

Health and Social Literacy Intervention to Improve Maternal Health: Study Protocol for a Randomized Pre-Post Test Design with a team-building intervention for primary healthcare teams and community needs assessment

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Study protocol

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Abstract

Background: The majority of poor, illiterate women of reproductive years in Pakistan are living in underdeveloped regions and are solely dependent on free primary health services provided by the state. This project aims 1) to collect baseline health and social data, 2) to deliver a health and social literacy intervention, 3) to deliver a team-building intervention for primary-level healthcare providers, and 4) to conduct a community needs assessment.

Methods: Electronic health and social data will be collected at baseline, which will be used to develop a comprehensive database and develop an index for Maternal Health and Wellbeing. A 24-month intervention will be delivered which will have 6 modules related to health and social literacy. The principal investigators will train the data collectors and intervention facilitators. Lady Health Workers will collect the electronic data and pre-post test data, and Community Social Workers will deliver the health and social literacy intervention. Cluster randomized sampling will be used to sample 6 BHUs across 6 different cities of Punjab, Pakistan. A total of 360 women will be sampled and assigned randomly to the experiment and control groups. The principal investigators will deliver the team-building intervention and conduct the community needs assessment. The participants for the latter will include doctors, nurses and community health workers; and for the former will include women from the community, women community health providers, community elders and religious leaders, and local government officials.

Discussion: Pakistan is falling behind on its sustainable development goals for maternal health, mainly due to the limitations of the existing services and literacy of women. There is critical need to support understaffing of current providers by partnering them with community social workers and training them for better care delivery. Similarly, women need support for gaps in both health and social literacy. Development of an index and community needs assessment report can support better identification of environmental and socio-cultural needs in the community and to advise policy makers and stakeholders about issues wider which directly and indirectly impact women's health.

Trial registration: This study has been registered with ClinicalTrials.gov. The identification number is: NCT05389501.

Background

The World Health Organization (WHO) has identified that building an effective primary health structure, with a focus on preventive healthcare, is the best approach to achieving the Sustainable Development Goals (SDGs) for maternal health [1]. High income countries have managed to improve maternal health indicators by strengthening the primary workforce with community social workers (CSWs) [2]. Countries from the Global North, like Canada and the Nordic nations, have gained favorable health outcomes at primary level for maternal and child health through the integration of social workers, who constitute one of the largest groups of interprofessional health workers in supporting women's health and wellbeing [3, 4].

The main aim of CSWs has been to identify the social determinants of health and support salient areas for improved health outcomes of vulnerable groups like women, children, elderly, and the disabled [5–11]. CSWs have been shown to successfully provide relief and improvement for primary health services of women through the following means: (i) Building databases and performing risk assessment; (ii) Directly providing or referring for counseling and therapy; (iii) Assisting in capacity building for financial inclusion of women; (iv) Collaborating with other professions for program development and policy intervention; (v) Improving social and health services through need assessment, liaising and referral; (vi) Developing community linkages and partnerships with community and government resources; and (vii) Providing education, literacy, and skill development to adult women in need [12–17].

Majority of women in Pakistan are dependent on primary healthcare

A majority of the approximate 110 million women in Pakistan depend on primary health services provided free of cost by the government within their community [18]. This is due to multiple reasons, such as poverty, unemployment or informal sector employment, and lack of health insurance [19]. Though the government Sehat Sahulat Programme claims to provide universal coverage in the country, its reach is minimal, at 5 million people to date, and it is not focused on maternal health services, and is limited mainly to coverage for hospitalization [20]. It is because of this that Pakistan has one of the largest out-of-pocket healthcare expenditures at 90% [21], with less than 1% of women covered by the private health insurance sector [22].

Maternal health indicators are not favorable in the country, with neonatal mortality at 55 per 1,000 live births and maternal mortality ratio at 274 per 1,000 live births [23]. Pakistan faces multiple social issues that compromises the health of mother, such as cultural traditions that dismiss health-seeking behavior, lack of permission to visit healthcare providers due to honor and patriarchy, and lack of access to digital technology and information which can provide updated information about health services [24, 25]. However, the key challenge facing women is low health literacy and inadequate social literacy to navigate cultural and structural barriers to maintain health. Of concern also is that within communities, women are living in isolation without comprehensive social services and low literacy and awareness that prevents personal initiative for health behavior modification. There is a critical need for health literacy to be supplemented with social literacy initiatives so women are able to apply their knowledge about health in their daily lives through social skills [26].

Pakistan's primary level services for maternal health

One of the main governance challenges facing Pakistan is to improve the primary healthcare system, especially for maternal and child health [27]. The total government health expenditure as a proportion of GDP is 0.8% [21], and from this extremely low allocation, the primary health sector is known to be allocated the least portion compared to the tertiary sector [28]. There is no electronic health database which includes both social and health indicators, or an index for maternal health in the country [29]. The

former is needed to understand the social and environmental challenges which prevent improvement in health outcomes, and the latter is important, so a composite figure or index score is calculated longitudinally to help track and improve initiatives. The existing primary health workforce for women's health consists of the lady health worker (LHW) programme. LHWs visit homes of women in the community and can also be found at the community basic health units (BHUs). The LHWs are responsible for services related to reproductive and maternal health, vaccination and immunization, promoting health awareness, referral to secondary and tertiary sector, and routine counseling [30]. With the coronavirus pandemic, the additional burden of infection control and preventive education has been placed on LHW shoulders [31].

There are currently 4,996 BHUs serving a population ratio of 1:10,000 and a total of 110,000 LHWs serving a population of 1,000–1,500 women clients in the country [32]. These ratios reflect the excessive burden on each LHW. Excessive role burden, understaffing and low salaries are major challenges to the motivation, job commitment, and service quality of LHWs [25]. Furthermore, many women living in underdeveloped regions of Pakistan still do not have access to BHUs or receive door to door visits by LHWs [33]. Each BHU includes a doctor, nurse, and LHW, however, the units are known for their limitations such as: lack of team work and coordination for patient care; distant locations; staff unavailability; low budget allocation; and governance problems [34]. One way forward to tackle the work burden of LHWs and service inefficiencies of the BHUs is the integration of CSWs in the team. CSWs have not been utilized to help improve primary health services or support the development of a social policy protection floor for women in Pakistan [35], as they have successfully done in developed countries [36].

Health and social literacy

Although a number of efforts have been made to improve health awareness in Pakistani women, there is still critically low health literacy and inadequate health practices in women of the country [37]. Low health literacy is known to be associated with demographic characteristics such as: illiteracy or limited education, lower income, conservative family structures, and living in underprivileged regions [38]. The consequences of low health literacy for women are not just limited to self-care, but extends to the care and health management they are able to provide to children, family and other dependents [39]. Given that women are considered primary care providers within the home, improved health literacy of women is critical to overall improvement in health indicators and family wellbeing. In addition, there are immense financial and social burdens placed on the healthcare system due to low health literacy in women, making this area a high priority for Pakistan.

Women in Pakistan are known also to be plagued with low social literacy, which prevents them from interpreting and dealing with life situations and challenges [40]. Social literacy skills and social knowledge is important for women to be able to understand, communicate and deal with complex situations through emotional intelligence [41]. Social literacy can also help women to find solutions to differences in opinions and conflict, through identification of the cultural and behavioral context and development of critical thinking [42]. Many high-income countries have included social skills in their educational curriculum to secure development in areas of personal and health wellbeing [43]. The

majority of women in Pakistan are facing multiple challenges related to culture and family, poverty and employment, climate change and environment, and thus social literacy skills would help them to manage their circumstances and relations to improve their health and wellbeing.

Disadvantaged women from developing and conservative regions, and belonging to patriarchal households, require both health and social literacy skills so they can negotiate and communicate with family and outsiders in a way that their own and their child's wellbeing is secured without compromising family traditions and values. By gaining skills in health and social literacy women can better recognize differences in practices, beliefs, and values, and thus learn how to deal with multiple agents, including inlaws, husband, and community healthcare providers. For women who have not been educated or schooled in a setup that has trained them for health and reproductive education or critical thinking, as is the case in Pakistan [44], an intervention for health and social literacy in adult years is imperative. In fact, LHWs regularly complain about the low health literacy and social skills of women clients, who are unable to modify health behavior for positive health outcomes [45].

Project research questions

This project aims to answer the following research questions:

- (1) Can LHWs collect both social and health data for women of reproductive years in one electronic health database, so this data can be used by principal investigators (PIs) to create a much-needed Index for Maternal Health and Wellbeing?
- (2) Can CSWs make an impact on women of reproductive years in primary communities through a health and social literacy intervention?
- (3) Can the delivery of a team-building intervention by the PIs improve and strengthen the collaboration and care plans of the BHU team?
- (4) Can an independent community needs assessment, completed by the Pls, be used by policy-makers and governments to identify ground-level challenges of social policy failure facing women in the community?

Methods

This is a cluster randomized control trial, which uses a pre-post test design to measure the impact of: (i) a health and social literacy intervention delivered to women of reproductive years and (ii) a teambuilding intervention to improve interprofessional collaboration of the primary healthcare team. The secondary aim of the project is to: (i) develop an electronic health database with health and social indicators, which can also be used to develop an index for Maternal Health and Wellbeing, and (ii) to develop a community needs assessment report which identifies environmental and social needs in the community which prevent optimal health outcomes. Senior peer consultancy has been taken from experienced researchers and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist [46] has

been used to plan this project. All surveys and intervention material will be translated in the Urdu language by team members who are bilingual through the forward backward method.

Recruitment and selection criterion of data collectors and intervention facilitators

We will be recruiting and training existing LHWs to collect the electronic health and social data and to conduct the pretest-posttest questionnaire. The selection criterion for LHWs will be (i) currently employed and under contract with the government of Pakistan, (ii) with work experience of at least 5 years, (iii) married with children, (iv) permanent residents of the community. Help from the LHWs will be taken for the recruitment of CSWs to deliver the social and health literacy intervention. This will help in the following ways: (i) LHWs will be able to identify women within the community who are accepted by the participants as 'insider' members of the community, (ii) LHWs will be able to identify women who are interested in working on the project and remain with the project for the next two years, and (iii) there will be higher chance of LHWs and CSWs working congenially together and providing support to each other. The selection criterion for CSWs will be: (i) married with children, (ii) permanent residents of the community, and (iii) minimum schooling of secondary years or 10th grade. The recruitment for participants, data collectors, and intervention facilitators started in July 22 and training for a month was conducted in August 2022. The intervention started in September 2022.

Training and fidelity of data collectors and intervention facilitators

The LHWs and CSWs will be trained over a one-month period through online videos and calls. A cascade-based approach of training will be followed. The LHWs will be trained first by the Pls using in-person (Fig. 1) and online sessions, including Skype meetings, Zoom meetings, and a WhatsApp group (Fig. 2), which will allow exchange of written text, audio messages, and video calls. The training support and communication will remain through the 24-month study period and Pls will be in daily contact with the LHWs and CSWs through the Whatsapp group.

Video tutorials will be recorded and sent to the LHWs and CSWs, so that they can watch these videos more than once and when needed (Supplementary File 1: Youtube links to training videos). After recruitment of the CSWs, the Pls and LHWs will train the CSWs together. When the CSWs will deliver the literacy intervention, the LHWs will be available in person and the Pls will be available online for support. CSWs will also be provided laminated content material so they can use and share it with participants through the intervention period for reinforcement. The continuous communication through online means and periodic visits by different Pls to site will give a chance for clarification, feedback and trouble-shooting of any problems during the intervention. One or two members of the Pls will be available on Whatsapp during the monthly group literacy sessions to support the CSWs and communicate with the women participants when and if needed. The LHWs will be collecting data on their smartphones and will also use these phones to show the principal investigator trainings, for each module, to the group

participants. The PIs will also be able to communicate with participants online and answer questions if needed.

Randomization and masking of participants for health and social literacy intervention

The selection criteria for the women participants are: (i) women of reproductive years, (ii) who are currently enrolled in the LHW programme, and (iii) who reside in the selected underdeveloped communities (having low literacy and poverty). We will be sampling women from Punjab, which is the most populated province of Pakistan with an estimated women population of 55 million [18]. The existing list of women clients enrolled with LHWs will be used to randomly select every third woman participant for inclusion in the study. Consenting women participants will be allocated to a control and experiment group. The experiment group will be sampled from three BHUs across three cities (Lahore, Faisalabad, and Multan) and two CSWs will be recruited in each area to deliver the intervention (Table 1). To prevent contamination, three BHUs from three other cities (Islamabad, Gujranwala, and Sialkot) will be sampled to include women in the control group. All six cities in the study are comparable in terms of population size and level of development. The sample size has been derived through the Taro Yamane formulae: $n = N/(1 + N(e)^2)$; where 'N' signifies the population under study. We estimated the women population receiving services from LHWs at 65.4 million women, as it is reported that 100,000 LHWs are working in the country to serve an estimated 60% of the women population [47]. Based on the formulae, and budget limitations, we targeted a final sample of 360 women of reproductive years- 180 in the experiment group and 180 in the control group. The CSWs, or intervention facilitators, and the women participants will know which group they are allocated to, however, they will not know the study hypotheses.

Table 1
Proposed data collection plan from Punjab, which is almost 60% of the population of Pakistan

City	Community Social Worker*	Lady Health Worker	BHU	Sampled women	Sampled women
				(Experiment)	(Control)
Lahore	2	1	1	60	
Islamabad		1	1		60
Faisalabad	2	1	1	60	
Gujranwala		1	1		60
Multan	2	1	1	60	
Sialkot		1	1		60
Total	06	06	06	180	180

Note: Each community social worker (CSW) will deliver an intervention to 30 women, in monthly group sessions with 10 women each (a ratio of 1 CSW: 10 women clients).

Baseline and pre-post test data collection

The health and social literacy intervention will be a 24-month project, which will start in August 2022 and last till August 2024. The electronic health and social data and the pretest-posttest data will be collected by LHWs, at the door-step of women respondents, through the assisted method as participants will be illiterate or semi-literate. Google survey forms will be developed for the project with different tabs for each data category to store relevant data. The data will be collected on LHW smartphones and then transferred to Pls, who will monitor data entry through shared google drive. The CSWs will deliver their monthly group sessions to 10 women participants and they will coordinate to include women living closest to each other in each group. The monthly group session will take place at the most convenient location for the participants, which may include the open space outside the BHU, or the home garden or veranda area of the CSW or a volunteer participant from the group, or a volunteer from the community. The choice will depend on permission, convenient distance for all participants, and the space that provides the most privacy. Table 2 includes information related to the project intervention stages, the deliverables, the Pls responsible for project part, and the budget allocation.

Table 2 Summary of the intervention steps, with details, deliverables, investigator responsibility and funding allocation

Intervention / Activity	Brief Details	Deliverables	PI Responsible
Database development using digital app	 Collection of health and social data at baseline and development of an electronic database Finalization and communication of Index for Maternal Health & Wellbeing 	- Socio-demographic predictors for health outcomes and index will be published in a paper - Electronic data and index will be shared with policymakers & healthcare professionals	thws + Supervisor Pls: SRJ, HA, AM & FNM
Community needs Assessment	- Assessment and observation notes by Pls, with FGDs and IDIs with community members and stakeholders will be conducted over a two-month period in the first 6 months of the project start	 A detailed community needs assessment report Meetings & seminars with community stakeholders and policy makers will be held for advocacy of needs 	<i>PIs</i> : SKB, RRD & SRJ
Team- building intervention for BHU health workers	 Three training workshops for BHU health workers will be arranged to improve communication, information-sharing and improved care plan development for clients A pretest and posttest survey will be administered at the beginning and end of the training 	 Impact results of intervention will be published in a paper Findings will be used to guide policy makers and BHU team about improvement in interprofessional collaboration 	PIs: AM, SKB & SRJ
Health and social literacy intervention	 Monthly groups sessions with participants and family members will be held over a 24-month period A pretest and posttest survey will be administered at the beginning and end of the intervention 	- Impact results of intervention will be published in a paper	CSWs + Supervisor Pls: SRJ, HA, AM, AJ, RRD, & SKB

Sampling and data collection for community needs assessment and team-building intervention

The community needs assessment and the intervention for team-building to improve interprofessional collaboration of the primary healthcare team will be conducted by the PIs, who have diverse specialties

and experience in delivering training for team-building and collecting data for community needs assessment reports. Six BHUs will be sampled from underserved areas of Lahore, which are known to have urban slum zones. Data for the community needs assessment report will be collected over a two-month period, with visits by Pls twice a week during the data collection period. The data will include assessment and observation notes by Pls, along with focus group discussions (FGDs) and in-depth interviews (IDIs) with LHWs, community elders, women of reproductive years, and local government officials from each city area, to gather the relevant data. The selection criterion for the BHU team-building intervention will be currently employed BHU healthcare providers who are under contract with the government of Pakistan. We will ensure that all team members including the doctor, nurse and LHWs of the BHU center are part of the workshop. A joint certificate from University of Health Sciences, University of the Punjab, and Forman Christian College University will be given to the participants, as an incentive to make them participate. The workshop will consist of a three-day training which will be interactive, include presentations by different experts, and including team-building and care plan development activities.

Project phases

The project phases have been summarized in Fig. 3 and described below.

1.Electronic Health and Social Data Collection and Index Development

The electronic health and social data collection will be done at six BHUs across Pakistan, where the intervention for social and health literacy is planned. The data will be collected by the LHWs once at the start of the study. Three resources will be used to select key health and social variables to be collected, including: (i) Demographic and Health Survey [48], (ii) 'Multimorbidity Assessment Questionnaire for Primary Care'[49], and (iii) A Practical Guide to Measuring Women's and Girls' Empowerment in Impact Evaluations [50]. The following domain areas will be measured: (i) Wellbeing, personal growth, and financial strain; (ii) Lifestyle, early life experiences, stress and trauma; (iii) Social relationships, closeness, and household tasks; (iv) Personality, conscientiousness, and extreme behavior; (v) Work satisfaction and work-life balance; and (vi) Self-related beliefs, constraints and social status (Appendix A). Based on this data we will also be able to screen participants for risk and determine need for specific services and further referral, such as therapy, chronic disability management, or other health risk. This data will be used to develop an index for Maternal Health and Wellbeing.

2. Community needs assessment

A community needs assessment will take place for three underserved BHU areas of Lahore city. The detailed and recommended guidelines and resources by University of Kansas: The Community Tool Box (2015) will be used for the assessment of the communities [51]. This is an adequate tool to assess underdeveloped regions and identify problems facing women and families. The report will include key areas related to existing services and quality of: (i) housing and sanitation, (ii) water and food security,

(iii) waste disposal and sewerage system, (iv) transport services, (v) schooling and education services, (vi) safety and security, and (vii) availability of loan, entrepreneurial and poverty schemes.

3. Team-building intervention for BHU health workers

Training workshops for team-building will be arranged for three BHU teams (including the doctor, nurse and LHW) of Lahore over a three-day period. The aim will be to improve teamwork and collaboration and help BHU providers to develop improved care plans for their clients. The agenda will also include opportunity to share challenges and trouble shoot. A pretest and posttest survey will be used to measure the impact of the workshop on the BHU team, using the "Performance of interprofessional primary health care teams" survey [52]. The domain areas that will be measured include: (i) Workload measurement and Staff experiences; (ii) Patient experience and patient health status; (iii) Collaboration and peer feedback; (iv) Patient goals; (v) Care coordination; and (vi) Co-treatment and referral (Appendix B).

4. Health and Social Literacy Intervention

The health and social literacy intervention will be delivered to the participants in the experiment group over a 24-month period across three different cities. Each CSW will be responsible for 30 participants and deliver monthly group sessions at a ratio of 1 CSW:10 women participants. In this way, each CSW will host 3 group sessions per month to cover all their allocated participants. In alternative months a target of 10 women community members and family members, including husband and mothers-in-law, of the intervention participants will be included in the group sessions. The impact of the intervention will be measured based on the results from a pretest and posttest survey (**Appendix C**).

The literacy content for each of the six sub-areas of the intervention have been summarized in **Appendices D-I**. Each of the six literacy sub-areas will be covered in monthly group sessions comprising of 24 points of contact, and each literacy sub-area will be covered minimum 7 times to maximum 9 times (**Appendix J**). The guidelines for the intervention literacy content have been prepared by the PIs and include checklists, case-studies, group activities, brainstorming sessions, and community social services information (example, local loan services and insurance providers) which will help to elaborate on the training, promote understanding, reinforce knowledge areas, and help in absorption and retention. We believe this will help to promote transfer of literacy to practice in the long-run. The six sub-areas of the health and social literacy include:

i. Health Awareness & Literacy: Reproductive and child health

We will use the following standardized international survey, with modification and regional relevancy, for the health awareness and literacy intervention for reproductive and child health: "Knowledge and Reported Practices of Women on Maternal and Child Health" [53]. The following domain areas will be measured including: (i) Pregnancy and antenatal care; (ii) Health knowledge; (iii) Accessing health care;

(iv) Vaccination coverage; (v) Child's father/husband's involvement in maternal and child care; and (vi) Household factors (e.g., hygiene, water and food preparation, waste disposable, and toilet quality).

ii Health Awareness & Literacy: Hygiene and sanitation & nutrition and immunity building

The following two surveys will be used for the health awareness and literacy for hygiene and sanitation and nutrition and immunity building intervention, with modification and regional relevancy: (a) "National Sanitation and Hygiene Knowledge, Attitudes, and Practices Survey" [54] and (b) "The Dutch Nutrition Centre Survey" [55]. The following domain areas will be measured including: (i) Awareness of hygiene and sanitation; (ii) Practices for hygiene and sanitation; (iii) Knowledge and salience of nutrition; (iv) Preoccupation with nutrition and immunity building; and (v) Deliberate control of nutrition behavior.

iii. Health Awareness & Literacy: Health-risk behavior modification

The following standardized international survey will be used for the health awareness and literacy for health -risk behavior modification intervention: "Kilifi Health Risk Behavior Questionnaire" (KRIBE-Q) [56]. The following domain areas will be measured including: (i) prevention for Injury and Violence; (ii) Use of intoxicants; (iii) Neglect of chronic disease management; (iv) Physical Activity Behaviors; and (v) Seeking health consultancy and follow-up.

iv. Social Awareness and Literacy: Mental accounting and savings habits

We will be using a scale from Bangladesh to measure mental accounting and saving habits in women [57]. These questions have been developed by the authors along with the support of Abdul Jameel Latif Poverty Action Lab. The following domain areas will be measured including: (i) habits for formal and informal savings; (ii) planning and budgeting according to house and family needs, for short-run and long-run; and (iii) habits for loan repayment and future income-earning possibilities.

v. Social Awareness & Literacy: Attitudes about women's role and knowledge of women's rights

We will be using items from a study conducted to measure attitudes about women's role and knowledge of women's rights [58]. These items have have also been used by Abdul Jameel Latif Poverty Action Lab to measure women's role and knowledge of women's rights [42]. The following domain areas will be measured including: (i) Attitudes about women's roles, compared to men; (ii) Attitudes about daughter's roles; and (iii) Knowledge of women's rights.

vi. Social Awareness & Literacy: Women's critical thinking ability

Items from two studies will be used to measure women's critical thinking ability [59, 60]. These studies have also been used by Abdul Jameel Latif Poverty Action Lab to measure women's critical thinking ability [42]. The following domain areas will be measured related to skills for: (i) Interpretation; (ii) Analysis; (iii) Evaluation; and (iv) Inference.

Data analysis

The data will be analyzed using SPSS and STATA. There will be quantitative data from the health and social data and the pretest-posttest survey, which will be analyzed using descriptive statistics and multivariate regression. The health and social data will be used to prepare results about the sociodemographic characteristics of respondents and predictors for improved health. The health and social data will also be used to develop an Index for Maternal Health and Wellbeing based on four domains: (i) Physical and Reproductive Health, (ii) Mental and Emotional Wellbeing (iii) Social Wellbeing and (iv) Financial Wellbeing.

$${\tt Maternal\ Health\ and\ Wellbeing\ Index} = \sum {\tt Weight*Domain\ Score}$$

Maternal Health and Wellbeing Index

$$=\frac{1}{4}*$$
 Domain Score $1+\frac{1}{4}*$ Domain Score $2+\frac{1}{4}*$ Domain Score $3+\frac{1}{4}*$

* Domain Score 4

The pretest-posttest results will be used to show impact of the intervention on: (i) women participants health and social literacy, and (ii) the BHU team-building and interprofessional collaboration. For the former (impact on health and social literacy), the dependent variables will be 'health literacy' and 'social literacy' of women respondents, and the independent variables will be the 'sociodemographic characteristics' of the women. For the latter (impact on BHU team-building), the dependent variables will be 'patient care plans' and 'team building collaboration', and the independent variables will be the 'sociodemographic characteristics' and the 'job satisfaction' of the BHU team. Multiple linear regression will be used to show the higher odds of improvement in participants post the intervention. P values of less than 0.05 will be considered significant for this study and confidence intervals will be reported.

The qualitative data from the community needs assessment, including participation observation notes, FGDs and IDIs will be analyzed using thematic analysis. Notes and interviews will be transcribed and transferred to an Excel file and NVIVO. Both the software and manual theme generation will be used to discover areas of needs and challenges in the community which impact the health and wellbeing of women. The manual theme generation will be done independently by three PIs and then discussions will be held to merge the information and finalize the findings. The final themes will then be shared with independent community members who were not part of the original sample to confirm findings and ensure reliability of data.

Cost analysis

The PIs have received a grant award of USD 8,030.38 for this project. The budget head for payment to intervention facilitators is USD 2,178.48. The PIs will be transferring their allocated share of grant money to pay the LHWs and CSWs a total monthly stipend of for their work on the project of USD 30.25 per month for the project. LHWs will be paid for collecting electronic baseline data and pre-post test data; whereas the CSWs will be paid monthly for the 24 months of the intervention. The limitation of intervention budgets for social science, public health projects, and women's health projects is a well-documented problem in Pakistan [61]. The final publications will include a detailed cost analysis to advise policymakers about role allocation and salary expectations of community health workers of Pakistan.

Data audit

The research project and data analysis will be conducted by the PI team. The funding body will not be involved in the research stages, data collection or data analysis. The project and data will be audited by Forman Christian College University (FCCU), Department of Office of Research, Innovation and Commercialization (ORIC). A six-monthly progress report will be shared with FCCU ORIC, the senior consultants for the project, and the sectoral collaborators for audit, for feedback during intervention and for overall assessment at the end of the project.

Data storage and sharing

All the data related to the project, and the soft copies (google drive data) and hard copies (observation and FGD notes from community needs assessment report), will be stored safely with the lead PI of the team (SRJ). Names of participants will be coded and anonymized before datasets will be shared with other researchers or publication bodies.

Patient and public involvement

This study includes perception-based surveys and literacy interventions, and do not involve any clinical interventions or any risks to the participants.

Pilot test

A pilot test of the baseline survey (including health and social data) and pretest and posttest survey will be held with the LHWs and approximately 15 women participants. These participants will not be part of the final intervention. This will help in finalizing the questions and the translation and providing feedback for improvement. The pilot test is scheduled in the month of July 2022.

Project investigators

An interdisciplinary team from the social sciences (sociology, education, economics, public health, and clinical psychology), humanities (mass communications, English language center), and life sciences (medical physician) will oversee the project. Senior researchers from FCCU will support the project for

peer review, consultancy, budget supervision, and audit. Sectoral consultancy and support for sampling of BHUs and recruitment of LHWs and CSWs will be provided by The Primary & Secondary Healthcare Department, Punjab, Office of the Director General Health Services, Policy and Strategic Planning unit (PSPU).

Dissemination

We intend to have workshops and seminars to disseminate results with key stakeholders, policymakers and the health sector. We also intend to disseminate our findings in international and open access academic journals of repute. We would have to publish results in separate academic papers related to: (i) the impact results for the social and health literacy, (ii) the results for health and social data and predictors for health outcomes, and the index for Maternal Health and Wellbeing, (iii) the community needs assessment report, and (iv) the impact results for the team-building workshops for BHU healthcare providers.

Discussion

The proposed project aims to improve primary healthcare services and preventive health practices for women, specifically related to maternal health. The existing primary healthcare team is critically overburdened and inefficient and this study aims to partner CSWs to improve service delivery for health and social literacy in women. The health literacy aims to improve awareness and practices for: (i) reproductive and child health; (ii) hygiene and sanitation, and nutrition and immunity building; and (iii) health-risk behavior modification. The social literacy intervention aims to improve awareness for: (i) financial accounting and savings habits; (ii) attitudes about women's role and knowledge of women's rights; and (iii) women's critical thinking ability. We intend to deliver these six modules of the interventions through CSWs who are trusted and accepted 'insider' community women. In Pakistan, child health and family health is the responsibility of mothers of the household, and thus literacy and awareness of women will have a positive impact on children and family wellbeing.

The electronic health and social data which will be collected to build a comprehensive electronic database with both health and social indicators, which is missing in Pakistan, and inform policymakers about leakages in a social protection floor for women. Such comprehensive electronic data which guides both health and social policy development is integral for the holistic wellbeing of women in the community [62]. The electronic health and social data will also be used for creating an index for maternal health and wellbeing, which includes social indicators, such as social support and decision-making, and can be valuable in assessing and mobilizing a more effective social and health policy in the future. The index for Maternal Health and Wellbeing could also be used in other regions with similar socio-cultural and environmental conditions for women's reproductive health, such as South Asian and other Muslim regions.

An intervention will also be held with the BHU team to improve care plans and teamwork for care delivery in the primary setup. This will have the effect of strengthening the health workforce team and care

services. It will also benefit collective policy advocacy to the center by a united primary health workforce. This is timely especially in consideration of the critical challenges facing the existing health workforce at primary level which is overworked, understaffed, inefficient, and unable to collaborate for optimal services and care plans or policy advocacy [63].

The community needs assessment will contribute to recommendations for improvement in housing and sanitation, water and food security, waste disposal and sewerage system, transport services, schooling and education services, safety and security, and availability of loan, and entrepreneurial and poverty schemes. Recommendations from the community needs report will also include suggestions for social protection schemes for improved wellbeing and better planning of communities. The community needs assessment report will help to bring attention to the environmental and social factors which are creating challenges for vulnerable women of Pakistan and preventing improved health outcomes.

This project will build a case for not just service efficiency at primary level, but also add to labor market innovations and demand-side employment for Pakistan. Pakistan is in critical need of both strengthening the health workforce [64] and creating jobs for women in the country [65]. Our project will provide impetus for integration of CSWs at primary level, which can create thousands of jobs per year for Pakistan, help to develop both the health sector, as well as provide opportunities for more health workforce development, like integration of public health officers [66]. In this way, this applied research project will benefit the following two industries of the country: (i) Health industry – by building primary health services for maternal and child health and improving preventive behaviors; and (ii) Human resource industry – by creating a demand for CSWs in the heath sector and at community level.

Currently, Pakistan is not meeting SDGs for establishing good health and wellbeing, reducing gender-based inequality, or building partnership for goals. Our project intends to address all three gaps by strengthening the primary health service sector, delivering a health and social literacy, and adding CSWs to the primary healthcare team. Targeting gender equality in health and social services for disadvantaged women is needed especially in consideration that the COVID-19 pandemic has directed policy and budget to infection control and health costs. It is also true that improving maternal literacy and preventive health will help to reduce national health costs in the long run at an estimated USD 45 billion [67]. Models of primary care from the developed world confirm that preventive health services in the primary sector saves lives and health costs over time [68].

There is very little funding and attention for developing social policy in partnership with health policy or expanding preventive health services in the country. Currently, the Sehat Sahulat Programme is covering mainly hospitalization and has not yet considered service improvement and strengthening of the primary health sector. Overall, interventions at primary level have tended to focus on satisfying cultural customs by training and supporting TBAs and local midwives [23]. This has its limitations as there is complete neglect for strengthening of human resources at primary level, and partnering providers with overburdened LHWs [69]. Furthermore, interventions for primary healthcare usually assess satisfaction of

women participants and neglect to improve the quality of services provided by the primary healthcare team [70].

Limitations

Community acceptance of primary healthcare providers and social support officers is always a problem in Pakistan due to cultural barriers. Choosing women CSWs from within the community is expected to help acceptance and participation. To help recruitment and reduce the risk of CSWs dropping out from the project, we will recruit CSWs from within the community, who are married and permanently settled in the area, and through the help of LHWs. The LHWs would be asked to recommend CSWs who are known to them and part of their close community circle so there is social pressure to complete the study. There is risk of violence and abuse against women community health providers in the country [71]. To prevent such a risk, we will be sampling functioning BHUs that are serving a population of above 5,000 people, so the area is reasonably populated, and where the LHWs program is already operational and accepted. This is another limitation of the study, in that we will not be sampling women who do not have access to BHU services.

As LHWs in Pakistan serve a large group of women (up to 1,500 clients), they have to travel quite a bit in the community to provide door to door services. We will have to include women intervention participants who live close to each other and near to the BHU to be a part of the monthly group sessions. In this way, women participants who live at a distance and have time restrictions due to family and work commitments may not be part of the final sample. The impact of the study results will be based on perception-based surveys. Though there is planning to prevent contamination, there is risk of biased responses. However, because there are no clinical interventions involved, there are no risks to patient safety in this study. Due to the intervention being planned for 24 months there is also risk of dropout of women participants. To mitigate participant dropout risk, we have planned client satisfaction surveys for feedback and intervention modification to suit participants. In addition, there will be family sessions, every alternative month, to encourage household support for retention. We have also planned to take informed consent from male heads of household so they would be onboard for women's active participation in the study. This is a practice that is known to support women participants from conservative regions to comfortably take part in a study that involves visitation and contact over a period of time.

Declarations

Ethics approval and consent to participate

Ethics approval for this study has been received from the Institutional Review Board of the Forman Christian College University (FCCU IRB reference code: IRB-257/04-2021). All anonymity, confidentiality and safety of participants will be guaranteed. There is no risk to participants as the study does not involve any clinical interventions. Informed consent (attached with appendices) will be taken from all

participants before data collection and intervention delivery. The study will be performed in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests. FF serves as Senior Editorial Board member of BMC Women's Health.

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The funding body does not have policy for peer reviewing protocol papers or other publications prepared for academic journals. The funding body is also not involved in study design, data management, or data interpretation. However, limited funding allocation meant that the original proposed sample had to be reduced considerably to continue the project.

Author Contribution

SRJ conceptualized the project and drafted the proposal for funding application with the help of HA. Sectoral collaboration was coordinated by HA and RZ. The content for the literacy intervention has been developed by SRJ, HA, AM, SKB, AJ, and RRD. The surveys have been developed and finalized by SRJ and HA. SRJ, HA, AM, FNM, and SS have assisted in finalizing the relevant sections of the survey related to their expertise. The protocol paper has been prepared by SRJ, reviewed by RZ and approved by all the authors. The initial draft of this manuscript was developed by SRJ. HA, AM, SKB, AJ, and RZ, commented on the draft and then again on the final version. SRJ, and RZ finalized the draft before submission. All authors read and approved the final manuscript.

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Figures



Figure 1

One-on-one training of LHWs by principal investigator using the training booklets

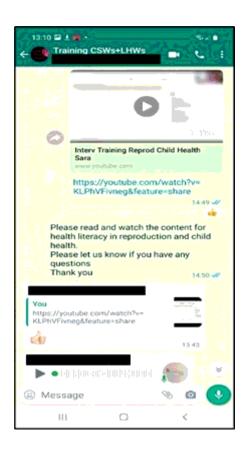


Figure 2

WhatsApp training group for CSWs and LHWs

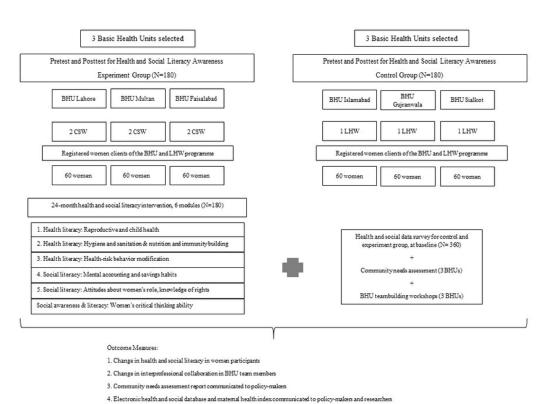


Figure 3

Overview about study process

Supplementary Files

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• Appendices.pdf