) transfers, and psychological interventions are complements, contributing to an emerging literature testing how psychological support interacts with other, more traditional anti-poverty interventions (Haushofer et al. 2020, Angelucci and Bennett 2021).

4. AIMS / OBJECTIVES / HYPOTHESES

Our goal is to address three types of adversities that hinder women's empowerment and early child development in low- and middle-income countries: low take-up of healthcare and other social safety net programs (including cash- and food-transfers), lack of knowledge about the importance of the early years on future child development and long-run outcomes, and psychological constraints associated with maternal depression. We aim to test to what extent these three interventions offer practical opportunities to improve maternal health, birth, and child development outcomes in cost-effective ways. We believe that these interventions might be even more effective than previous similar interventions because we will be targeting women

early in pregnancy (and in some cases even prior to conception), which is considerably earlier than most previous studies aimed at improving maternal and child outcomes.

Our specific **objectives** are:

1) Explore what are pregnant women's views about the idea of a "healthy pregnancy" and how these perceptions translate to actual health behaviours and investments in children.
2) Investigate if providing the three following targeted interventions to women early in pregnancy offers cost-effective ways to enhance maternal wellbeing and children's physical and mental development:
    a. Information about women's eligibility to health services and other safety net programs and assist them with the enrolment process.
    b. Information to pregnant mothers and their families on the importance of the early-life environment, and especially the 9-month in utero period, in laying the foundations for a child's lifelong success.
    c. Psychological counselling to pregnant women starting early in pregnancy.

Our study has four main **hypotheses**, each of which will be tested by a different intervention:

1) According to government data, programs aimed for women with children are often undersubscribed, which may be largely explained by the fact that many poor women are not aware of the existence of these programs, their potential eligibility, or how to navigate the system to get enrolled. In fact, among the relatively few mothers that do get enrolled, they are often enrolled too late into (or even after) their pregnancy, missing critical windows for fetal development. Given this, we hypothesis that providing information on government programs and enrolment support will improve program take-up and women and children's outcomes.
2) While knowledge on the signature importance of the "fetal origins" and early childhood periods (Barker, 1990, Almond and Currie 2011) is widespread among clinicians and social scientists, the full range of effects may be less known to disadvantaged groups such as women in remote areas in low- and middle-income countries. Thus, to the extent that expectant mothers' beliefs underestimate the returns of prenatal investments on children's future outcomes, or misperceive the malleability of fetal health, we hypothesise that interventions that target maternal beliefs starting in early in pregnancy will be effective at promoting children's future potentials.
3) Research has shown that while psychological interventions conferred substantial benefit to mothers, they have not been effective in improving outcomes for children (Baranov et al. 2020, Angelucci and Bennett 2021). A likely cause is that interventions typically start too late (in the third trimester of pregnancy), and we hypothesis that a early start of psychological interventions will result in substantial benefits to mothers' and children's outcomes.
4) In low-income settings agents are often faced with numerous challenges that may interact in ways that prevent information or psychological interventions alone from generating significant or sustained improvements, and even more so to other agents within the household. Indeed, recent work suggests that poverty and low psychological

well-being mutually reinforce each other in a vicious cycle (Ridley et al. 2020). We hypothesis that relaxing multiple constraints, namely through information provision, economic transfers (cash, food, services), and psychological counselling will be complementary, reinforcing each other (Haushofer et al. 2020, Angelucci and Bennett 2021)

5. PARTICIPATING SITES

Our main participating sites are two sub-districts of Gazipur district of Bangladesh. One of the sub-districts will be Kapasia, while the other is yet to be selected. In each sub-district there are about 10 Union Health and Family Welfare Centre (UHFWC). We will randomly select 120 villages within two subdistricts, stratified by UHFWC, to participate.

6. RESEARCH PLAN / STUDY DESIGN

Our study is comprised of three treatments. In treatment 1, project officers employed by the research team, who will be located in study area, will provide information over the phone to each treated household on their eligibility (yes or no) of government's cash and food transfer programs, as well as where and how to enrol, and assistance with enrolment for eligible mothers.

Treatment 2 involves providing information to pregnant mothers and their families on the importance of the early-life environment, and especially the 9-month in utero period, in laying the foundations for a child's lifelong success. Eligible and willing participants who would be randomly assigned to receive this treatment will be contacted by our project officers, and the officer will provide the following information over the phone:

> "A healthy pregnancy, wherein mothers take care of themselves and their children during their pregnancy, is extremely important for their children health and economic outcomes. Starting from as early as the 9th week of pregnancy, mothers who eat nutritious food and think positively give birth to healthier children who grow up to be healthier adults. A healthy diet during pregnancy such as this one, (this is based on study conducted in a similar setting, see: https://bmjopen.bmj.com/content/bmjopen/7/8/e015393.full.pdf)

Table 2 Five-meal menu for pregnant women (English)

Meal	Food	Quantity (one dish=250 mL)
Breakfast	Rice	1.5 dishes
	or	
	Chapati (medium size)	3 pieces
	Vegetables	1 dish
	Egg	1
	or	
	Lentil (thick)	1 dish
Mid-morning snack	Seasonal fruit(s)	1 piece/dish
	Milk product(s)	1 dish
Lunch	Rice	3 dishes
	Lentil (thick)	1 dish
	Leafy/non-leafy vegetables	1.5 dishes
	Meat/fish/egg	1 piece
Afternoon snack	Milk	1 glass
	Seasonal fruit(s)	1 piece/dish
	Puffed rice with molasses or Biscuits	1 dish 1 dish
Dinner	Rice	2 dishes
	Lentil (thick)	1 dish
	Leafy/non-leafy vegetables	1.5 dishes
	Meat/fish/egg	1 piece
	Milk or	1 glass
	Curd	0.5 dish

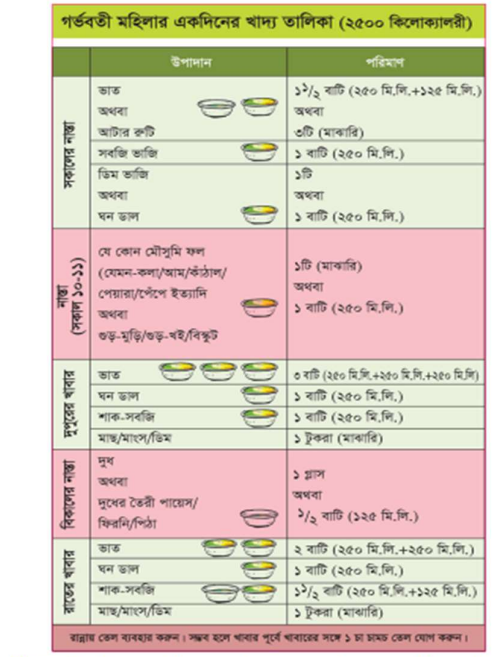

Figure 3 Five-meal menu for pregnant woman (*Bengali*).

can protect a child against low birth weight and stunting (short height) in infancy, and psychological problems, and diabetes or hypertension in adulthood. In contrast, children of mothers who suffer from long periods of stress during pregnancy can develop future health problems when they become adults themselves. Therefore, taking nutritious food regularly, managing stress, and thinking positively from the earliest stages of pregnancy are important for the child in the near- as well as in the long-term. It's never too early to incorporate these positive changes to your routine."

The third intervention involves offering psychological counselling based on Cognitive Behavioural Therapy, which will be provided by trained counsellors from Moner Bondhu (https://www.monerbondhu.org/). The content will follow the WHO-adopted and evidence-based programme called Thinking Healthy, specifically focusing on only the early (pre-delivery) sessions. Thinking Healthy has already been translated and adapted to Bengali (with the full manual for the management of perinatal depression available for free from the WHO website here: https://apps.who.int/iris/bitstream/handle/10665/152936/WHO-MSD-MER-15.1-ben.pdf?ua=1&ua=1. Eligible and willing participants who would be randomly assigned to receive this treatment will be contacted by an officer from Moner Bondhu. Participants will be invited to take part in 4 group counselling sessions, each lasting approximately 1-1.5 hours. The group will consist of other pregnant women from the same village enrolled in this study. We anticipate the groups will be approximately 22 women or less. Counsellors from Moner Bondhu will identify an appropriate venue with comfortable furnishing and privacy to hold the sessions. The sessions will use narratives, or stories, to engage women and then open the floor to discussion on the issues of (1) mother's physical health, (2) coping with stress, (3) and mother's relationship with the people around her. They will be modelled after the THPP

intervention (specifically see Chapter 2 in the THPP Manual). However, we will adapt the sessions to include a focus on identifying and coping with stressors.

To evaluate the impact of these three interventions, we will conduct a 3x2 factorial RCT across two sub-districts in rural Bangladesh. The two information treatments will be cross randomized with the one mental health intervention. The mental health intervention will be randomized at the Union Health and Family Welfare Centre (UHFWC) level (there are 20 total UHFWCs across the 2 Upazilas), stratified by sub-district, and allocated at a 1:1 ratio. We will then randomly select 120 villages within subdistricts, stratified by UHFWC, to participate. The information interventions will be randomized at the village level, stratified by UHFWC, with 40 villages receiving information and enrolment support for government programs, 40 villages receiving additional information on the importance of early life conditions, and 40 control (no information) villages. Eligible participants will be pregnant women and mothers with young children aged 6 months or younger. We will aim to recruit 22 women per village to be part of the study sample.

We will use two types of data, (i) the data from the digital information system of Kapasia Model built at the sub-district level by the local government, which we call *administrative data*, and (ii) household and individual survey data including elicitation of maternal beliefs of prospective and existing mothers that we will collect as a part of the study, which we call *household survey data*. This survey will be conducted on the sample of 22 women per village for a **total sample of 2,640 women**. The administrative data include information (e.g., age, education, occupation, mobile phone number, pregnancy status, birth outcomes, number of children) on *all* registered newly married couples in our study area, including the 22 women per village in our study sample, and will identify key outcomes such as pregnancy status and birth outcomes. We will conduct a baseline survey with an endline 10 months later, and we plan to conduct a midline survey by phone (which will likely be funded using internal funds[2] from the University of Sydney and University of Melbourne) to measure parental inputs in the in utero period. The schedule of enrolment, intervention and evaluations is given in Figure 1.

[2] They have not been mentioned in the budget as no firm commitment has been received yet.

The study schedule	Study period													
	Baseline							Midline				Endline		
	1st month	2nd month	3rd month	4th month	5th month	6th month	7th month	8th month	9th month	10th month	11th month	12th month	13th month	14th month
Enrolment														
Eligibility Screening	X													
Consent collections		X												
Randomization & allocation to treatments and control group			X											
Interventions/ Treatments														
1. Information and enrolment support to govt. programs				X	X	X	X	X	X	X	X			
2. 1 + Information on the importance of early life conditions				X	X	X	X	X	X	X	X			
3. Psychological counselling				X	X	X	X	X	X	X	X			
Evaluations														
Compliance Check - if individuals and groups assigned to treatments and controls are in fact complying to the assignment					X	X	X	X	X	X	X			
Household characteristics and other basic information, houses, lands, and asset ownership, economic activities and employment, beliefs, women mental health, preferences		X										X		
Parents time and monetary investment on children								X						
Anthropometry & health, children's mental health and development, take up of health care services, participation in social transfers/safety net programs, parenting style, parents time and monetary investment on children, food intake/share, food insecurity & non-food expenditures, women empowerment, intimate partner violence												X		
Data Analysis													X	X
Report Writing/ Publication													X	X

Figure – 1: Schedule of enrolment, intervention, and evaluations

Power Calculation: Given the sample sizes above and accounting for the varied clustered design, we would be powered to detect a Minimum Detectable Effect (MDE) size of 0.31 of a standard deviation (SD) change for the mental health intervention (randomized at the Health Centre (UHFWC) level with the conservative estimate of 20 centers). For the information arms, we would be powered to detect a 0.19SD change for either of the information interventions (main effects only). As benchmark for the MDEs on mental health interventions, Rahman et al. (2008) found that a mental health intervention similar to the one proposed here improved mothers' mental health by 0.70SD, while Sikander et al. (2019) found that a more scalable, peer-delivered version of the intervention increased mothers' mental health by 0.30SD. A tele-counseling intervention in Bangladesh improved mental health by 0.65SD (Vlassopolous et al. (2021)).

7. ETHICAL CONSIDERATIONS

Ethical approval for this study will be obtained from the Human Research Ethics Committee (HREC) of the University of Sydney. Consents of local governments will be sought in study sub-districts through the sub-district administrations. Upon agreement with the local administration, the study will progress; the local administration will advertise about this study

to its members of the Kapasia model through its own network before the research team make any contact to the potential study participants.

The participant information statement (PIS) will be translated to local language, namely Bengali, and a study team member or his/her representative will give the PIS to each eligible and selected study participant. The consent form will be read out to all potential participants who face difficulties in reading and writing, and a copy will be given to them so that the participants or his/her family members read and discuss it within the household before consenting to it. It will be ensured that the form is read out and given to potential participants at least a day prior to any survey visit.

We will obtain written informed consent from each study participant, which will be in Bengali. The PIS that we have prepared provides full disclosure regarding the study. The participants will be informed what does participation in this study involved and what they will need to do if they decide to participate. They will be informed that the participation in this study is entirely voluntary, and their decision to participate will not affect any government services that they currently receive. They will also be informed if participation involves any risk. The participants will be informed that they could drop out at any time without any penalty or loss of any benefits they currently receive under the Kapasia Model.

We will strictly maintain the privacy, anonymity and confidentiality of the information that we will access through Kapasia Model's digital data base, and any information that we will collect from the study participants. All information will be stored in encrypted database with all identifiers removed. Only associated investigators and data management team will have access to collected data. Findings will be published in peer-reviewed journals towards the end of the study.

8. SAFETY CONSIDERATIONS

Aside from giving up participants' time, we do not expect that there will be any considerable risks or disadvantages associated with taking part in this study. Nonetheless, the research team and field management staff will meet weekly via Zoom to manage trial coordination and oversee participant safety, study design, database integrity, and study conduct.

9. OUTCOMES

Our primary outcomes include measures of women's empowerment, parental investment, mother's physical and mental health, and intimate partner violence. Our secondary outcomes focus on the child and include measures of physical health and cognitive and socio-emotional development. We list the specific primary and secondary outcome variables below.

Primary outcomes: Women's empowerment (women's agency in fertility planning, personal expenditures and expenditures on children, children and household investment decisions, savings accounts, and participation in social programs and local leaderships); Women's beliefs (about importance of early life conditions, self-efficacy in parenting, beliefs about modifiability of child skills); Parental Investment (time, monetary, and warmth); Physical health (self-

reported physical health, body-mass index, and mid-upper arm circumference (MUAC)); Mental health (PHQ-9 a screener for depression, GAD-7 a screener for anxiety); IPV; and Stress (Cohen Stress Scale, Biomarkers of stress using hair samples[3]).

Secondary outcomes: Child's health at birth (birth weight and low birth weight); Developmental outcomes (Bayley Scales of Infant and Toddler Development that captures children's cognitive, language, motor, adaptive); Health (weight-for-length, length-for-age, acute respiratory illnesses); Stress (Biomarkers of stress from hair samples).

10. DATA MANAGEMENT

Data Capturing Method: In the baseline household survey (henceforth baseline), all interviews with participants will be conducted in-person face-to-face in the field. A local experienced and reliable survey firm will be recruited. Each participant will be compensated 150 Taka (about $2 AUD) for their time if they participate in the baseline survey. The corresponding amounts for the midline telephone survey, and the endline face-to-face survey are 50 Taka and 150 Taka, respectively. Similarly, participants invited to take part in group meeting will be given 50 Taka per participant per meeting to cover their transportation cost. This compensation scheme is based on inputs received from local survey firms and study collaborators.

All primary surveys (baseline, midline, & endline) will be administered digitally using Qualtrics (or SurveyCTO conditional on its meets USyd privacy and security requirements) on Android Tablets. Once an enumerator marks a filled-out questionnaire as "finalized," the contents will be encrypted using an encryption key. From this point forward, the questionnaire can no longer be edited (not even the device that was used to complete the questionnaire will be able to decrypt it). Data will then be transmitted to the Qualtrics (SurveyCTO) server using 4G or another locally available Internet network, and the data will be encrypted in transit using SSL. From there, it will be downloaded by the research team the University of Sydney server (OneDrive (Enterprise) that the University of Sydney currently supports). When the data will be downloaded by the research team members, it will again be doubly encrypted by the key and SSL. A copy of the data will also be retained temporarily on the tablet until it is confirmed that the data is securely transmitted to the server, upon which the data retained in the tablets will be permanently deleted.

Data Quality Monitoring: A team led by one of the CIs will develop a data monitoring protocol, and the collected data will be regularly monitored to ensure its quality. This will be

[3] We plan to collect biomarkers of stress from mothers and their infants. Using hair samples, we can extract HPA axis hormones such as cortisol. Hair-derived biomarker measurement indicates HPA axis activity over the course of months (analytes in each centimeter of hair approximate hormone secretion over one month), and thus more accurately reflect chronic hormone secretion (see Baranov et al. 2022 for a discussion and an example of successful hair cortisol measurement with mother and child dyads in Pakistan). Hair sample collection will be funded with this proposal but further funding will be sought for laboratory extraction of analytes. Hair samples are easily storable and stable for 1-2 years.

done in two steps – firstly, a small team independent of the survey firm will reinterview about 5% of the respondents selected randomly. This data will be matched with data collected by enumerators employed by the survey firm. Secondly, all field data will be matched with administrative data on key variables. Based on the above, a daily report will be generated specific to enumerator, which will be followed up by the field supervisors/ research assistants that we will employ.

Data Safety and Access to Data: All electronic data will be anonymized, encrypted, and stored at a secured server owned by the University of Sydney. The access to the server will be password protected and will be limited to the research investigators only. Similarly, all scanned copies of the consents will be similarly stored in a secured server, where access will be password protected, and only authenticated users will be allowed to access them. All hard copies of the consent forms stored in the local collaborator's office in Dhaka will be destroyed once the project is completed and it is no longer required to keep the hard copies.

All individual identifiers will be removed and will be replaced with codes, which would be used in case the research team plans to re-identify the participants. Such re-identification will be arranged with the Kapasia Model of Maternal and Child Health authority and will give the option to conduct long-term follow studies that track the effects of early intervention on human capital accumulations in adulthood. Such a study would be of significant interest to many policy makers and researchers alike.

Regarding the consents, which will be collected in papers, all the hard copies will be securely stored in the local collaborator's office in Dhaka. They will be scanned and electronically stored to the same server following the same procedure mentioned above.

The hard copies of the consent forms will be disposed once all of them are scanned, stored electronically, and the research has been completed. The electronic records of all materials will be deleted once the storage period requested in this application is over. Professional help from the IT manager at the School of Economics will be taken to ensure that the deleted records are not recoverable in any form.

Access to data will be restricted to the study investigators only and such access will be given through the University of Sydney server which will require password and user authentication. The secured access protocol will be further developed and monitored with the help of the IT at the School of Economics, University of Sydney.

11. TIMELINES / MILESTONES

An approximate study timeline is provided in Figure 2. We plan to complete the study within 14 months from start. In the first month, the eligibility criteria of participants which will be selected from the Kapasia Model digital database, will be re-checked, and informed consents of the eligible participants will be sought. This will be followed by commencement of the baseline survey in the second month of the study, and the random allocation of participants to different treatments will be achieved in the third month. The list of participants that will receive psychological counselling will be given to the relevant implementing partner Moner Bondu,

and the rest of interventions will be carried out by the research team. In the fifth month, compliance to treatments and control status will be checked followed by a midline telephone survey in the eighth month. We will conduct the endline survey after 10 months of the intervention followed by data analysis and report writing / manuscript preparation.

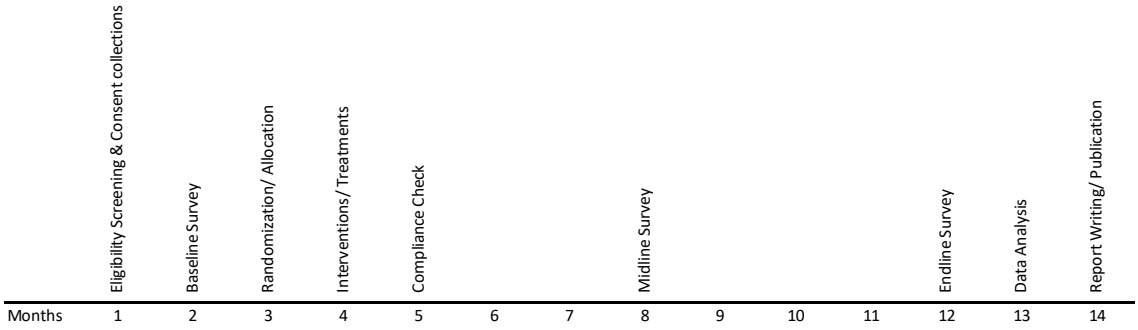

Figure 2: Study Timeline

12. FUNDING

The study is being funded by J-PAL/EPoD SPI, Massachusetts Institute of Technology, USA. The amount of this grant is: $74,707.60 USD. J-PAL has no role in study design and management, delivery of the interventions, data collection and interpretation of study findings, report writing or manuscript publication.

13. PUBLICATION POLICY / DISSEMINATION OF RESULTS

Our primary aim is to disseminate our results widely throughout Bangladesh. In particular, in collaboration with the Bangladesh Ministry of Health and Family Welfare, we will disseminate our results through seminars and workshops to the other relevant ministries such as the Ministry of Women and Children Affairs, the Ministry of Food, other public-sector stakeholders, foreign aid agencies such as the United Nations Population Fund, UNICEF, and nongovernment organizations interested in the women and children's well-being. In addition to the seminars and workshops, our results will be communicated to a larger audience both locally and abroad through emails and policy briefs. Furthermore, we will publish the analysis of the outcomes in the form of internal documents, working papers, and in international peer-reviewed journals.

14. COMPETING INTEREST

The authors declare that they do not have any competing interest.

15. ACKNOWLEDGEMENT

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