

**Men Engagement in Women Empowerment for Improving
Maternal Mental Health through Cash Transfer and Life Skills
Building**

MEWE (Men Engagement in Women Empowerment)

NCT Number: **04125251**

Date of Document: **20th Jan 2021**

Principal Investigator: Dr. Zulfiqar A. Bhutta

Co-Leads: Dr. Rozina Karmaliani, Dr. Tazeen Saeed Ali

Technical Advisor/consultant: Dr. Judith McFarlane

Co-investigators: Dr. Saima Hirani, Ms. Shireen Shehzad, Dr. Nargis Asad, Mr. Hussain Maqbool

Research Specialists: Dr. Nasim Zahid Shah, Zahid Hyder Khuwaja

Research Coordinator: Mr. Shiraz Lalani

Center of Excellence in Women and Child Health (COE-WCH)

School of Nursing and Midwifery (SONAM)

The Aga Khan University, Stadium Road – Karachi 74800

Funding Agency: Bill and Melinda Gates Foundation

Investment ID: OPP1148892

Executive Summary

Background: In developing countries, women under most circumstances are deprived of basic human rights of education, health, and economic independence. They remain dependent financially and socially on their husbands and fathers. Studies have shown that Cash Transfer (CT) and Life Skills Building (LSB) training reduce depression and violence and improve household financial situation. Interventions that combine LSB training with cash support have not been tested in Pakistan. The results of this study have direct implication to women in lowest income quintile in Pakistan

Study Hypothesis: Introduction of LSB intervention to Benazir Income Support Program (BISP)-CT beneficiaries in couples will reduce domestic violence and depression in married women of reproductive age by 20% and improve women empowerment by 20%.

Study Objective: To measure the impact of men engagement in LSB and CT on maternal depression, domestic violence, improved self-efficacy and women empowerment.

Study Design: Phase I: Formative phase

Phase II: Cluster Randomized Controlled Trial (cRCT)

Methodology: A two phase study will be conducted including formative phase for initial 1.5 years and cluster randomized controlled trial (cRCT) for 2 years. There will be three arms for cRCT. The first arm will receive LSB to couples and BISP-CT. The second arm will receive LSB only to women receiving BISP-CT. The third arm will be the control arm who will receive BISP-CT only.

Sample Size Estimation: With baseline prevalence of depression 60% (Gadit (as cited in Ali & Zuberi, 2012)), we anticipate the reduction of depression by 20% in intervention arm. A total of 9 clusters per arm would be needed over a period of two years assuming an average cluster size of at least 25 couples. There are three arms and 9 clusters in each arm so a total of 675 couples (225 in each arm, 25 in each cluster). By accounting for the attrition rate of 25%, a minimal of 846 couples (282 per arm) would be needed.

Study Outcomes:

Primary Outcomes: Reduced Maternal Depression and Domestic Violence, Improved Self-Efficacy and Women Empowerment.

Secondary Outcomes: Improved Household food security, Gender Attitude, Economic Solvency and Resilience.

Intervention Package: The intervention will consist of LSB training along with BISP-CT. The intervention will consist of LSB training to BISP-CT beneficiaries for a period of 10-12 sessions (10 for couples, 2 for family including mother-in-law, supporter or head of the household) for 2 hours per week in the selected arms. The LSB package will focus on the skills essential for Effective Communication, Understanding Roles of Men and Women, Understanding the Power Dynamics, Work Life Balance and Time Management, Conflict Management, Decision Making, Building Self Confidence, Dealing with Abuse and Harassment, Money Management and Income Generation. The modules will be offered by trained LSB teachers from the community to ensure sustainability and community trust and allow the results of the research to continue for a longer time. The LSB teachers will be trained by AKU researchers to deliver the modules, delivery mechanisms, community mobilization and management skills along with monetary compensation as stipend. The LSB teachers will be offered refresher training 2-3 times on monthly basis for debriefing, expanded education, resource information and skill enhancement advocacy.

The pre-intervention formative phase of the project will be of one to one and half years. The objectives of the formative phase are for staff recruitment, the development of operational plan and development of women and couple empowerment tools, planning and refinement of intervention, development of training modules for couples, meetings with government and community stakeholders, community mobilization, capacity building and networking. The LSB intervention will be delivered in individuals/groups in the intervention arms, after the completion of recruitment and baseline assessment. Once the intervention is delivered, end-line (five months of intervention) follow up assessments will be completed.

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Background and Introduction

Empowerment of women is an important component to ensure family health and economic development. Number of interventions have been implemented to make women economically independent by providing micro-finance either with or without skill building training. Governments and donors have been supporting Non-Governmental Organizations (NGOs) in the developing countries as partners in the development process to improve the economic status and quality of life of people living in the developing countries (Buller et al., 2018; Roy et al., 2017).

According to WHO report of 2000, the global health burden of mental disorders has reached epidemic proportions, which is associated with significant burden of morbidity and disability. WHO 2004, further suggested depression as the third most important cause of disease burden worldwide. Depression is often a byproduct of domestic violence with the incidence being reported by 60% of the female victims. The negative consequences of maternal depression on children have been documented. Evidence also suggests that children who witness either partner violence or violence at mothers at home have greater problems with social skills and learning (Hurt, Malmund, Brodsky, & Giannetta, 2001; McFarlane, Groff, O'Brien, Watson, 2003). However, recent research studies shows that treatment of the abused and depressed mother can improve the functioning of the children in just six months (McFarlane, Groff, O'Brien, & Watson, 2005a and 2005b). Apart from affecting psychosocial wellbeing; children's mental health issues such as depression and anxiety also affect reproductive health. Hampshire Depression Project reports articulates the positive relationship between depression and lower socio-economic status (Ostler & Thomson, 2001). A large scale study including 152 countries that aimed at assessing association between Infant Mortality Rate (IMR) and socioeconomic determinants found that, socio-economic variables predicted 92% of national IMR at the global level. Hence, the problem of women mental health affects various aspects of her life (Schell et al., 2007).

According to USAID studies, measurement of couple empowerment is difficult and there are only a few quantitative studies performed in this regard. However, a many qualitative studies suggest that the view of women within their communities changes due to their activities in microfinance leading to increase in their decision making capabilities and more control over resources (Todd 1996). This microfinance or cash transfer will be further benefitted if LSB training will also be

given to the women. Life skills interventions undertaken in developed countries suggest to be effective in promoting positive behaviors around smoking, alcohol, drug abuse, HIV, AIDS, contraception, perception about sexual activities and condom use through refusal skills, communication skills, assertiveness, self-awareness, attitude change and safer behaviors (Teyhan et al., 2016; Weichold & Blumenthal, 2016). The LSB training along with microfinance will provide essential skills to women for better utilization of money for herself and for her family's health. In order to understand the impact from the specific interventions on women, it is important to know where she stands in the larger picture of family dynamics and what her bargaining power is (Duvendack et al., 2011).

Child Survival

In 2012, 6.6 million children died before reaching their fifth birthday. It is a sharp decrease from 1990, when more than 12 million children died under age five (UNICEF, 2012). Infant mortality and mortality of children less than five years in Pakistan emphasize that children usually die from malnutrition and infection cyclic syndrome. The malnutrition-infection syndrome occurs when young children, who are undernourished, usually die due to family food insecurity, and gastrointestinal infections. Child birth weight is the most important factor of children's chances of survival and it is influenced by the mother's age and her nutritional status, child's birth weight and socio economic status of the mother. Current high-impact, low-cost interventions such as nutrition availability, and improved breastfeeding practices through economic building of the family are suggested interventions.

Economic Empowerment to Improve Maternal Mental Health and Child Survival

The health status of a woman is only improved, if special emphasis is given to her mental health. As a result of improvement in mother's mental health the entire family will be less stressed and can obtain better cohesion and higher functioning. Although research evidence indicates an association between women's mental health and domestic violence, the existing knowledge on associations between women's mental health determinants, economic development and child health outcomes is still unclear. The link between mental health and low income amongst urban women has been well documented in developing countries (Blue, Ducci, Jaswal, Ludermir, & Harpham, 1995). Research evidences point out that low socio-economic status assessed by

maternal standard of living is consistently associated with a higher prevalence of depression and other mental health related morbidities in cross sectional studies (Lorant et al., 2003).

Moreover, women's mental wellbeing is closely linked to many other core components such as: financial independence, family harmony, empowerment and self-efficacy. A number of studies have supported counseling as an intervention utilizing group approach for problem solving thus reducing depression and stress, thus fostering effective interpersonal skills. Microfinance and cash transfer have proved to be a successful intervention in many developing countries, leading to increased household economic wellbeing, greater food security, increased children school attendance, gender equity, women empowerment, self-confidence, communication and reduction in the vulnerability of violence among women and their children (Paul, 2006 & Duvendack et al 2011). Interventions in developing countries have shown effectiveness of life skills training for enhancing communication and assertive skills, decision-making, building self-esteem, self-efficacy, reducing learning difficulties, decrease aggressive behavior, anger control, and changing attitudes towards engaging in sexual behavior (Ahmed, Petzold, Kabir, & Tomson, 2006; Naseri, A., & Babakhani; Maryam, Davoud, & Zahra, 2011). There is a dire need to empower women through programs such as cash transfer and LSB to reduce poverty, depression and violence.

The research team involved in this study is building this proposal from the successful completion, and published randomized clinical trial with marginalized, impoverished women in Karachi, Pakistan where they tested the intervention of Economic Skills Building (ESB) for women (Karmaliani et al 2011, Karmaliani et al 2012). The training modules (Hirani et al., 2010) of the prior research included domains of communication, time management, conflict resolution, effective parenting, work life balance, dealing with violence, and personal grooming. The published results and positive health outcomes for Pakistani women suggest that women in ESB report significantly higher ($p < 0.05$) for self-efficacy scores, as compared to counseling and control group women and more employment (Hirani et al., 2010). The results indicate that ESB is potentially effective intervention to improve maternal health and increase economic sufficiency. To date, little research has been done regarding women empowerment through cash transfer or micro-finance initiatives in Pakistan. Therefore, the current study is an attempt to evaluate the effect of these interventions in the context of Pakistan.

Micro-finance or Cash Transfer as an Intervention for Women's Economic Empowerment

The literature also supports that when CT or microfinance interventions are combined with educational programmes including health education, training on gender roles, and/or women's empowerment, the outcomes are improvement in women and child health status, social status of women and financial betterment of a family (United Nations Population Fund and Microfinance Summit Campaign, 2006; Leatherman & Dunford, 2009). Moreover, it is found that anchoring microfinance programmes with social development interventions can assure effectiveness and sustainability of these programmes (Amin & Li, 1997). Similar kind of program, when evaluated for its impact in rural Bangladesh, revealed an improvement in children's immunization rates and a decline in child mortality rates, among women who were part of the credit program versus their counterparts who were not (Ahmed, Petzold, Kabir, & Tomson, 2006).

Additionally, Dy Khoy and Sieng (2005), sharing the example of a microfinance scheme developed during 2000 in Cambodia, stated that; its success is attributable to the fact that it was developed in collaboration with the Reproductive and Child Health Alliance (RACHA), which offered health education and health services. This microfinance/CT scheme resulted in an increase in community people's ownership, knowledge on maternal and child health, and health seeking behavior.

Thus, CT fills the gap in many developing countries, where cultural and social constraints limit opportunities for poor women. Improved health when CT is applied, offers promising results especially when it is implemented with LSB and women empowerment by involving men. Examples of positive health outcomes for women include: reproductive behavior, women's empowerment, reduction in domestic violence as well as depression and anxiety, health literacy, maternal and child health, nutrition, and business success (Doyle et al., 2018).

In a country like Pakistan, every woman lives in a web of relationships within her household. Her 'bargaining power' within the household is to be found in her own resources and capital and her skills and relationships within her maternal family. Thus, her bargaining power within the household can draw upon relationships outside her home. Women's actions for her health are determined by a number of factors, such as her own agency, and her relationships within the household and outside her household. The larger picture of a woman's social milieu is important

to know in order to understand the impact from specific interventions, such as life skills development, and CT or micro-finance.

To be able to provide the right intervention it is necessary that community is involved to share their problems and its solution. One of the known approaches is called Participatory Action Research (PAR). These strategies have been used in the field of health and violence against women for enhancing the reflection and analysis of participants. It can be used for any health issue provided the researcher believes the participants (i.e., couples) have the agency to take action on the basis of their reflection and analysis, and not on the basis of what is prescribed to them.

The current research team was involved in a multi country study on women's empowerment. Participatory Reflection and Analysis tools were used with groups of urban and rural women, whereby they reflected and analyzed women's empowerment, health, mental health, and violence. Eleven Participatory Reflection and Analysis tools were used. In the mega project, Tawana, Participatory Reflection and Analysis was used to draw attention to malnutrition issues, and how malnutrition can best be addressed. Participatory Poverty Assessment for the planning commission of Pakistan used Participatory Reflection and Analysis tools for reflection and analysis of the livelihood of the poor and to identify the vulnerabilities of successful livelihood. A chapter was written for Pakistan Participatory Poverty Assessment about women's mental health, which was written based on women's perception of their mental health as they described it when Participatory Reflection and Analysis methods were used. Researchers of the LSB team are exceptionally prepared and experienced in Participatory Reflection and Analysis methods.

Rationale

A mother who is mentally ill is unable to provide support and care to her family and children. Similarly, men with low self-esteem cannot contribute to a healthy family bond. The purpose of this project is to enhance the self-worth of both mothers and fathers through the joint training of couples in the LSB 10-12 week program. The combination of LSB and BISP-CT has the potential of successful economic and health outcomes. Pakistan has major maternal/child health deficits where men in couple are largely absent from the picture and their involvement is neither given consideration nor has it been properly documented. Therefore, to empower women and achieve

gender equality is a global challenge requiring new and bold initiatives like the ones proposed by this study.

Since men are frequently neglected in global health programs to improve maternal and child health, the BISP-CT plus LSB proposal for "couples" is an innovative strategy to test the involvement of men towards better maternal and child health. The extent of major maternal health deficits in Pakistan cannot be stressed enough; therefore, involving men is the new initiative which is being tested in this project. Previously mixed results were obtained in terms of reducing poverty and violence against women when BISP-CT & LSB were administered specifically to women only. Through the addition of men, the impact of LSB is proposed to be enhanced. Furthermore, the proposed study not only measures women empowerment alone but also couples' empowerment through the interventions mentioned above. The purpose is to improve maternal and child health by empowering women through LSB training to BISP beneficiary married couples.

Problem Statement

Women in Pakistan are deprived of basic human rights of education, health and economic independence. Women remain dependent on their husbands, financially and socially.

Studies conducted in other part of the world have supported CT and LSB to reduce poverty, depression and violence. Recently, the negative consequences of maternal depression on children have also been well documented.

Situational Analysis

The current situation of women in Pakistan due to financial dependence and poor life skills, as described above, makes the role of our research more imperative in combating this issue through innovative interventions.

More specifically, the scope of this project is to improve maternal mental health by decreasing depression, empowering women economically and psychosocially so that they can prevent their victimization from violence and improve their health and family. Since children brought up in a healthy environment will grow up to build stronger families and hence the vicious cycle of continuing violence can be interrupted and stopped.

Therefore there is a need to test the interventions related to financial enhancement with LSB training to decrease maternal morbidity (depression), domestic violence, increase women financial empowerment, maternal and child health and nutrition.

Hypothesis

Introduction of LSB to BISP-CT beneficiaries in couples will reduce domestic violence and depression in married women of reproductive age by 20% and improve women empowerment by 20%.

Aim and Objective

The aim of this research is in line with the 2030 agenda for Sustainable Development Goals. This agenda is a plan of action to strengthen universal peace and recognizes poverty as the greatest hurdle in sustainable development. The first goal of this document is concerned with a step of reducing poverty and the second goal aims to bring the efforts for gender equality by empowering women. Through BISP-CT intervention, it is hoped that the overall economic wellbeing of the women and their families will improve and through LSB, women will become more empowered. Ultimately they will be able to compete in the world as global citizen alongside men (Agenda for Sustainable Development, 2030). This study aims to engage men in women empowerment (MEWE) through LSB and BISP-CT to improve maternal mental health in Pakistan using a randomized control trial.

Primary Objectives

To measure the impact of men engagement in LSB and CT on maternal depression, domestic violence, improved self-efficacy and women empowerment.

Secondary Objectives

To measure the impact of men engagement in LSB and CT on Household food security, Gender Attitude, Economic Solvency and Resilience.

Primary Outcomes

Reduced maternal depression, domestic violence, improved self-efficacy and women empowerment.

Secondary Outcomes

Improved household food security, gender attitude, economic solvency and resilience.

Method

Program Implementation and Approach

The proposed study areas for the Formative Phase of the project are Punjab (Rahimyar Khan), Balochistan (Lasbela), Khyber Pukhtunkhuwa (Peshawar) and Sindh (Thatta). The cRCT will be conducted in district Thatta.

Key Intervention

The LSB modules' training will be given to those who are receiving BISP-CT to perform their business and support their family. The intervention will consist of LSB training to BISP-CT beneficiaries for a period of 10-12 sessions for 2-3 hours per week in the selected arms. The LSB package will focus on the skills essential for Effective Communication, Understanding Roles of Men and Women, Understanding the Power Dynamics, Work Life Balance and Time Management, Conflict Management, Decision Making, Building Self Confidence, Dealing with Abuse and Harassment, Money Management and Income Generation. The modules will be offered by trained LSB teachers from the community to ensure sustainability and scalability. The LSB teachers will be trained by AKU researchers on pedagogy and delivery mechanisms, community mobilization and management skills along with monetary compensation as stipend. The LSB teachers will be offered refresher training 2-3 times on monthly basis for debriefing, expanded education, resource information and skill enhancement advocacy.

These trained LSB teachers will teach the LSB module to a group of 10-15 married couples. Separate training sessions will be conducted for wives and husbands and similarly female LSB teachers will conduct sessions for wives and male LSB teachers will conduct for husband. These training sessions will be carried out simultaneously for both men and women.

The quality and efficacy of training by LSB teachers for couples randomized to the LSB intervention will be cross-checked using process indicators, including number of sessions conducted, change of couple's knowledge, increased in health seeking behaviors of couple along with additional measures of food security and family livelihood.

Study Design

This study will be conducted in two phases; (1) Formative Phase (2) cRCT.

Phase 1: Formative Phase (details available in separate section)

This phase will take 1.5 years to execute the following activities

1. Human Resource

Identification, recruitment and training of Human Resource will be done.

2. Planning Meeting with Stakeholders

Meeting will be conducted with different stakeholders such as government official that includes BISP, community leaders etc.

3. Qualitative Research through Participatory Reflection and Action (PRA)

This strategy will be used at two points in time i.e. in the beginning of the study within the formative phase and after the completion of the cRCT intervention. The purpose is very specific at both ends:

First end it will be utilized for culturally sensitive development of multiple tools such as, women empowerment, masculinity, and attitudes towards gender roles and module development for men.

Second point of PRA is after cRCT where the purpose of PRA is to make research meaningful to the research participants. It will enable optimum opportunities for couples to share their thoughts, feelings and suggestions about the intervention and research processes. This will also enable research participants to reflect and analyze their experience of being part of this intervention.

4. Development of Operational Plan for Interventional Design and Delivery Mechanism

This will include; enrollment/recruitment point of BISP beneficiaries, mode of intervention delivery either group level i.e. males and females separately or couples together or individual couples, setting of intervention being delivered (facility or community), who will deliver the training (trained LSB teachers from the community), number of modules to be trained, number of districts/UCs/tehsil for interventional study, incentives for participants, definition and number of clusters required for randomization.

5. Community Mobilization

Additionally, community and district level systems assessment will be done to thoroughly assess; the geopolitical and sociocultural characteristics of the setting, the process of BISP-CT and feasibility of integrating LSB for married couples.

Phase 1: Formative Research

The formative research will provide a rapid assessment of the local needs. This will guide the researchers to open a dialogue about how the families wish to empower women with the involvement of husbands. Together with community members, researchers can identify factors responsible not only for designing a locally tailored, culturally appropriate integrated intervention, but factors that help in sustainability and scale up of the intervention in long run.

Objectives

- To access and review the administrative structure and BISP beneficiary data from the selected districts for selection of eligible couples
- To access the community in the selected districts to gain understating of the contextual factors that should guide the modification of proposed intervention (LSB with CT)
- To identify and train human resource (trained LSB teachers from the community) for implementation of LSB module to eligible couples
- To develop a national level LSB curriculum for men and women
- To review the existing curriculums i.e. Rozan, Blue Veins, Men Engage, Sonke Justice, Promundo Pak-IMAGES
- To develop tools for assessment of men engagement and gender roles
- To explore the appropriate language for the translation of quantitative tools

Theoretical Framework: Social Ecological Model

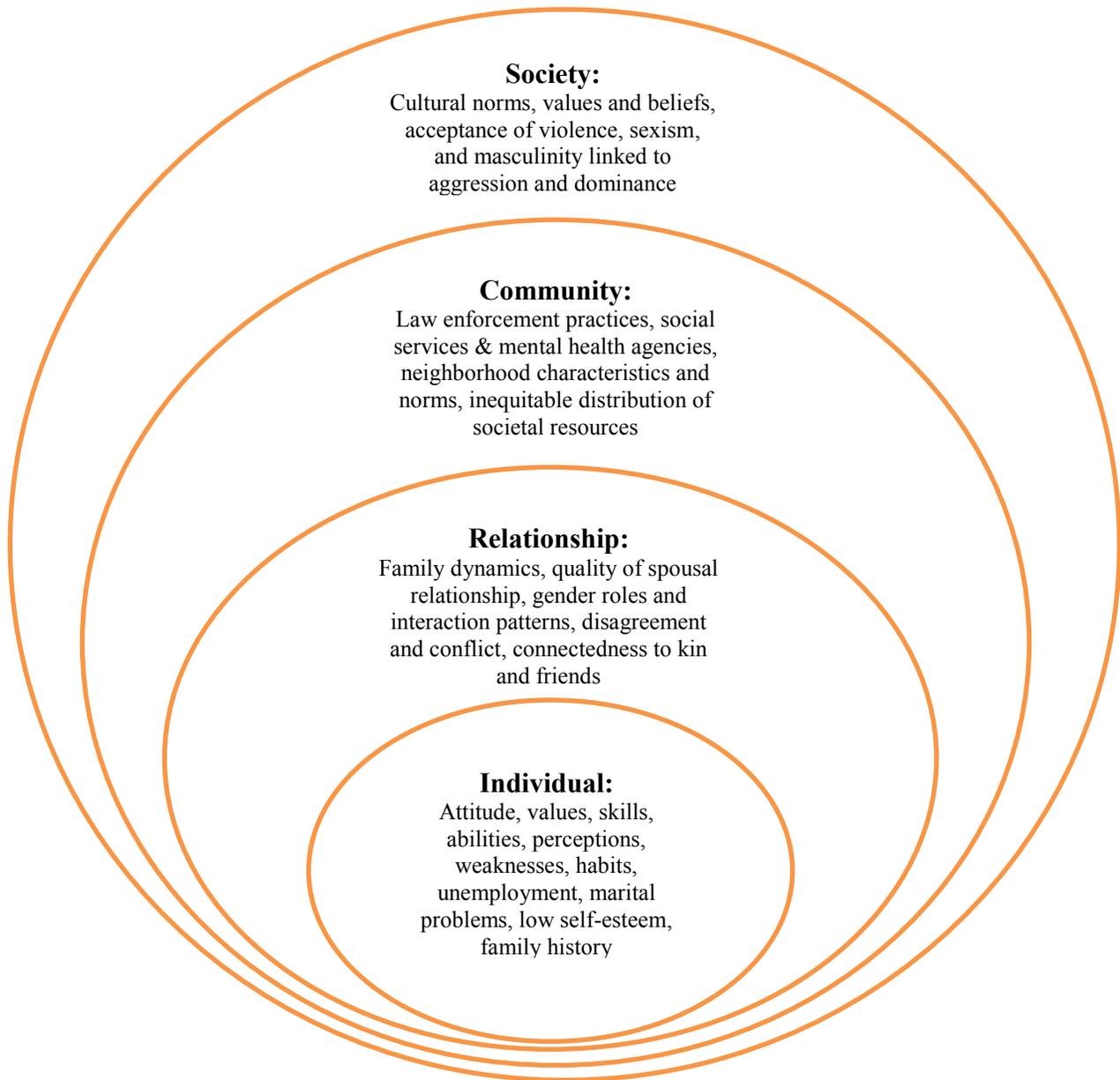
In a country like Pakistan, every woman lives in a web of relationships within her household. Her ‘bargaining power’ within the household is to be found in her own resources and capital and her skills and relationships within her maternal family. Thus, her bargaining power within the household can draw upon relationships outside her home. Women’s actions for her health are determined by a number of factors, such as her own agency, and her relationships within the household and outside her household. The larger picture of a woman’s social milieu is important to know in order to understand the impact of the proposed intervention.

Therefore, in order to gain in-depth understanding of women’s status in local context we will use the Social-Ecological Model (SEM) in this formative research. SEM is theory based framework for understanding multifaceted effects of factors that determine a behavior.

According to this theory, the derivers of behavior i.e. violence, affecting women and child health outcome are found at every level of ecological model, within her family, community, neighborhood and society at large. These derivers can be best explained by using the SEM. Secondly, using this model, an appropriate intervention can be designed that can best address the impact of the behavior at all the four levels.

The proposed intervention of LSB to women with the involvement of their husbands will help in decreasing domestic violence, maternal depression and increasing women empowerment. At individual and relationship level, the LSB training will lead to development of positive attitude for prevention of violence, effective communication between husband and wife, cash management for improved maternal and child health outcomes, mutual household decision making for family nutrition, health service utilization, better understanding of gender roles leading to improved status of women in the family. Similarly, at community and societal level, the LSB training to couples is anticipated to reduce social isolation of women by increasing women status or sensitizing the formal safety groups available within the community. Provision of environment where violence will be inhibited with the formation of resilient society.

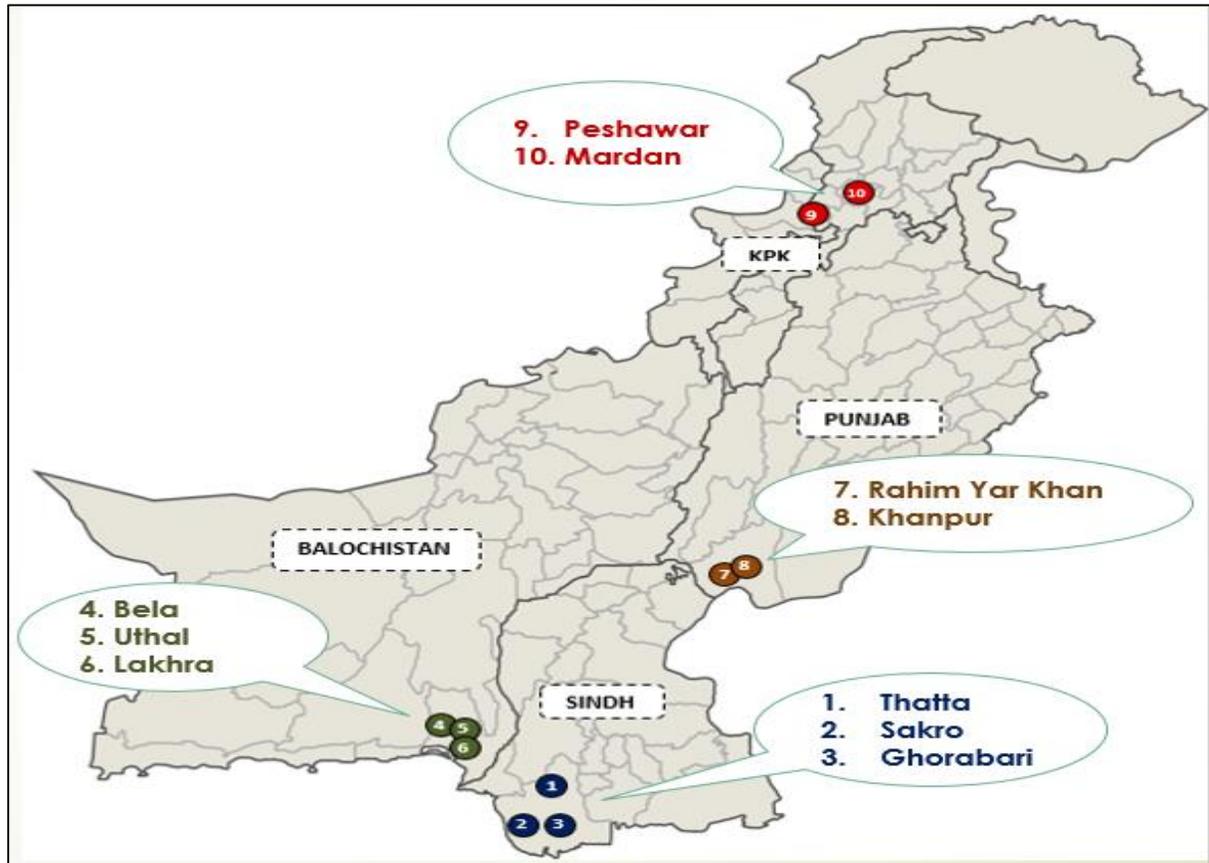
Theoretical Framework: Social Ecological Model



(Heise, 2016, 2011 & 1998; Carlson, 1984)

Study Site

The formative phase of the study will be conducted for a period of 1.5 year in selected districts from four provinces of Pakistan: Sindh, Baluchistan, Punjab and Khyber Pukhtunkhuwa (KPK). The proposed districts are Thatta in Sindh, Rahimyar Khan in Punjab, Lasbella in Baluchistan and Peshawar in KPK. The purpose of conducting formative research in all provinces is to develop a National (Pakistan) level LSB curriculum for men and modification to the existing female curriculum. If there are not much differences in cultural context across the provinces and curriculum outcome is same, then the trial in Sindh is applicable for intervention in Pakistan and can be scaled up. The second phase of the project will be carried out in Thatta based on learnings from the formative phase.



Sindh

According to Multiple Indicator Cluster Survey (MICS) by UNICEF and Sindh Bureau of Statistics (2014), the total Fertility Rate in Sindh for the one year period before the survey was 4

children per woman. Almost 80% of ever married women receive antenatal care from a skilled provider. The prevalence of institutional deliveries is 64%. More than four out of ten children under the age of five in Sindh are underweight (42%) and 17% are classified as severely underweight. Almost half of children under five years (48 percent) are stunted or short for their age and one quarter (24%) children are severely stunted.

Overall, 49% of women in Sindh feel that a husband is justified in hitting or beating his wife in at least one of the five situations i.e. when a wife neglects the children (36.5%), arguing with him (37%), going out without telling her husband (35.5%), wife refuses to have sex with the husband (30%) and about the same proportion reported if she burns the food, 34.5% if she does not perform household chores and 27.5% if she uses mobile phone, television or social media.

Overall, 70.4% of women either watch television or read a newspaper or magazine or listen to the radio at least once a week which is a positive indicator for planners from the communication perspective.

Punjab

MICS by UNICEF and Bureau of Statistics, Planning and Development Department, Punjab (2014), found that the total fertility rate in Punjab for one year preceding the survey was 3.5. Almost one in three children under age five are moderately or severely underweight (34%) and 11% are classified as severely underweight. 34% of children are moderately or severely stunted or too short for their age and 18% of children are moderately or severely wasted or too thin for their height. The results show that 17% of women do not receive antenatal care. Coverage of antenatal care by a skilled birth attendant is 79%, marginally higher in urban (89%) than rural areas (74%). The majority of the women receive antenatal care from medical doctors (67%) while the traditional birth attendants (TBAs) provide antenatal care to a small proportion of women (2%). 84% of live births, both the mothers and their newborns, receive a health check following birth within 2 days of birth, whereas for 9% of births neither mother nor newborn received it. 11% of women in Punjab read a newspaper or magazine, 5% listen to the radio, and 64% watch television at least once a week which is a positive indicator for planners from the communication perspective.

Overall, 40% of women age 15-49 years believe that a husband is justified in hitting or beating his wife for any one of five reasons that she; goes out without telling him (26%), neglects the children (27%), argues with him (26%), refuses sex with him (21%), and burns the food (15%).

Baluchistan

According to MICS by UNICEF and Planning and Development Department, Baluchistan (2011), the total fertility rate in Baluchistan is 4.2. 39% of the surveyed mothers received antenatal care from a skilled health provider (doctor, nurse or a midwife) at least once during their last pregnancy in two years. 63% of urban women received antenatal care from a health professional compared to 31% in rural areas. The survey showed that 35% women visited a doctor during their last pregnancy for checkups while 4% visited a Nurse/Lady Health Visitor/Midwife. However, 54% who gave birth in the two years before the survey did not receive any antenatal care.

Overall, 62% women feel that a husband has the right to beat his wife for any of these reasons if she; go out without telling (42%), argues with him (39%), neglects the children (28%), refuses sex with him (21%) or burns food (22%).

Khyber Pukhtunkhuwa (KPK)

According to UNICEF and Planning and Development Department, NWFP. (2010), the total fertility rate in KPK is 5.16 children. 47% of women receiving antenatal care at least once during their pregnancy by any skilled personnel. Antenatal care coverage was 70% in urban areas, which is substantially higher than in rural areas (43%). 52% of women had not received any antenatal care and this rate was higher in rural areas, as expected. About 41% of births were delivered by skilled personnel compared to 28% in 2001. The proportion of institutional deliveries was approximately 39% with this happening more frequently in urban areas. One in three of the births (33%) were delivered with assistance from a medical doctor. The infant mortality rate was estimated at 76 per thousand live births, while the under-five mortality rate (U5MR) was 100 per thousand live births. The maternal mortality ratio was reported to be 275 per hundred thousand live births.

More than half (52.17%) of females responded that a husband can beat his wife if she disobeys her, 26.09% responded that a husband can beat her wife is she does not take care of her husband,

21.4% responded that a husband can beat her wife s she goes out of the home without his permission, while 8.70% marked the option if wife visits to the male doctor without husband's permission.

Project Initiation

The scope of formative research is wide, as it will be carried out across four provinces, therefore, for smooth functioning of project activities a good rapport building with the government stakeholders is one of the requirement. In order to establish rapport, meetings will be conducted with officials from BISP including; the Chairperson, Director General and BISP local representatives in the proposed sites. No Objection Certificate (NOC) from BISP Sindh will be obtained for timely initiation of project activities.

For an in-depth understanding of local context, scope & network of BISP, access to administrative as well as BISP beneficiary data/documents will be required. For this purpose, a visit to proposed districts will be planned, starting from district Thatta in Sindh to achieve the following objectives.

1. To verify the number of tehsils, union councils, approx. Deh within each district
2. Identify missing union council's information along with number of beneficiaries
3. Identify stakeholders i.e. BISP beneficiary committees (BBCs), Non-Governmental Organization (NGOs), Universities, etc.
4. To understand the geographical distribution and distance (similarities and dissimilarities, environmental factors, Socio-economic status (SES), education, occupations, etc.)
5. To explore the extent of saturation of district Thatta with other projects and programs
6. To meet at least one beneficiary and BBC mother leader for better understanding of context, family dynamics and willingness for innovation

A thorough review of the data will be done (once received from BISP head quarter) by the research team for identification & selection of eligible field side locations (Tehsil/UC/Deh & clusters vs. control) and to locate the right participants (beneficiary couples) for the intervention to be carried out in phase II of project. Further, this data will help the research team for calculation of an appropriate sample size for the proposed intervention to be carried out in the next phase of project. To make this process more comprehensive, consultation from senior statisticians will also be done.

Qualitative Research through Participatory Reflection and Action (PRA)

In order to design/plan the right intervention, it is necessary that community should participate to fully share their problems and solutions. One of the known approaches is called Participatory Reflection and Action (PRA). It can be used for any health issue provided the researcher believes the participants (i.e., couples) have the agency to take action on the basis of their reflection and analysis, and not on the basis of what is prescribed to them. The purpose of using PRA for qualitative research during the formative phase is very specific i.e. it will guide the team to gain an in-depth understanding of:

- Existing status of the women in the large picture of family dynamics
- Couples perception of role of men in women empowerment and family harmony
- Existing maternal & child health related issues and their solutions in order to design and develop an appropriate intervention for couples
- Identify factors which would help in sustainability and scale up of proposed intervention in the long run
- Review of the existing literature for the development of:
 - Tools for masculinity, economic solvency, gender roles, etc.
 - LSB curriculum for women and men
- Modification of existing measurement tools

This qualitative research will be done by conducting Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs) in the selected districts. A total of 10 FGDs and 10 KIIs will be conducted in each district. The details are given in Table 1 and 2.

Table 1: Total Number of KIIs by Study Site

	Sindh	Punjab	Baluchistan	KPK	Total
KIIs (Male)	5	2	2	1	10
KIIs (Female)	2	-	-	2	4
Total	7	2	2	3	14

Table 2: Total number of FGDs by Study site

	Sindh	Punjab	Baluchistan	KPK	Total
FGDs (Male)	3	2	2	2	9
FGDs (Female)	3	2	2	2	9
Total	6	4	4	4	18

Participants Recruitment and Sampling

The participants for the FGDs and KIIs will be identified and recruited purposively through the BISP district network. The participants for FGDs will include BISP-CT beneficiary couples or couples belonging to similar socio-economic status from other provinces. For KIIs, BISP Beneficiary Committee (BBC) members and provincial/district BISP representatives from local BISP district network, social mobilizers, community workers and health care professionals were also included have also participated for KIIs. Two separate teams comprised of one moderator and one note taker will be assigned in each study district for conducting FGDs with males and females.

Data Collection

As explained above, the data collection will be carried out through FGDs and KIIs. The FGDs will be conducted with the group of participants consisting of 10-15 people and the duration of each FGD will be 60 to 90 minutes. The FGD participants will be a homogenous group with respect to age, gender, socio-economic status, etc. Each KII will be conducted for the duration of 30 to 45 minutes. Separate interview guides will be developed for FGDs and KIIs with predefined domains including understanding about gender roles, concept of masculinity, violence and women empowerment. The interview guides will be developed by reviewing the available literature and mutual consultation with experts within the team. All the interviews will be tape recorded after taking informant consent from the participants. The data collection will continue till the level of saturation is achieved. All the interviews and discussions will be conducted in the local language, convenient to the participants.

Data Management

Transcription and Translation

A thorough meeting will be conducted at the end of every interview and discussion sessions. The audio tapes and field notes will be properly labeled with the date, time, name of the group and participants. The moderator and the note taker will examine all the field notes. After the discussion, further probes and additional questions may be added to the interview guide for next interview or discussion, if required. All the recorded interviews will be transcribed to Sindhi/Urdu followed by

translation to English language. After the translation, the moderator and translator will check the translated script against the recorded tapes for accuracy and consistency.

Data Analysis

Analysis of the qualitative data will be conducted using Braun and Clark's thematic analysis (Braun & Clarke, 2006). The researchers will begin by familiarizing with the data, generating codes, searching, reviewing and naming themes. Relevant categories will be picked from the transcribed data and linked to the different themes. All disagreements will be discussed and consensus will be reached on the overall analysis. All the transcripts will be reviewed again in the end to make sure that the necessary information had been captured.

Phase 2: Cluster Randomized Control Trial

In the second phase, a Cluster Randomized Control Trial will be performed for 2 years.

Inclusion and Exclusion Criteria

The couples will be recruited from the list of women who are receiving BISP-CT and meet the eligibility criteria of: adult married women who: receive BISP-CT, have one child of at least 18 months and have no family migration plan for next 2 years.

The couple in which either of the partners has gross mental impairment, physically challenged or bedridden, will be excluded.

Sample Size

There will be three groups for cRCT. The first group will receive LSB to BISP-CT beneficiaries and their husbands. The second group will receive LSB only to women receiving BISP-CT. The third group will be the control arm who will receive BISP-CT only. Assuming an average cluster size of at least 25 couples, with the baseline prevalence of depression 60% and expected reduction of 20% in intervention arm, 9 clusters per arm would be needed over a period of two years. There are three arms and 9 clusters in each arm so a total of 675 couples (225 in each arm, 25 in each cluster). By accounting for the attrition rate of 25%, a minimal of 846 couples (282 per arm) would be needed.

Sampling Strategy

During the first level of assessment, out of the four Tehsils in District Thatta, Tehsil Mirpur Sakro will be finalized for the intervention, since Tehsil Thatta is saturated with other NGOs/Projects, Tehsil Ghorabari and Tehsil Ketu Bunder are difficult to manage administratively, being far away and coastal areas. At the second level of assessment in Tehsil Mirpur Sakro, the UCs will be assessed based on the demographic characteristics, infrastructure, health facilities, accessibility and women mobility. The UCs being administratively hard to reach i.e. lack proper infrastructure (roads), saturated with other projects, being close to city with urban settlements, will be excluded. Three UCs i.e. Gharo, Gujjo and Chowbandi will be identified as the potential sites for the intervention. Within the UCs, Deh/Village is the smallest unit, but since there is no clear demarcation between Dehs, therefore village or a group of small villages will be considered as a cluster. The clusters will be created by grouping small villages with respect to geographic boundaries, ethnic cast and number of households. Each cluster will have sufficient number of households to achieve the targeted cluster size. The large geographically separated villages will be considered independent clusters. The mapping of clusters will be done in a way to maximally avoid contamination. A minimum of 27 clusters will be selected randomly from a sufficient pool of clusters i.e. 9 from each arm keeping same number of clusters per arm in each UC. At the third level of assessment, the clusters of the selected UCs will be randomly assigned to three arms. The clusters will be selected for randomization based on the assumptions, i.e. having sufficient number of BISP beneficiary households meeting our eligibility criteria, the intervention and control clusters will not be in close proximity thus chances of contamination are minimal.

Operational Plan

The implementation of the manualized LSB curriculum will be delivered through 10-12 sessions (10 for couples, 2 for family including mother-in-law, supporter or head of the household), one session per week for each cohort of 282 couples. Therefore, for three cohorts, a total of 846 couples, will require nine months. There will be 12 LSB teachers (8 females, 4 males) working in six pairs for six groups (4 women, 2 men) for the entire year. The purpose is to ensure high quality staff, optimum delivery of the intervention between the cohorts, and proper fidelity monitoring. Regarding the data collection plan, the data collection points are pre-intervention (baseline) and post-intervention (end-line, five months). The schematic illustration is mentioned below in figure 4.

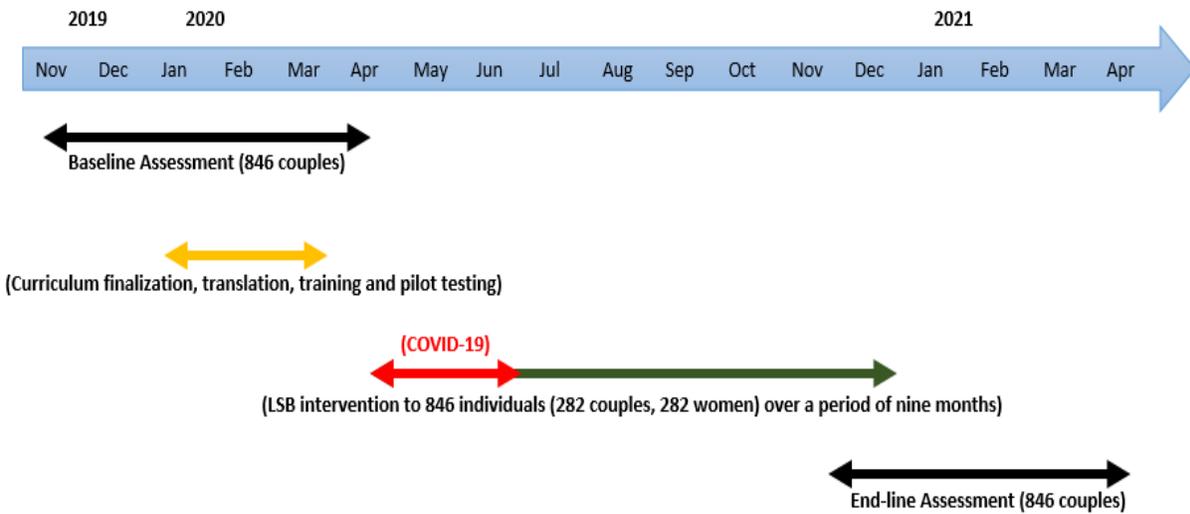
Safety protocols amid COVID 19

Capacity building of the research team will be carried out, where a comprehensive COVID-19 awareness training will be offered to the field team. The field preparations will include; adequate supply and use of PPEs (face masks, sanitizers), information communication material (in local language) to be used in field office and community settings. Furthermore, the team will work closely with the DC office Thatta to obtain the list of nearby health facilities assigned by the provincial government to provide COVID-19 screening, testing, isolation/quarantine, treatment/referral in the study area. This exercise will ensure the safety and wellbeing of staff and community participants, before the actual delivery of LSB intervention in the study area.

Moreover, to ensure the wellness of field staff, an orientation regarding the use of CoronaCheck; a new mobile app that enables them to easily and safely evaluate symptoms with an in-home screening tool and understand the next steps they need to take to look after themselves, will be provided. The app allows the staff to understand their symptoms, identify whether they may have contracted COVID-19 and seek help in a timely manner. It also helps the staff to identify potential coronavirus carriers and limit their risk of transmission. It will be assured that, the staff should use the app on daily basis as they come to office and contact AKU employee health service for initial screening and if needed testing.

In community, the participants will be provided awareness sessions on novel corona virus and measure to keep the surroundings safe and healthy. Furthermore, they will be provided PPEs (face masks and sanitizers). In order to maintain the safety and wellness of both LSB teachers and participants, social distancing and frequent hand washing will be ensured during each session. Large groups sessions will be avoided and the number of participants will be restricted between 5-6 per session. Two sessions per day will be conducted instead of one by each pair of LSB teacher, to train 10-12 participants as per the plan of delivery.

Figure 4. Schematic illustration



Process Outcome Measures

Outcome measures for men and women receiving LSB training are the same. Process indicators include number of couples trained, number of sessions attended by couples, and number of follow-up assessments completed.

Data Management

Pre-testing

The translated versions of the questionnaires will be pre-tested by being administered to approximately 10% of the sample size in a district similar to the selected district. The completed questionnaires will be sent for data entry so that the psychometric properties of the scales will be checked. Any difficulties in translation, comprehension or item performance will be resolved by team discussion after this and final changes made to the questionnaire.

Tracking Participants

The study dataset will be a closed cohort and so it is important to track participants to determine cause of any loss to follow up and also to be able to connect interviews completed at different rounds. In order to do this we will complete an enrolment form for each couple in the study. These will be completed on paper and will be stored under lock and key at Aga Khan University. Each tracking form will include a randomly generated 6 digit number which will be that couple's

research ID and initials. In electronic data the couples will only be identified by research ID and initials which cannot be electronically linked to their name.

The tracking form will include the following information:

- Allocated ID
- Name
- Union Council, Tehsil, District
- Address
- Contact numbers
- CNIC numbers of couple

Assessment Tools

The outcomes will be assessed through validated instruments including Patient Health Questionnaire (PHQ-9), The Revised Conflict Tactics Scale, General Self-Efficacy Scale, Resilience Scale, Economic Solvency, Gender Equitable Attitude Scale and Six-item Food Security Questionnaire. Pilot testing will be done followed by modifications in the tools, if and where required.

Demography

Demographic profile will be used to assess the overall information about the family, its economic and educational status. This form was designed and utilized in the Global Network Research Unit (GNRU) project on perinatal infections and pregnancy outcomes which was funded by National Institute of Health (NIH), with AKU and University of Alabama as partners and other AKU funded researches (Karamaliani et al., 2009). This demographic profile form includes two sections:

Section A: Demographic profile: age, education, language, number of family members, number of married or unmarried and previous pregnancies and number of children.

Section B: Socio-economic Status: number of people actively working including type of work, timings and utilization, type of living with accessories and water drinking.

Section C: Economic Solvency: Financial assistance received other than BISP, financial assistance received for child support and cash assistance received from other people.

General Self-Efficacy Scale (GSE-10)

This 10-item instrument was created to assess a general sense of perceived self-efficacy with the aim to predict coping and adaptation after stressful life events (Schwarzer, 1995). Responses to each item are made on a 4-point scale: 1=Not at all true, 2=Hardly true, 3=moderately true, 4=exactly true. The possible range of scores is 10 to 40. In samples from 23 countries, Cronbach's alphas ranged from 0.76 to 0.90, with the majority in the high 0.80s. For the GSE, the total score ranges between 10 and 40, with a higher score indicating more self-efficacy (Schwarzer, 1995). For this study, the Urdu adaptation of the GSE tool, developed by Tabassum, Rehman, Schwarzer, and Jerusalem was used (Tabassum et al., 2003).

The Revised Conflict Tactics Scale (CTS2S-20)

The revised conflict tactics scale consists of 20-item and is self-administered. The scale includes items regarding Negotiation (1-4), Psychological aggression (5-8), Physical assault (9-12), Sexual coercion (13-16) and Injury (17-20). The scoring criteria consists of a scale from 1-8, 1-6 indicates the frequency of conflict happened in the past year ranging from once to more than 20 times. 7 indicates conflict happened not in the past year but happened before that. If it never happened, 8 will be marked (Douglas & Straus, 2004). There are many ways to score the CTS: Respondents who reported being a victim of or perpetrating an item or items (Prevalence). The number of times an item occurred in the past year (Frequency). Classifying each case into three categories: none, minor only, or severe (severity level). Classifying each case as respondent only, partner only, or both (mutuality types). For this study, Sindhi translated version will be used after pre-testing.

Patient Health Questionnaire (PHQ-9)

The Patient Health Questionnaire (PHQ) is a self-administered instrument for common mental disorders. The PHQ-9 is the depression module, which scores each of the 9 DSM-IV criteria as "0" (not at all) to "3" (nearly every day). It is used to monitor the severity of depression and response to treatment. It can be used to make a tentative diagnosis of depression in at-risk population (Kroenke, Spitzer, & Williams, (2001). For this study, the Urdu adaptation of the PHQ-9 tool will be used (Ahmad et al., 2018). This tool has been translated into Sindhi language and will be used in this study. PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5,

10, 15, and 20 represent cut points for mild, moderate, moderately severe and severe depression, respectively.

The Resilience Scale (RS-14)

We will use Wagnild's resilience scale for our study. This tool has been validated in Urdu in Pakistani context. This resilience scale comprised of five core characteristics of resilience that include: purposeful life, perseverance, equanimity, self-reliance and existential loneliness. It comprised of validated 14 items with 7-point Likert scale to rate the individual's evaluation ranging from 1 (Strongly Disagree) to 7 (Strongly Agree) (Shehzad et al. 2015). Item scores are summed to yield a total score ranging from 14 to 98, with higher scores suggestive of greater perceived resilience categorized as very low (14-56), low (57-64), on the low end (65-73), moderate (74-81), moderately high (82-90), and high (91-98).

Gender Equitable Attitude Scale (GEAS-21)

The Gender Equitable Attitude Scale is a 21 item scale with Likert scale ranging from 4 (strongly agree) to 1 (strongly disagree). It has been adapted from 34-item original "The Gender-Equitable Men Scale (GEM Scale)" and 13-item "Gender Equitable Men Scale" adapted in the context of Pakistan. This scale has been tested by Pak-IMAGES study by Promundo and Men's HUMQADAM program by Rozan (Ashfaq et al., 2018). Factor analyses support two subscales, and the scale is internally consistent ($\alpha = .81$) (Pulerwitz & Barker, 2008). The total score ranges from 21-84, where higher score shows more gender equitable attitudes.

Six-item Food Security Questionnaire (FSQ-6)

A six-item food security questionnaire (FSQ) will be used to assess the food insecurity. The scale is valid, reliable and sensitive screening tool of food insecurity in people. One study had found that a strong correlation between the two-item and six-item FSQ ($\rho: 0.895$; 95% CI 0.821, 0.940; $P, 0 < 0001$). Cronbach's α coefficient was found to be 0.94 and 0.90 for the two-item and six-item FSQ, respectively. FSQ yielded a sensitivity of 100% (95% CI 75, 100) and a specificity of 78% (95% CI 61, 90). The negative predictive value was found to be 100% (95% CI 88, 100) (Young, et.al 2009). The total score ranges between 0-6, where score 0-1 shows high or marginal food security, score 2-4 shows low food security, score 5-6 shows very low food security.

Data Analysis

To avoid possible human error of missed or incorrect entries, the entered data will be cross checked initially by data coordinator, and discussed with research team and principal investigators, if required. All the data will be double entered in Excel, followed by congruence check and cleaning. It will be imported to STATA version 12.1 for the analysis, after cleaning.

Descriptive Statistics: Descriptive statistical analysis will be run to look at the distribution of variables of interest and for outcome variables. Mean and standard deviation will be calculated for continuous variables, proportions will be calculated for the categorical variables.

Logistic regression will be used to assess the effect of LSB with maternal depression and other outcomes. All variables meeting the criteria will be used for building the final model. The variable found most significant in the univariate analysis will be subsequently added first and the next significant variable one after the other. Variables found statistically non-significant (>0.05), biologically not meaningful will be removed from the model. Multivariate logistic regression will be carried out to reach to the most parsimonious model.

Communication Plan and Stakeholder Management

The project team will involve stakeholders at multiple levels. At national, coordination with BISP office in Islamabad and other relevant programs on maternal and child health will be carried out to sensitize them about the study scope and the outcomes and their implications on policy. Study team will meet regularly in coordination with Umeed-e-Nau program management over the study period and will discuss the project implementation.

Local stakeholders will include the BISP offices in Sindh province. Regular coordination is needed with the provincial office Local Health Department in the study will also be presented the results. Biannual meetings will be set with local stakeholders to share research progress and milestones.

Monitoring and Evaluation Plan

The primary responsibility for monitoring the fidelity of the intervention delivery will rest with Aga Khan University and they will be required to ensure that a log sheet is kept recording the trainings conducted by faculty of AKU to train LSB teachers and number of couples who attended the training. This information will be reported quarterly to Principal Investigators. The information

will be compared to the planned intervention delivery schedule and deviations will be flagged and fed back to the project management team.

The research team will have responsibility for spot checks on the fidelity logs and field visits to ensure accurate, timely and smooth data collection and the LSB intervention delivery. The field coordinators will visit each intervention site independently for the monitoring of data collection and LSB intervention.

Project Management Structure and Organization

The overall responsibility for the study is on PI, component lead and co-lead and Co-PIs from the Aga Khan University School of Nursing and Midwifery, Psychiatry and Community Health Sciences department and they will have final scientific responsibility for the study including the research conduct, reporting of main outcomes, stakeholder relations and dissemination of findings. They will be supported in this role by technical advisor Professor Judith McFarlane of Texas Woman University. The project is multidisciplinary and will draw on expertise from a range of faculty members from other disciplines at Aga Khan University.

Technical and Financial Reporting

This team will report technically and financially to PI and Co-PI of Umeed-e-Nau (UeN) at COE-WCH, AKU and the funding agency.

Ethical Considerations

Ethical approval will be obtained for the present study from Ethics Review Committee (ERC) of Aga Khan University (AKU) Karachi. Permission for data collection will be taken from the concerned stakeholders. Study related material will be explained verbally and a brief description of study will also be provided in the consent form. It is also clearly explained in the consent form that there is no benefits or potential risk attached with the study. Furthermore, the members were given the right to withdraw at any stage of the study. Keeping in view the comfort level of participants the qualitative data collection (FGDs & KIIs) will be carried out in local languages. For Sindh the guides will be used in Sindhi language while for Khyber Pakhtunkhwa (KPK) the guides will be used and facilitated in Pashtu language. However, participants from Rahim Yar Khan and Labella will mainly be facilitated using Urdu version of interview guides will be used.

During the data collection and analysis time the data will be stored in lock and key and only PI and designated study members will have access to it. Confidentiality and anonymity of the participants will be maintained during the entire process of the study. However, direct access will be provided to regulatory bodies for monitoring and audit purpose.

Not a single participant will be enrolled in the study until the trial is registered with the Clinical Trial Unit (CTU). The process of trial registration will be initiated once the pre-testing of assessment tools has been completed.

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