

ASHA: Integrated Depression Treatment and Economic Strengthening

The ASHA Project:

Protocol of an integrated depression treatment and economic strengthening intervention for low-income women in rural Bangladesh

Alison Karasz, PhD<sup>1</sup>

Kazi Istiaque Sanin, MPH, MBBS<sup>2</sup>

Md. Khaledul Hasan, MSS<sup>2</sup>

Arundhati Debnath, MS<sup>1</sup>

Bharati Rani Roy, MSc<sup>2</sup>

Abul Kasham Shoab, MSS<sup>2</sup>

Shareen Joshi, PhD<sup>3</sup>

Ryung S. Kim<sup>4</sup>

Fahmida Tofail, PhD<sup>2</sup>

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<sup>1</sup> University of Massachusetts Chan School of medicine

<sup>2</sup> icddr,b; 68 Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka 1212, Bangladesh

<sup>3</sup> Georgetown University

<sup>4</sup> Albert Einstein College of Medicine

## **Abstract**

**Introduction:** Depression is highly prevalent in LMICs. Despite the high prevalence of depression in LMICs, few individuals suffering from depression receive effective treatment. Poverty plays a major causal role in depression, while constraining treatment access, treatment uptake, and treatment response. Researchers have recently pointed to the potential value of poverty alleviation in addressing the public health crisis of depression. This research will examine the short- and long-term impact of ASHA, a novel, integrated depression treatment and economic strengthening intervention for low-income women with depression in rural Bangladesh.

**Methods and analysis:** 660 low-income women at risk of depression will be recruited into a cluster randomized controlled trial (CRCT) in the Birganj upazila of Dinajpur district of Bangladesh. Research interviews will be conducted at baseline, 6-, 12-, 18- and 24 months. The experimental arm will receive an integrated intervention combining psychotherapy (Group Problem Management Plus (PM+)) and a poverty alleviation intervention. Controls will receive psychotherapy alone. We hypothesize improved short- and long-term mental health impacts in the experimental group compared to controls. We will examine the potential mediating roles of reduced economic vulnerability on depression, as well as the impact of improved mental health on economic vulnerability. We will conduct a mixed methods implementation analysis to assess program implementation and will assess the mediating role of program fidelity.

**Ethics and dissemination:** Informed consent will be obtained from all participants. The privacy, anonymity, and confidentiality of data/information identifying the study participants will be strictly maintained. Findings will be disseminated via required reports and scientific presentations/publications. The study protocol was approved by the Institutional Review Board (IRB) of icddr,b (PR# 21105, version No. 4; version date 26 October 2021).

**Trial registration number:** [Clinicaltrials.gov NCT06295250](https://clinicaltrials.gov/ct2/show/study/NCT06295250)

**Strengths:**

- An integrated intervention model combining poverty alleviation and depression treatment addresses weaknesses in current approaches to treating depression among the very poor.
- If the ASHA model is effective, results could impact health policy, pointing the way to productive collaborations and partnerships among international development groups, government agencies, and ministries of health.
- A robust mixed methods evaluation design allows us to draw inferences regarding the short- and long-term impacts of specific intervention components.

**Weaknesses:**

- The asset transfers and cash supplements provided in this intervention are large - leading to higher program costs than typical DT 'packages of care. 'This has implications for sustainability. However, comparable large scale asset transfer programs are becoming increasingly common in LMIC settings and have been implemented with millions of households in recent years.

## Introduction

Poverty is a major driver of the global burden of depression. Both poverty's material sequelae—hunger, deprivation, and disease—and its social sequelae—exclusion, marginalization, and stigma—are closely associated with depressive symptoms. On the other hand, depression also impacts economic well-being, compromising productivity, future orientation, and decision-making [1-5]. Among women in South Asian societies, as in many others, gender inequality contributes to both depression and poverty—via increased violence, reduced social participation, and limited access to education, health care and employment [6-11]. Consequently, in these societies, gender, poverty and depression are locked together in an intractable syndemic [12-14].

This research will examine the short- and long-term impact of ASHA, a novel, integrated depression treatment (DT) and economic strengthening (ES) intervention for low income women in rural Bangladesh. If successful, the integrated model proposed in this application has potential to impact current policy in health and poverty alleviation in LMIC.

Though depression is highly prevalent in LMICs, rates of treatment are very low. Over the past few decades, researchers and policy makers have advocated 'task shifting' approaches to address the treatment gap—the heavy burden of untreated illness [15-17]. Task shifting approaches use lower-cost health workers to deliver DT in low-resource settings via manualized 'packages of care' [18-26]. Two meta-analyses found that task sharing depression treatment interventions in LMIC provided benefit, at least in the short term, compared to controls [27, 28]. Consequently, the WHO has widely promoted these manualized treatments as evidence-based and has recommended their use in a variety of low-income settings.

Yet key barriers limit the potential effectiveness of task-shifting approaches in LMIC. The first is **weak treatment effects**. Research demonstrates that poverty, a powerful structural constraint on individual agency, sharply reduces the impact of DT. Research in the West shows that income predicts depression treatment impact: lower income is associated with weaker treatment effects [29-38]. Poverty likely plays a role in weak treatment effects in LMIC. Several recent large, well-designed studies implementing packages of mental health care in South Asia and elsewhere report disappointing outcomes [34, 39-42]. A study of therapeutic process in a large-scale task sharing intervention in South Africa found that poverty and deprivation played a key role in poor treatment outcomes [43].

The second barrier is **low treatment engagement**. A key assumption underlying current research and policy in global mental health is that *low access* is the major barrier to effective treatment of depression in LMIC. Yet, even when access to treatment is improved, uptake and engagement

often remain low. The PRIME/Sehore study [39], for example, sought to address the gap between high rates of untreated mental illness and low access to care by offering packages of mental health care via the local health systems. Yet treatment uptake was unaffected, with only 10% of persons with depression seeking care. Furthermore, of those who received treatment-- a low-burden intervention of four sessions--only 14% attended all four sessions. Increasingly, critics have questioned the notion that access is the most significant barrier to treatment uptake [43-45].

Finally, depression treatment benefits are **transient**. Though few depression trials include long term outcomes, studies show that approximately 50% of remitted patients in DT trials relapse within 18-24 months [46] [47-50]. Across the board, intervention-control differences decline rapidly starting at six months' post baseline [51, 52]. A specific weakness in many task-shifting study designs is the very short follow-up period. In evaluations of depression treatment in LMIC study design—specifically, the length of the follow-up period—influences outcomes, with short-term assessments tending to show greater benefits, e.g. [28, 51, 53].

Increasingly, critics have called into question policies advocating the broad implementation of low-cost 'packages of care' for depression [43, 54-56]. While potentially beneficial, the task shifting approach is arguably *insufficient* to address the depression-poverty syndemic in LMIC. A potentially productive approach is to supplement depression treatment (DT) with economic strengthening (ES) strategies [34, 43, 54, 57]. Yet little research has implemented interventions integrating ES and DT. Research on asset transfer based economic empowerment programs indicates a consistent—though modest-- impact on mental health [4, 58-64], though not all cash transfer programs are effective in this regard [65]. One study that compared an integrated ES/DT program to both DT and ES alone found no benefit to the DT program [62]; however, the study did not target persons with mental health problems. Given the reciprocal impacts of poverty and depression in the global syndemic, interventions that target depression and poverty simultaneously are a promising new direction.

### **Treatment mechanisms and process variables**

Understanding the 'active ingredients' in an intervention allows for the development of effective-- and cost effective—intervention models and is key to the development of a systematic science of interventions. Yet in the case of mental health treatment, to date, little is known of the mechanisms of change active in common treatments [66]. Notably, similar deficits have been observed in ES intervention research. Though ES researchers have proposed several hypotheses regarding the 'active ingredients' of ES interventions, including: 1) capital [61, 67]; 2) social

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empowerment [61, 67, 68]; 3) social support; and 4) psychological well-being [69, 70]. Yet few ES studies have closely examined these mediating variables [71-73].

Another important influence on program outcomes are implementation variables. Implementation variables: 1) reflect the quality or intensity of program implementation (e.g. treatment dose, fidelity, reach, adherence, and satisfaction); and 2) help to explain contextual variables facilitating or impeding treatment impact [74-76]. Research on implementation processes and outcomes has lagged in mental health treatment research, with the result that relatively little is known of factors which may differentiate between successful and unsuccessful programs. A recent review found that treatment fidelity variables were reported in only 10% of psychotherapy outcome studies [77]. This research gap is associated with the problem of replication, with promising models failing to replicate in large scale studies—a problem seen recently in large LMIC studies, e.g.[40, 41].

### **The ASHA Project**

Designed to interrupt the toxic poverty-depression cycle, the **ASHA** intervention integrates evidence-based DT with ES. A randomized controlled trial (RCT) will test the hypothesis that an integrated intervention (ES + DT) increases the impact of depression treatment, as well as treatment uptake and engagement, compared to depression treatment alone. Pilot research found strong treatment impacts ( $\downarrow$ Patient Health Questionnaire -9 (PHQ-9) =9.5,  $p<.001$ ), as well as high engagement, with participants attending a median of 12/12 treatment sessions [57].

Embedded within the RCT is an implementation study which will assess standard implementation outcomes including treatment uptake, retention, attendance, fidelity, and acceptability. This will be accompanied by a qualitative process evaluation which will examine participants' experiences and perspectives of treatment participation across the two study arms.

Study partners include the University of Massachusetts Chan Medical School, the International Centre for Diarrheal Disease Research, Bangladesh (icddr,b), and Rangpur-Dinajpur Rehabilitation Service (RDRS), a large NGO with fifty years of history of providing economic empowerment and agricultural support and programs in the region.

The project includes two sub studies. **Study 1** is a 2-arm cluster RCT of the ASHA intervention, which will compare the impact of an integrated Economic Strengthening (ES)/Depression Treatment (DT) intervention to that of DT alone; **Study 2** is a mixed methods implementation study examining implementation outcomes and stakeholder perceptions/experiences. We will implement a **capacity building project** designed to enhance research skills in qualitative implementation research among icddr,b scientists and doctoral students. Fellows will receive

didactic and field training in implementation science, depression treatment trials, and qualitative research skills.

## Conceptual Model

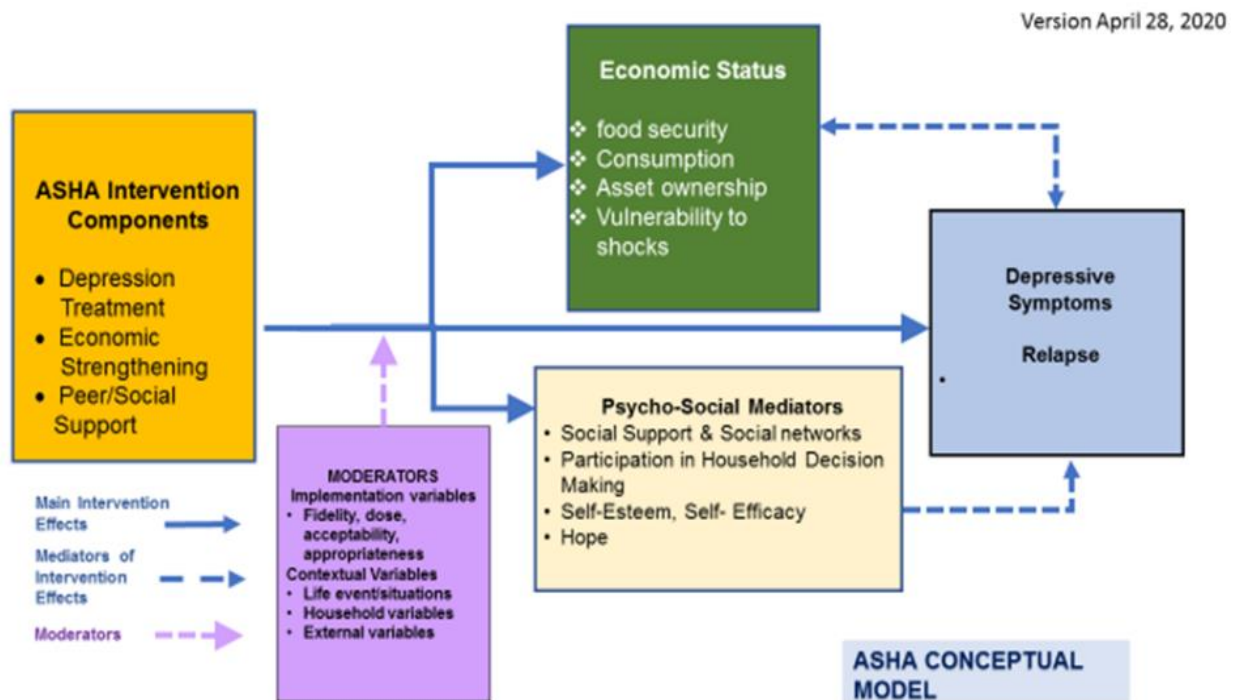


Figure 1

The main outcome of the intervention is depressive symptoms at 6- and 24-months post treatment. Additional outcomes include economic vulnerability, 24-month relapse, disability, quality of life, and cultural/somatic idioms of distress developed specifically for Bangladeshi women [78]. We hypothesize that economic vulnerability mediates the impact of treatment on depression symptoms; and that depressive symptoms mediate impact of the ES intervention on economic vulnerability. Additional mediators include: 1) social variables: social support, social networks, and household decision making; 2) psychological mediators: self-esteem, and future orientation. In addition to commonly measured moderators such as demographics, we hypothesize two key sets of moderators: program/implementation, and contextual variables, some of which also function as mediators (not shown). These will be evaluated via a mixed methods process analysis.

### Setting:

The study will be conducted in the Birganj upazila of Dinajpur district. The district is one of the poorest in the country, with limited economic opportunities, inadequate access to healthcare and education, and a lack of basic infrastructure. Four unions (administrative subdivisions) from

Birganj upazila in Dinajpur district were selected as study sites. Within these four unions, we identified sixty-six villages or village clusters. Forty-four villages were selected from a pool of sixty-six villages for recruitment and program implementation.

### **Randomization**

We will randomize 44 villages 1:1 to two arms DT, ES+DT; 22 villages per arm). From each village (or village cluster), fifteen participants will be enrolled for a total of 660 participants. Four groups (60 participants) will serve as pilot intervention groups.

### **Blinding**

In economic empowerment programs, the control group may be vulnerable to increased distress when learning that they have not received a beneficial treatment [79]. To avoid this potential confounder and ethical challenge, we have taken efforts to blind project stakeholders to study hypotheses and trial design. Complete blinding in behavioural trials is never possible. However, we took several steps to increase the likelihood of blinding. First, we hired separate project teams for the two treatment arms. Neither treatment providers nor data collection staff are aware of study hypotheses and trial design. Second, we gave two separate names to the treatment programs in each arm of the trial. Third, we used a computer algorithm to establish a minimal geographic distance of at least .5 kilometres between each study site. Although this distance may seem small, evidence suggests that for most low-income rural women in the setting, travel outside the immediate surroundings is unusual.

### **Participants**

Low-income women with depressive symptoms will be recruited into the trial. Specific inclusion criteria include: 1) age 18-65; 2) poverty as measured by either household income  $\leq$ 15000 TK per month OR reported food insufficiency, defined as any household member having had to skip meals over the previous six months; 3) family willingness to participate in the program; 4) basic literacy as measured by the ability to read a simple sentence; and 5) a PHQ-9 score of  $\leq$ 10. Exclusion criteria include pregnancy, inability to attend sessions, cognitive or physical impairment precluding participation, and plans to relocate within the next 24 months.

## **Interventions**

### **Depression Treatment (DT)**

We have adapted an existing psychological intervention developed by the World Health Organization (WHO) called Group Problem Management Plus (PM+). PM+ was designed to help with low resource settings, including those impacted by conflict, to manage common mental



health problems, such as depression and anxiety. The intervention is delivered by non-specialist providers, using a structured manual and problem-solving approach that helps individuals identify, prioritize, and solve their problems [80]. This curriculum has been adapted for use in various settings [81]. A randomized controlled trial of individual-based PM+ in Pakistan showed that the intervention led to significant short term (3-month) reductions in symptoms of depression, anxiety, and post-traumatic stress disorder (PTSD), and improvements in psychosocial functioning, compared to the control group [82]. A second study tested the group model, similarly finding short term, 3-month benefits to the treatment group, compared to control [83]. However, a study employing a longer-term assessment found a different result. A three-armed trial comparing PM+, Cash/skill transfer, to an integrated treatment that included both, found no benefits to PM+ at six months, although the study did not specifically focus on depressed individuals [62].

In adapting PM+ for use in our study, we were guided by two considerations. First, we expanded the number of PM+ group sessions to assure that participants in the DT arm received equal exposure to treatment. The DT arm consequently includes six (rather than the standard five) sessions of psychoeducation, plus four support group meetings following the didactic sessions. Other studies have combined support groups with formal problem-solving therapy [84]. Second, we considered local, cultural, social, and economic contexts. Although we use the PHQ-9, a conventional measure of depression, our adapted didactic materials rarely use this term. Instead, the focal condition is labelled “tension,” a cultural syndrome with wide relevance in South Asian contexts that includes a variety of social, somatic, and psychological symptoms of distress [11, 57, 78, 85, 86]. There are several advantages to the selection of ‘tension’ as the public facing label for our intervention. Tension is a universally recognized as an idiom of distress in South Asia. It is also widely regarded in the South Asian context as a natural reaction to economic and social adversity that does not necessarily reflect individual pathology [85]. This may reduce its potential for stigma, compared to psychiatric disease categories. The tension idiom also fits well with the PM+ framework focusing on behavioural management and problem solving in the context of adversity.

**Training and supervision of peer interventionists:** Facilitators are women from the local area who have received the equivalent of a high school degree. They receive 18-day training on the PM+ and the integrated PM+/ES curricula. Participatory (learner-centred) approaches are used in the training. Techniques include: avoiding lecture, active listening, using questions, encouraging learners to teach each other, valuing the perspective of each learner, and embracing humility [87]. Across all groups, supervision and oversight is provided by icddr,b staff, who receive training specific for this role. Supervisors provide bi-weekly supervision sessions,

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conducted in person at least once per month and otherwise by teleconference. Regular supervisory observations are also conducted. Two fidelity checklists—one for facilitators, and one for supervisors—that include facilitation competencies, time management, and content fidelity is being implemented.

### **Economic Strengthening Intervention Overview**

In past decades, LMIC governments and NGOs, as well as international development organizations, have sought to implement ES interventions. These now reach close to one billion people around the world. Turning away from controversial micro-credit approaches, governments, donor agencies, and researchers have increasingly directed resources into “asset transfer programs” which provide direct cash payments and income-producing assets to poor individuals (usually women) and families [88-90]. These usually feature substantial transfers ranging from \$500 to \$1400. The large investment is justified as the ‘big(financial) push’ necessary to help participants escape the ‘poverty trap,’—a combination of constraints and incentives that combine to keep poor people poor. Program outcomes frequently include increased income and food security, along with improved health and psychological wellbeing [61, 67, 91, 92]. There is little evidence of disincentivizing work or increasing spending on ‘temptation’ goods such as tobacco or alcohol [61]. One of the best known, most widely disseminated ES models is the Graduation Program—a name given to the program to reflect its goal of graduating very poor families out of extreme poverty. Originally developed by the NGO BRAC in Bangladesh in the 1990s, the model involves large asset transfers, participant savings accounts, financial literacy/business training, and temporary cash stipends [93]. The ASHA ES intervention is based closely on the Graduation Program.

### **Program Components**

A four-session **Financial Literacy** curriculum is adapted from recent successful financial education training programs in India [94, 95]. It includes goal setting, financial planning, budgeting, savings and interest calculations, and debt-reduction strategies. See Table 1 for a complete list of session topics.

**Savings accounts:** A common feature of many ES interventions, savings accounts are expected to support a habit of saving, support the financial independence of women, and help families adapt to financial shocks. Very few women in our pilot study had their own personal bank accounts before starting the intervention [96]. In the ASHA trial, RDRS will enrol experimental arm participants into the local RDRS savings scheme. Accounts pay 5% interest.

**Consumption support:** A cash stipend, the equivalent of one kilogram of rice per participant per

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day over six months (~US \$122), will be provided to ES/DT arm participants. The stipend is intended to stabilize income, enable savings, encourage debt repayment, and prevent participants from selling/consuming productive assets.

**Productive asset transfer:** Participants in the ES arm will receive a list of productive assets to choose from. Participants will be encouraged to choose a flock of 3-4 mature female goats, each of which will have had at least two successful previous births. Some participants—those with the space and capacity to build a cowshed within their homestead--may elect to purchase a young calf in place of goats. Once the asset transfer is effected at approximately six months, participants will receive 12 months of animal feed and veterinary care, including preventive vaccinations. Additionally, participants will receive seeds and fertilizer sufficient to develop a “Baliki” vegetable garden. This intensive crop cultivation model, designed to be implemented in very small spaces, is designed to include high vitamin vegetables with a 12-month, rotating crop yield [97]. For participants interested in developing a garden who have no planting space, sac/vertical gardening, and house margin gardening will be shared. The average value of the asset transfer, including livestock and gardening supplies, is \$286. Feed and veterinary care are valued at \$143.

**Agricultural training/skill building:** During the initial, six-month phase of the program, participants in the ES/DT groups will receive three visits from an RDRS agricultural officer (Sessions 2,4, and 8), who will explain the choices of asset type and the pros and cons of each. Additionally, each group will receive a five-day, intensive tailored training in agricultural skills.

### Data Collection

**Research Visits/Study Procedures.** All study interviews will be conducted in a private space, at Baseline (T1), T2 (6 months’ post baseline), T3 (12 months), T4 (18 months) and T5 (24 months) by trained interviewers. Interviews will last 90 minutes; participants will receive 200TK (about \$2.50) as an honorarium for participation. [98] Interviewers will be trained on rapport building.

### Outcome and Mediator Variables

**Depression (primary).** The PHQ-9 has been extensively used and validated in cross cultural settings, and is frequently used as an outcome measure in DT trials in LMIC (e.g.[39]). To measure depression symptoms over time and determine whether relapse occurred between study visits, participants will be asked to complete the PHQ with regard to both the usual time frame (“over the past two weeks,”) and retrospectively (“Since your last visit, 6 or 12 months ago”). This simple retrospective strategy has been found valid for the detection of the detection of depression episodes over time [99]. **Secondary outcomes.** To capture **local idioms of distress**, we will also administer the Tension Scale, a measure developed with and for South Asian women

[78]. Symptoms frequently associated with depressive states, [78] such as anxiety, anger, headaches, nausea, and body pain, are included in the Tension Scale. Additional outcomes include: the GAD-7 (Anxiety), WHODAS (function and disability), and the EQ-5D-5L (quality of life).

**Economic outcomes.** We will determine changes in economic status through the examination of several economic measures. First, we will construct an aggregate index for “financial security” by aggregating the balance in each participants’ savings account, the value of assets held by the household and the net value of household debt[100, 101]. To understand changes in living conditions, we will also examine “household consumption” by aggregating expenditures on food, other necessities, and business expenses. This will be supplemented with a measure of “investment” which will cover spending on physical as well as human capital (health and education)[102]. Since consumption can occur in social networks, our survey will be careful to examine the shared aspects of consumption/investment decisions. Finally, **we will construct a composite “index of vulnerability”** by aggregating indicators on self-assessments of vulnerability to hunger, difficulty of meeting investments, reliance on others for basic needs, and overall economic well-being relative to others in the community[103]. This index of vulnerability will be our **leading economic outcome**.

**Mediator variables.** Additional mediator variables include social variables (social support, social network size, household empowerment, and exposure to household violence). Social network size will be assessed using Lubben’s social network scale, which asks participants for the number of persons in their network who can offer emotional, informational, or instrumental support[104]; Household Empowerment is measured by the Mason Economic Empowerment Scale, which was developed for use in the development context. The scale has several domains reflecting the woman’s participation in household decision making (large and small purchases); geographic mobility; exposure to physical violence or coercion; and gender role norms. Psychological mediators include self-esteem and hopefulness/future orientation. A complete list of variables may be found in Table 2.

### **Implementation Study**

**Quantitative outcome variables.** We have adapted the broad framework proposed by Proctor et al [76]. Implementation outcomes, specified by Proctor’s model, include *feasibility* (operationalized the percentage of patients attending at least seven (70%) of depression treatment sessions) and *fidelity* (operationalized as the degree to which intervention was delivered as planned, including: # sessions delivered, facilitator adherence to curriculum, and ‘quality of

delivery’—facilitator competence and interpersonal skills). These outcome variables will be assessed using a combination of study records, facilitator self-assessments, and supervisory and observations conducted in person or via taped sessions. To measure some of the fidelity constructs (content and facilitation) we have developed two fidelity checklists. The first is used by supervisors during direct observations. The second is used as a self-evaluation by the facilitator following each group meeting. (see below).

**Qualitative Implementation Study.** The qualitative implementation/ process evaluation is based on an adaptation of the Consolidated Framework for Implementation Research (CFIR).[74], a widely used framework that focuses broadly on implementation processes and factors influencing these processes. **Qualitative Data Collection (see Table 3).** We will develop qualitative interview guides, addressing the variables of interest for ASHA participants, staff, and RDRS field staff and officers. Interview guides will be amended in iterative fashion as data collection proceeds. Interviews will be conducted in a private space and will be audiotaped. 40 participants per arm (80 total) will be randomly selected from each study arm and recruited into the qualitative study. Other respondents will include intervention staff, including facilitators and supervisors, (n = 10), and RDRS staff, including administrators, and Agricultural/Market Officers (n= 20).

### Analysis

**Intention-to-treat analyses:** In primary analyses, we will use the intention-to-treat principle using multiple imputation with a secondary exploratory analysis using a per-protocol approach. We will examine the treatment effects and mediation effects varied by subgroups defined by depression severity, economic vulnerability, demographic factors, and other variables.

**Sensitivity analysis accounting for loss-to-follow up.** Potential bias due to loss-to-follow-up (LTFU) will be addressed by applying stabilized inverse probability weights (IPW) to the analysis. [105, 106] To calculate the stabilized IPW, selected baseline variables will be considered in LASSO model [107] to predict **inclusion** probability (i.e., the probability not to be LTFU. Then stabilizing scales will be calculated as the predicted inclusion probabilities by a simple logistic regression model with site as the sole covariate. Finally, the stabilized IPW will be constructed by dividing the stabilizing scales from the logistic regression models by the inclusion probabilities from the LASSO models. Finally, the weights will be scaled so that the total weights are equal to the number of non-missing observations in the full data set.

**Checking model assumptions:** For general linear mixed effects regression models, we will perform graphical residual check [108] for over dispersion, homogeneity of variance, linearity,

and outliers, as well as formal tests of independence between standardized residuals and fitted values, as well as over dispersion test based on Pearson residuals.

### **Primary outcomes**

#### **Primary hypotheses for the study include:**

**H1a:** At T2 (6M) participants in combined arm (ES/DT) will have greater ↓ depressive symptoms from baseline, compared to DT; **H1b:** By T5(24 months) participants in the combined ES/DT arm achieving remission(PHQ-9<5) at 6M will be less likely to relapse (PHQ-9 >=5) than participants in the DT arm; **H1c:** By T5 (24 months) participants in combined arm (ES/DT) will have greater ↓ depressive symptoms from baseline, compared to DT.

#### **Secondary hypotheses include:**

**H2a:** Decrease ↓ in depressive symptoms. T2-T5 will be mediated by financial vulnerability, empowerment, & psych mediators (hope, self-esteem, self-efficacy); As an exploratory aim, we will study whether the relationship between financial wellbeing and depressive symptoms are reciprocal.

We will test **H1a** using a linear mixed effects regression model (R, lme4) with the reduction in PHQ-9 scores at T2 as the response variable, and the villages effect (i.e. randomized clusters) will be accounted by the random intercept. The binary indicator for treatment condition (ES+DT vs. DT for H1a) will be the predictor of interest. We will control type 1 error at 0.05. For **H1b**, we will analyze only those who achieve remission at T4. We will test the difference in the relapse rate between the treatment conditions using logistic mixed effects regression model with the binary indicator of relapse at 24 months as the response variable, and the binary treatment condition (ES+DT vs. DT) as the predictor of interest, and the villages (i.e. randomized clusters) as the random intercept. We will control type 1 error at 0.05. For H1c, we will use the same approach as for H1a but for PHQ-9 scores at T5.

**Mediators/mechanisms.** For the sub-aim **H2a**, we will use the product of coefficients approach to test potential mediators (e.g., financial wellbeing, empowerment, social support, hope, self-esteem, etc) between treatment condition and change in depressive symptoms. Specifically, we will fit (a) regression model for the outcome (e.g., PHQ-9 reduction) using both the treatment condition and the mediator (e.g., financial wellbeing), together with (b) the regression models for the potential mediators with the treatment condition as the predictor. We will conclude that a potential mediator mediates the effect of the treatment condition on the outcome if the null hypotheses for the association between the potential mediators and the treatment conditions, and the effect of the mediators on the outcome are both rejected. As an exploratory aim, we will perform non recursive path analysis using structural question modelling to study whether the

relationship between financial wellbeing and depressive symptoms are reciprocal[109].

### **Implementation outcome evaluation.**

**Primary hypothesis: H3a:** Participants in the ES/DT arms will demonstrate increased feasibility, defined as: increased retention ( $\geq 6$  treatment sessions), in ES/DT arm compared to DT arms.

**Secondary hypothesis: H3. b:** Increased engagement and other implementation outcomes (fidelity/dose) will moderate depressive symptom outcomes.

For the primary aim **H3a** in Aim 2, we will test the difference in the treatment retention rate between ES/DT vs. DT arms with logistic mixed effects regression model with the binary indicator of retention ( $\geq 6$  DT sessions) as the outcome variable, the binary treatment arm (ES+DT vs. DT) as the predictor of interest, and the village as the random intercept. We will also perform a secondary analysis to directly test the difference in the number of intervention sessions between the two arms with Poisson mixed effects regression model with the number of interventions as the outcome variable. For the secondary aim **H3b**, we will perform a test whether increased engagement, fidelity, or dose are effect modifiers. We will control type 1 error at 0.05. To do so, we will use the linear mixed effects regression model with PHQ-9 change as the response variable, treatment condition and each potential effect modifier as well as the interaction term as the predictors, and village as the random intercept. We will test whether the fixed effect of the interaction is zero.

### **Qualitative Analyses**

Interviews will be audiotaped and transcribed. Transcriptions will be uploaded into NVivo, a qualitative data analysis program which facilitates the rapid organization and retrieval of thematic data. Three groups of interviews will be conducted: participants, ASHA staff, and RDRS field staff including the Agricultural and Market officers. The Qualitative Analysis team, composed of the PIs, team scientists, and student members, will develop preliminary coding schemes. Each scheme will be applied to a subset of the data by all members of the team; evaluated and revised. This procedure will proceed through several iterations until the coding scheme is judged sufficiently comprehensive and parsimonious. At that point, the entire data set will be coded using the revised scheme. Once data is coded in NVivo, the analysis will proceed in two steps. First, we will generate a descriptive analysis that includes themes identified in the data. In a second step, we will use the matrix functions in NVivo to identify patterns--conducting detailed comparisons among groups of participants—leading to the generation of explanatory hypotheses. In keeping with a grounded theory approach, [110] as hypotheses emerge from the data, we will search for both for confirming and disconfirming cases.

This rigorous comparative process should permit the emergence of a complex understanding of program processes and participant outcomes. **Program Processes.** For example, using program staff and RDRS data in a comparison across the program sites (including 20 control sites), the analysis will elucidate important factors varying across sites and impacting program delivery, including local contextual factors, such as floods or other weather events that may impact agricultural activity. Other program comparisons will include the treatment arms. **Participant contexts, perceptions, and experiences.** Using participant data across the four study arms, our proposed analysis is designed to elucidate both known and unknown contextual factors that may influence the impact of treatment, and how these vary across the treatment arms. Participants' personal qualities, their perceptions of the interventions, and household variables are among the contextual factors that will emerge. A key comparison will examine differences in these contextual factors among participants and their impact on outcomes—a variable that remains poorly understood in mental health treatment research. Other comparisons include differences in baseline depression (low vs high), baseline financial stress (low vs high), depression remission (yes/no) at T4 (PHQ < 10), reductions in economic strain/vulnerability (yes/no). Once trial results are available, we will conduct a second set of analysis comparing interview data for those who achieved remission/did not receive remission, with the goal of understanding contextual influences.

### **Sample Size Justification and Power Analyses**

Our power analysis is based on a sample of 600. Assuming a 20% drop-out rate (a conservative estimate: we had 0% dropout in the pilot study), we will have 240 per arm. The following power calculations are based on a randomized cluster design (i.e., on average 12 subjects after attrition from each of 20 villages). In a recent study in South Asia, the average 6-month reduction of PHQ-9 scores among DT and control arms were 6.26 and 3.69, respectively.[39] Based on these results and the standard deviation of 6-month changes in PHQ-9 scores from our pilot study (3.07 in the ES+DT)[111], the proposed sample sizes yield 80% power for H1a to detect the difference between ES+DT arm vs. DT arm if 6-month reduction in PHQ-9 score among ES+DT arm is at least 7.29 (or equivalently, 1.03 more than DT arm) using the significance level of 0.05. For H1b, we will analyze only those who achieve depression remission (i.e., PHQ-9 < 5). Based on literature,[46, 112, 113] we estimate that proportion of those who achieve remission at T2 is 30% (i.e. approx. 72 subjects) in the DT arm, and, conservatively, 34.5% (82 subjects) in ES/DT arm (38% in the pilot). In the literature, the relapse rate at T5 in DT arm is reported to be at least 50%.[51, 52] The sample size can detect the difference in relapse rates between the two arms at 80% power if the relapse rate in ES/DT arm is less than 27.1%. It was assumed that the intra-



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cluster correlation is 0.05 (see below) and the coefficient of variation of the number of participants across 20 villages to be 0.65 [114].

Implementation analysis. We will test the difference in retention rate (defined as attending at least 6 intervention sessions; H3a) in ES/DT arm compared to DT arms. Based on recent LMIC research of DT interventions not delivered in the home, we estimate the retention rate in DT arm to be 50% [34] [39]. The sample size (240+240) achieves 80% power to detect a difference in the retention rates between the two arms if the retention rates is at least 65.5% among the DT/ES arm. (Note: the median number of sessions attended in the pilot was 12). **Note: Intracluster correlation coefficient.** Based on ICC used in several depression treatment studies in South Asia, [115] [41] [40] we estimate the intra-cluster correlation to be 0.05.

### **Patient and Public Involvement Statement**

The ASHA model was developed through structured conversations between researchers, clinicians, and community members, during the course of partnership development grant from the National Institutes of Health in 2008-2009 (R21MH083892). The partnership studied depression among South Asian women immigrants in New York City. Core precipitants included social isolation and economic dependence. Consequently, the partnership group designed a depression intervention for South Asian low-income women that included economic empowerment and psychotherapy. A pilot study of the integrated intervention in 20012-13 in rural Bangladesh found the intervention to be highly acceptable, with high rates of attendance. In preparing to implement the proposed project, we have piloted sessions extensively with community women in our catchment area, a process which led to numerous changes to the original protocol, most designed to improve the comprehensibility of intervention messages.

### **Discussion**

Depression among low-income women in LMIC settings is at epidemic levels, with impacts on the health and wellbeing not only of women, but of children and families. Poverty is a major driver of depression, while gender plays a key role in increasing economic dependence and social marginalization. Depression, in turn, has an impact on economic activity and decision making.

Finding interventions that can break the poverty—gender--depression syndemic cycle is of major public health importance. Over the past few decades, researchers and policy makers have assumed that solving the problem of access to mental health treatment, via implementation of brief manualized psychotherapies delivered by non-professionals—has potential to address the public health problem of depression. Our review of the evidence suggests that solving the access problem may not be sufficient, and that the use of these psychotherapies among very low-income

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persons may be inadequate to address a problem with roots in deep poverty and structural inequity. Integrated depression treatment/economic empowerment interventions could be a solution; yet have been very little researched.

The study described in this application has the potential to generate powerful findings regarding the impact of poverty alleviation efforts on depression in low-income women. The ASHA project will implement a big-push poverty asset transfer program with an evidence based manualized psychotherapy treatment. Although the GP program proposed here is resource intensive, evidence suggests that it is effective in helping women to move out of poverty. Should the integrated SHA model be found effective, the results could have major impacts on both economic development and health policy and might point the way to productive collaborations and partnerships among international development groups, government agencies, and ministries of health.

### Ethical Considerations

The study protocol was approved by the Institutional Review Board (IRB) of icddr, b (PR#21001, version No. 1.3; version date 24 October 2021). Informed consent will be obtained from all participants. The privacy, anonymity, and confidentiality of data/information identifying the study participants will be strictly maintained.

### Dissemination

We have created a dissemination plan for this project which reflects its potential impact on policy. Study findings will be disseminated via required reports and scientific presentations/ publications. Results will also be disseminated to study participants in the form of a brief report. Current WHO policy advocates low cost ‘packages of care’ for depression and other mental disorders in LMIC, yet growing evidence suggests that such packages of care may be insufficient to address the LMIC depression pandemic. If found effective, our study results could indicate the importance of integrated models to address poverty and depression simultaneously and contribute to building collaborations between health and poverty alleviation researchers, practitioners, and funders.

**Authors' contributions**

The first and last author conceptualized the study and obtained funding. The second author helped with drafting the paper. The third, fourth, fifth, and sixth authors reviewed the manuscript and made editing suggestions. The seventh author designed the economic strengthening component of the intervention. The eighth author designed the statistical analysis.

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**Table 1**

*Session topics for the 2 arms: Depression Treatment (DT) and Integrated Economic Strengthening with Depression Treatment(ES/DT)*

	<b>DT (ASHA) Session Topics</b>	<b>ES/DT (Shopno) Session Topics</b>
Session 1	Introduction and Managing Tension	Introduction and Managing Tension
Session 2	Get Going Keep Doing Part 1 (Behavioral Activation)	Get Going Keep Doing Part 1 (Behavioral Activation)
Session 3	Get Going Keep Doing Part 2 (Behavioral Activation)	Get Going Keep Doing Part 2 (Behavioral Activation)
Session 4	Strengthening Social Support	Strengthening Social Support
Session 5	Managing Problems	Managing Problems
Session 6	Review of Strategies and Looking Forward	Review of PM+ Strategies
Session 7	Support Group	Financial Education: Escaping the Poverty Trap and Financial Planning
Session 8	Support Group	Financial Education: Budgeting, Saving, and Earning Interest
Session 9	Support Group	Financial Education: Consumption, Saving, and Borrowing
Session 10	Support Group	Financial Education: Financial Plans and Looking Forward

**Table 2**

*List of baseline questionnaires*

PHQ-9
Demographics questionnaire
Health and anthropometric measurement questionnaire
Economic Vulnerability Questionnaire
Generalized Anxiety Disorder Questionnaire (GAD-7)
Tension Scale
World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0)
EQL-5D-5L
Rosenberg Self-Esteem Scale
Multidimensional Scale of Perceived Social Support (MSPSS)
Lubben Social Network Scale
Women's Empowerment Scale (Mason and Smith 2000)
Childhood Psychosocial Adversity Scale (CPAS)
Beck Hopelessness Scale

**Table 3**

*Qualitative Data Collection Process Measures*

<b>CFIR Construct</b>	<b>Components/Variables</b>	<b>Data Collection</b>	<b>Stakeholders</b>
<b>Intervention Features</b>	Plausibility, perceived need, appropriateness to the setting, complexity, and difficulty	Qualitative interviews	Group facilitators, Supervisors, RDRS Admin, Participants
<b>Setting</b>	Characteristics of local RDRS center, village, local economy, seasonal variations	Qualitative interviews, Gov't data	As above
<b>Individuals</b>	Life situations, household characteristics, history of depressive symptoms, experiences with ASHA program, perceptions of intervention	Qualitative interviews	Intervention participants across 4 Treatment Arms
<b>Processes</b>	<b>Training, treatment delivery, oversight, adaptation to the curriculum, barriers to implementation</b>	<b>Qualitative interviews</b>	<b>Group facilitators, Supervisors, RDRS Admin, Participants</b>