BMC Health Services Research

STUDY PROTOCOL | Article in Press

UDAAN: scaling up health system response to and prevention of domestic violence: Protocol of a cluster randomised trial

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Received: 21 October 2025 / Accepted: 7 September 2026

Abstract

Background Violence against women is a public health problem, a gender inequality issue, and a human rights violation. WHO's Clinical and Policy Guidelines on *Responding to intimate partner violence and sexual violence against women* (2013) recommends integration of response to violence against women in primary healthcare services. However, there are several gaps in understanding how integration of these Guidelines can be achieved in low- and middle-income country settings, in particular at primary healthcare level and including community health workers in preventing violence. This manuscript describes a protocol for a study which aims to integrate violence against women response and prevention in primary healthcare services by strengthening health systems, including training health workers in Maharashtra, India.

Methods The study is a cluster – randomised controlled trial using randomized block design to examine both the effectiveness of the intervention in reducing domestic violence and testing the strategies to implement the intervention. The intervention activities including capacity building of health workers and community health workers, and other elements of health systems strengthening including improving patient flow for privacy and confidentiality, establishing protocols, documenting cases and strengthening referral mechanisms. The intervention will be implemented in two randomly selected blocks in Chhatrapati Sambhajinagar district of Maharashtra, India. A cross- sectional survey to assess reduction in domestic violence will be carried out among women visiting health facilities in intervention and control arm at baseline and end line (i.e. after 18 months). The effectiveness of capacity building of health workers and community health workers, and system strengthening activities, will be assessed by a knowledge, attitude and practice survey and facility readiness assessment respectively. In- depth interviews and focus group discussions will be carried out with health workers to understand their perceptions about relevance and experience of implementing the intervention. The study will also employ methodology to establish the cost of this health system response to domestic violence.

Discussion The proposed study will build understanding on the integration of violence against women responses at the primary health system level. The findings will be helpful in operationalizing the policy and legal mandate of healthcare providers to respond to domestic violence in the Indian context. Further, we will obtain evidence

Published online: 19 September 2026

on what is required at the level of the health system, including the role of community health workers to prevent domestic violence.

Trial registration The trial is registered with Clinical Trial Registry of India which is government of India's official trial registry. The trial registration number is CTRI/2024/07/071367. It was registered on 26th July, 2024. (https://ctri.nic.in/Clinicaltrials/pmaindet2.php?EncHid=MTEwNTAw&Enc=&userName=).

Trial status The protocol is Version 1, dated July 26, 2024. The trial is registered on ClinicalTrials.gov, CTRI/2024/07/071367, with public title Health system response to violence against women. The enrolment was on October, 1st, 2024. The trial is currently recruiting participants.

Keywords Violence against women · Study protocol · Health system · Violence prevention

Background

In India, the last National Family Health Survey (NFHS) from 2019 to 21 demonstrated that 29% of women aged 18 to 49 years experienced physical or sexual violence perpetrated by their husband or male partner [1]. Further, National Crimes Records Bureau (NCRB) data of 2022 showed that almost one-third of all crimes against women were categorised under 'cruelty by husband or his relatives' [2]. In the Indian context, the term domestic violence is used and is inclusive of intimate partner violence and family violence because domestic violence includes perpetrators who are husbands as well as other cohabiting family members. Domestic violence is widely prevalent among Indian families [3] and, hence, will be the focus of the study and be used as the terminology.

Health impacts of domestic violence include injuries, unintended pregnancy, adverse pregnancy and birth outcomes, HIV and sexually transmitted infections, depression, alcohol-use disorders and other mental health problems [4]. Women who have experienced violence are more likely to seek health care than non-abused women [5], even if they don't disclose their specific experiences of violence to the health worker [6]. A qualitative meta-synthesis demonstrated that women expect health workers to respond with empathy and support women navigate safety in their relationships. When health workers express judgement, women experience negative emotions [7]. Thus, health workers are in a unique position to critically influence the healing journey for women who have experienced violence.

The health sector has a critical role to play in a multisectoral response to violence against women. The 2013 WHO Guidelines, *Responding to intimate partner violence and sexual violence against women* (henceforth, the Guidelines), recommend a health systems approach to responding to violence against women, including training of health workers in clinical care, psychosocial support provision and referrals, and integrating response in primary health care services [8]. The Guidelines recommend integration of the response in primary health care to increase access to services for women. They emphasize the centrality of providing woman-centred care which, at a minimum, includes how to identify survivors and provide first-line support (i.e. adaptation of psychological first aid into a job aid with mnemonic – LIVES). LIVES encompasses five steps – Listen with empathy; Inquire about needs and concerns: Validate her feelings; Enhance safety; and facilitate Support. First-line support includes addressing the practical and emotional needs of survivors with a focus on their safety and autonomy, which may include referrals to other sector services. The Guidelines also emphasize the centrality of taking a systems strengthening approach that goes beyond training to implement procedures for privacy and confidentiality, put in place protocols and documentation systems as well as referral mechanisms between health and other sectoral services.

Study rationale

WHO has published three tools to translate the Guidelines into practical "how to" instructions and job aids [9, 10]. However, there is limited evidence existing in context of low-and middle-income countries [LMICs] on how to implement these guidelines in low resource settings. To fill this research gap, the World Health Organizations Department of Sexual and Reproductive Health, which includes the Human Reproduction Programme [HRP] and the Centre for Enquiry into Health and Allied Themes [CEHAT] collaborated in 2018-19 to carry out an intervention research study in Chhatrapati Sambhajinagar and Sangli districts of the state of Maharashtra. CEHAT, a Mumbai-based research organisation, led research and intervention implementation. The study demonstrated that it was feasible and acceptable to providers and healthcare managers to respond to domestic violence given capacity building of healthcare providers and system strengthening [11]. The proposed study, Udaan – flight in *Hindi*, or "destined to soar" figuratively – builds on the research within tertiary health facilities in Maharashtra, as well as previous pilots conducted in Cambodia, Uganda, Pakistan, Zambia, and Namibia. Udaan focuses on primary health care, reflecting the recommendation in the Guidelines that responses to domestic violence are integrated into existing health services at the level of primary health care to increase access to services for women as close to the community as possible. It takes a systems strengthening approach going beyond training to implement activities across the WHO health systems building blocks [11].

In addition, as part of the health systems component, this study includes Community health workers (CHWs), also called Accredited Social Health Activists (ASHAs) or ASHA workers in the Indian context, to play a role in addressing domestic violence. CHWs are often members of the communities they serve, having an embedded understanding of the community dynamics and norms. Systematic review literature has highlighted that CHWs in LMICs provide a unique value in reaching communities in vulnerable situations, such as domestic violence survivors and/or those from stigmatized groups, to promote health equity [12]. While there is a paucity of evidence examining the impact of CHWs on violence prevention in India, a review of over 20 CHW-implemented violence prevention programs in the United States indicated that robust training of CHWs can result in increased awareness and changes in community attitudes toward domestic violence [13]. Moreover, community mobilisation is an important approach for changing social norms related to violence in LMICs [14]. Udaan therefore incorporates training of CHWs in the intervention blocks to provide domestic violence prevention messages through their routine health promotion activities. This component leverages the unique position of CHWs to contribute to community norm change efforts through awareness raising and facilitating referrals for women who have voluntarily disclosed their experience to them. Therefore, this study will add a violence prevention component within health system response.

Study aims and objectives

The overall aim is to improve quality of care for women who have been subjected to domestic violence, and to reduce such violence. Two overall objectives are to test the effectiveness of implementing the Guidelines in order to improve health system to domestic violence at the primary health care level in Sambhajinagar, Maharashtra state, India, and to test the efficacy of a health system prevention intervention (i.e. ASHA workers outreach) on reducing prevalence of domestic violence. Sub-objectives are to:

1) Test the efficacy of a combined CHW and health systems strengthening intervention on reducing domestic violence.
2) Explore the influence of health systems interventions and community health worker intervention on uptake of services and women's perceptions of quality of care.
3) Determine what factors lead to improvements in health workers (including CHWs) skills and clinical practice in identifying and responding to women survivors of domestic violence and/or preventing domestic violence.

4) Identify what factors lead to improvements in health facility readiness to deliver care to women survivors of domestic violence.
5) Identify the most relevant questions/ items to measure changes in health workers (including CHW)'s knowledge, attitudes and practices/skills and in health facility readiness.

Establish a costing of the health intervention to respond to domestic violence.

Methods

Study design

This study is a hybrid of an implementation effectiveness and intervention efficacy trial, designed to (1) establish the effectiveness of scaling up the implementation of a health system strengthening interventions, using WHO guidelines, on health workers' knowledge, attitudes and practices, and (2) test the efficacy of a health systems strengthening intervention with an added component of community health workers (CHWs) on reducing domestic violence among women who attend primary health services. The hybrid implementation research and intervention efficacy study design can yield useful information for policy makers and rapid gains in terms of translation of evidence to practice/policy [15]. Formative research via qualitative interviews with CHWs, will precede study implementation. A process evaluation, via in depth interviews with participants, will be implemented at the cessation of the study.

The design of this study is a cluster-randomized controlled trial using randomized block design whereby two blocks or sub-districts are randomized and all facilities within the two blocks are assigned to intervention and similarly two blocks and all facilities within those are assigned to control group. This is because health service delivery and management are structured at sub-district/block level and health-care seeking of communities does not follow a pattern of going to nearest/within catchment area of primary health facilities. In such situations, randomisation at facility level will likely lead to cross-over contamination, whereas randomisation at the sub-district/block level would minimise contamination. Blocks or sub-districts will be matched on pre-selected parameters (e.g. similar number of facilities and population level) and allocated to study arms to balance out potential confounders. Clustering will be adjusted at the facility level. It is proposed to be a two-arm trial. The control arm will include standard of care (i.e. referrals to other services for those who self-disclose domestic violence to the health workers). The intervention arm will include a combined intervention involving health systems strengthening of VAW response including training of health workers, as well as the CHW intervention to integrate prevention activities in their routine outreach work (see details in the intervention description). At the end of the trial, the control arm will also receive the training of health workers based on the 'Guidelines' as part of scaling up of the health systems strengthening response.

The preference for a cluster-randomized trial is primarily driven by the fact that, while the intervention impacts individual health workers and their patients, the implementation of the training, health system strengthening intervention and CHW intervention is delivered at a group/organization level within health facilities rather than at the individual level [16]. Importantly, there is likely intra-class correlation within clusters given the cross-cutting nature of health care provision and the cross-fertilization of knowledge between health workers in each facility. This cross-fertilization of health workers also exists, to some extent, between facilities, which hinders the ability to double blind the study. A cluster randomization method provides a rigorous method for an intervention that will necessitate implementation with entire health facilities involving all health workers and managers who will be trained to offer care and improve facility readiness in the intervention arm. We have used SPIRIT checklist (2013) to report the protocol [17].

Study setting

The study will be implemented in the Chhatrapati Sambhajinagar district in the state of Maharashtra, India. Sambhajinagar district is one of the two districts where the first implementation research study was implemented by CEHAT and WHO (Phase 1). The findings of Phase 1, which aimed to assess feasibility and acceptability of the health systems strengthening response using the Guidelines in tertiary hospital, showed that the study was feasible and acceptable [18, 19]. Therefore, this study builds on the Phase 1 to scale up from tertiary hospital to primary health facilities in the district. The district is situated at the centre of the state of Maharashtra and has a population of about 5 million and has 9 blocks/talukas/sub-districts or towns. The total number of public health facilities in Sambhajinagar include: 1 government medical college and hospital which is a tertiary health facility, 1 district level hospital, 3 sub- district hospitals and 73 primary health centres.

The literacy rate for Sambhajinagar district is 79% and the female literacy rate is 70% which is lower than that of the state. About 56% of the population in the district lives in rural areas. In terms of populations that are marginalized based on caste and religion, the Scheduled Caste (SC) and Scheduled Tribe (ST) constitute 18% of the population and Muslims constitute 21% of the population. Historically, the district has witnessed many social movements and is a politically conscious district. Women's rights groups, non-governmental organisations working on health and/or violence against women and girls, and trade unions are also present in the district and will be included as part of strengthening referral linkages between the health facilities and other sectoral support services.

Intervention

Based on the learning of Phase 1 of the project, we propose the intervention to focus on health systems strengthening for responding to domestic violence (which, in the Indian context, includes violence perpetrated by an intimate partner but also violence by other cohabiting family members as family formation norms mean that women cohabitate with their spouse, his parents and other family members and are exposed to violence in the home). The health systems strengthening approach applies the Guidelines and includes intervention activities along the WHO health systems building blocks. This includes (1) strengthening the health work force capacity through training, supervision and mentoring (2) strengthening multisectoral coordination through improved referrals with other sectoral services and provision of a referral directory; (3) strengthening service delivery through establishment of standard operating procedures (SOPs); (4) strengthening leadership and governance through creating champions within the health systems; 5)improving health infrastructure for privacy and confidentiality (e.g. private consultation spaces and confidentiality mechanisms for data) 6) improving evidence through establishment of facility registers to gather data on domestic violence cases and response. These building blocks constituted core intervention activities in Phase 1 and are to be continued in the scaling up of the health systems response for this study (see Table 1). The training of health workers to respond to domestic violence using the Guidelines focuses on competencies in survivor-centred communication; clinical inquiry of domestic violence based on signs and symptoms and offering first line support using the job aid called LIVES. It involves 5 elements – empathetic Listening; Inquiring about survivor's needs; offering Validation; Enhancing safety; and facilitating Support. A key lesson from Phase 1 was that health workers in the tertiary hospitals when trained were able to offer the L, I and V components of LIVES, but did not have the time to offer safety assessments and planning that are part of the E or facilitate Support, which involved counselling to identify formal and informal sources of support and carrying out warm referrals. Therefore, in this study, given that human resources for health are stretched in primary health services, dedicated counsellors will be deputed to the health facilities on a rotational basis to support existing health worker staff to carry out the safety assessment and planning and facilitating formal and informal support [20].

Additionally, a new component has been added to that of Phase 1, involving ASHA workers. Adding this new component of the health systems approach will involve strengthening capacities of ASHA workers who are attached to Primary Health Centres (PHCs) and sub-centres and cover the villages that are in the catchment areas

Article in Press

https://doi.org/10.1186/s12913-026-15586-9

Table 1 Intervention components

Symbol	Theme	Details
	Strengthening health workforce capacity	Training of trainers and training of health workers: • This will include training master trainer health workers with managerial/supervisory responsibilities using the WHO curriculum adapted to context • Master trainers will conduct minimum 2-day trainings of health workers. • All master trainers and health workers will be given access to online eLearning WHO training curriculum. • Master trainers will also conduct refresher trainings (18 months), supportive supervision (using a job aid from WHO health manager's manual) • Supervisors and senior clinicians in the facilities will be asked as part of regular clinical case review to review challenging cases of intimate partner violence.
	Strengthening leadership	• Champions will be identified from the health service administrative heads and senior clinicians based on the criteria of having a supervisory and mentoring role, decision-making responsibilities and a willingness to give time to mentoring health workers. Health managers with supervisory responsibilities will be given additional training on how to mentor, offer supportive supervision, and advocate for a health system response to domestic violence.
	Strengthening multisectoral coordination	• Outreach will be conducted with nongovernmental organizations, community structures, and other services (e.g. protection services, legal, livelihood support etc.) in the catchment area of the health services. • Referral directory and mechanisms for regular follow up with referral services for multisectoral coordination to be set up in consultation with local NGOs, including women's groups. • Refresher trainings may also be conducted. Training of community health workers: • This will include training CHWs to recognize domestic violence and transmit messages to the community about domestic violence as a public health and human rights issue and to refer survivors who voluntarily disclose to health facilities and other services that they may need. • The duration, frequency, and implementation mechanism will be informed by findings from formative research • All CHWs will be given access to online eLearning WHO training curriculum.
	Improving data and evidence for monitoring	• Documentation will be strengthened by introducing single-page facility register forms with information on symptoms, type of violence, perpetrator relationship, treatment given, and referrals provided. • Depending on facility, the facility register will be either introduced as electronic or paper-based.
	Improving service delivery	• Standard operating procedures will be established, translated and provided in writing regarding pathways to care and for confidentiality and privacy • Printed and electronic Job aids will be produced in local language and provided in formats accessible to health workers to aid skill recall and aid continuous learning. • Information, education and communication materials will be made available in public and private areas of the health facilities (e.g. female toilets) for patients letting them know that there are health workers onsite with whom they can speak to about VAW.
	Improving health infrastructure	• There will be discussions, including a patient flow mapping exercise with health managers in the selected facilities to identify where there are spaces for consultation with visual and auditory privacy and where there are likely to be breaches in confidentiality. • Ideas to strengthen privacy and confidentiality within the existing infrastructure or by small improvements will be brainstormed with facility staff • If additional resources are needed to strengthen private and confidential spaces for patient consultation, this will be explored as needed.

of the PHCs. ASHA workers in the intervention arm will be trained to integrate domestic violence prevention messages in their routine health promotion activities as they are primarily engaged in education and information about various health topics during home visits or in health camps. They will also offer information to women who voluntarily disclose their experience of violence about seeking help from health workers or depending on the need of survivors offer information about other sectoral services they can access. For safety and ethical reasons, ASHA workers will not be trained to actively identify women experiencing domestic violence as they live and work in the communities and therefore are at risk of backlash from perpetrators if they engage in pro-active identification. Instead, they will serve as conduit of information about available services and raise awareness about the health impacts of violence. To establish the costs of this intervention to the health system which is an important element of a health systems approach, the elements for costing have been identified using the WHO One Health Costing tool [21] (see Table 2).

The adaptation and roll out of the intervention was conducted as a co-design with health workers in Phase 1 through a stakeholder consultation. This practice of co-designing the adaptation and roll out was continued for this study through stakeholder consultation. This consultation helped identify appropriate timings, location, and approaches to training, supervision and mentoring and adaptations to the facility protocols. The stakeholder consultation also led to the naming of the study as project "Udaan".

Study population

The Udaan study will cover all the public health facilities at primary and secondary levels in the intervention arm. The study will be carried out in four out of the nine blocks. Two blocks each will be randomly assigned to intervention and control. The four blocks randomised to intervention and control include one set based on matching for population size and number of health facilities, resulting in a total of 17 primary health facilities in the intervention arm and 19 in the control arm. Thus, the study population in intervention arm will include all the healthcare providers at primary and secondary level and all ASHA workers affiliated with the PHCs in the intervention arm, and women who attend any of the intervention health facilities and/or impacted by ASHA workers' activities in their communities. The study population in control arm will include all the healthcare providers at primary and secondary level and all CHWs affiliated with the PHCs in the intervention arm, as well as women who attend any of the control health facilities and/or impacted by ASHA workers' activities in their communities.

Theory of Change

A specific theory of change has been developed for the Udaan study, to identify the potential pathways of change from women's disclosure of domestic violence to self-efficacy, coping, mental health. In addition, the theory of change addresses how changes in attitudes of those exposed to CHW messages can result in potential reductions in prevalence of domestic violence (See Fig. 1).

The Theory of Change is based on the assumption that well trained health workers who identify survivors and offer them first line support, and a system that is prepared to offer survivor-centered care, can contribute to early identification and response to survivors. In turn, early identification and support to survivors can reduce recurrence, frequency and severity of violence (i.e. secondary prevention) by improving women's self-efficacy, coping and help seeking. It is expected that CHWs will also contribute to prevention by raising awareness in communities about the harms of domestic violence on health and that such violence is unacceptable. The same messages will be conveyed by health workers in the facility as well. Thus, it is expected that such messaging will contribute to shift in community norms towards acceptability of violence, reduced blaming and stigma towards survivors and improved support for survivors to seek help. Referrals facilitated by health workers and CHWs to other sectoral services are also expected to contribute to survivors' self-efficacy, coping and help seeking and thus contribute to reducing recurrence, frequency and severity.

Table 2 Data collection overview

Data collection tool	Primary measurement	Sample size / participants	Timing of data collection
Quantitative (individual-level)			
KAP survey with health workers	Knowledge related to VAW as a health issue; attitudes towards acceptability of VAW and towards asking about VAW in a health facility; perceived preparedness to identify and respond to survivors, and; numbers of women identified and responded to in a 3-month time frame prior	**Intervention**: 124 health workers across the 16 sites **Control**: 147 health workers across the 19 sites	**Intervention**: morning of pre-training, evening of post-training, 18-months post training **Control**: baseline (around same time as intervention training), 18-months post-baseline
KAP survey with CHWs	Knowledge related to VAW as a health issue; attitudes towards acceptability of VAW and towards asking about VAW in a health facility; perceived preparedness to respond to survivors who voluntarily disclose, numbers of women referred to services, and; number of community outreach events to in a 3-month time frame prior to the survey	**Intervention**: All CHWs participating in intervention **Control**: All CHWs attached to PHCs in control sites	**Intervention**: morning of pre-training, evening of post-training, 18-months post training **Control**: baseline (around same time as intervention training), 18-months post-baseline
Cross-sectional prevalence survey for survivors	Self-reported frequency of experience of physical, sexual, and/or emotional violence and/or controlling behaviour in the past 6-month, by perpetrator (current partner or other family member); attitudes toward acceptability of VAW, and; household decision making	**Intervention**: 4160 facility-attending women, per data collection timepoint **Control**: 4968 facility-attending women, per data collection timepoint	**Intervention and Control**: baseline (pre-intervention training) and 18-months post baseline
Quantitative (facility-level)			
Health Facility Readiness Checklist	Service delivery / provision; health workforce, infrastructure and medical product, leadership, governance and accountability mechanisms; budget and financing considerations; multi-sectoral coordination and community engagement activities, and; information, monitoring and evaluation	**Intervention**: 16 facilities **Control**: 19 facilities	**Intervention and Control**: baseline (pre-intervention training) and 18-months post baseline
Intervention log	Costs of staff, commodities, facility improvements, training, supervision, materials	N/A	**Intervention**: ongoing throughout 18-month study period **Control**: N/A
Facility registers	How many women identified and/or disclose violence; the type of violence experienced; relationship to the perpetrator(s); presenting signs and symptoms; response to violence offered by the provider, and; referrals made to other services	N/A	**Intervention**: ongoing throughout 18-month study period **Control**: N/A
Qualitative			
IDI and FGDs for health workers and health facility managers	Health care providers' roles; beliefs/attitudes and motivations in providing care to survivors; the relevance of the intervention components; whether the intervention was found acceptable and feasible to implement, and; any unintended effects	**Intervention IDIs**: maximum 20 health workers **Intervention FGDs**: minimum 4 groups of 6–10 Health workers	**Intervention**: 18-month post-baseline KAP survey **Control**: N/A
IDI with women survivors	Perceptions of quality of care they received; expectations from health workers; perceptions of what enabled or hindered their ability to disclose violence; willingness to return for services and refer others to the facilities for violence services; changes their help-seeking; coping behaviours, and; situation at home.	**Intervention**: minimum 15 survivors who sought counselling no earlier than 3-months prior to endline	**Intervention**: 18-month post-training **Control**: N/A

https://doi.org/10.1186/s12913-026-15586-9

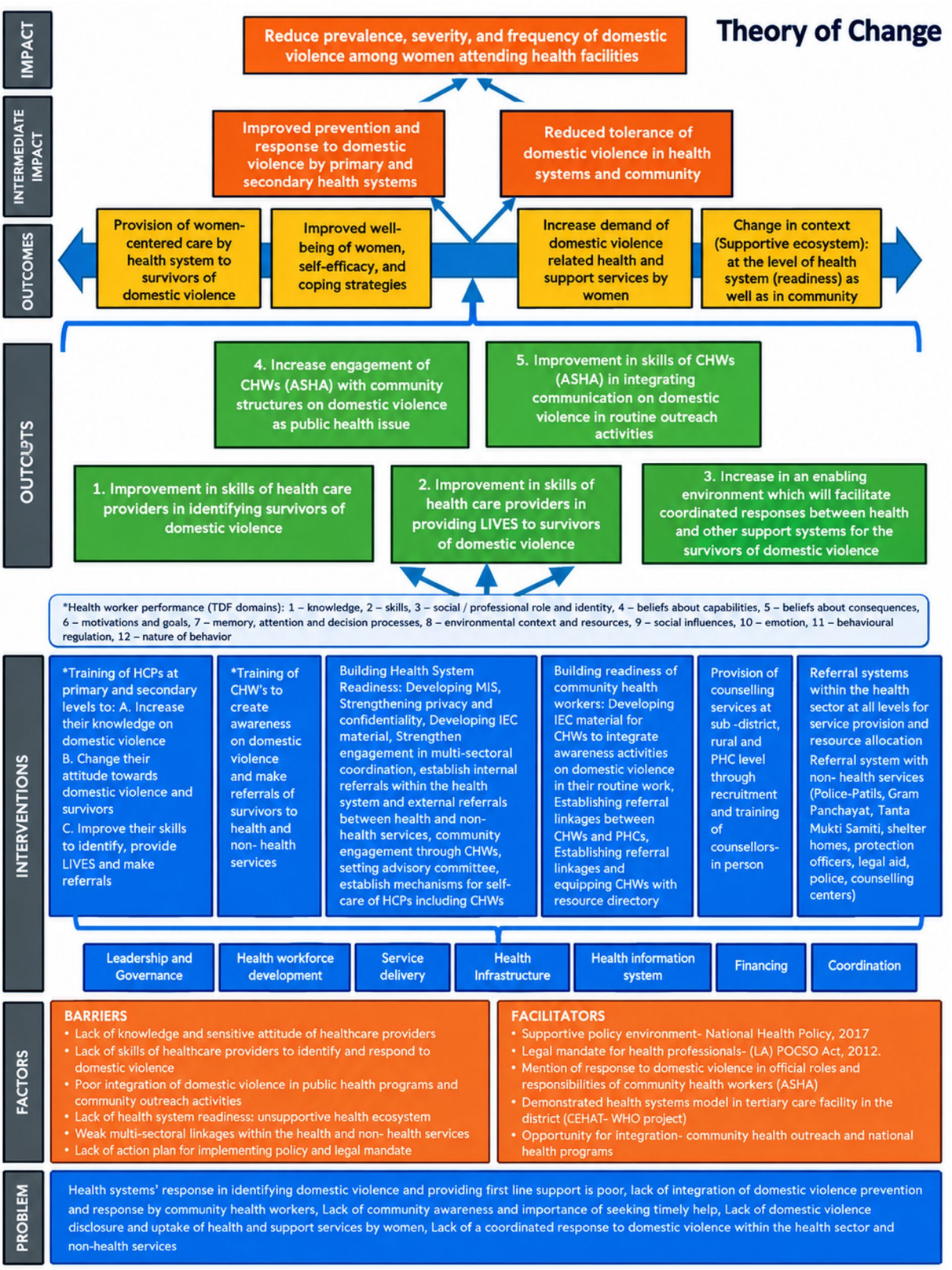

Fig. 1 Theory of Change

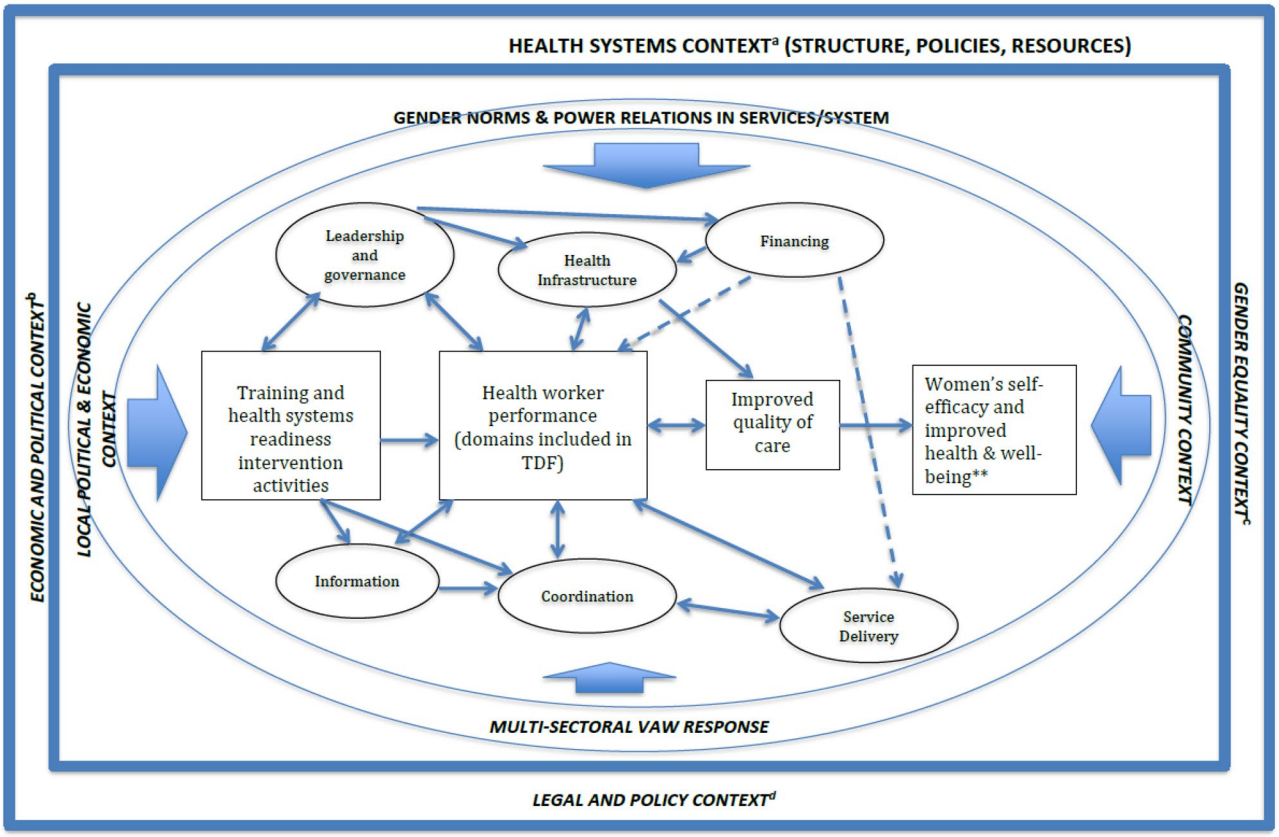

Fig. 2 Theoretical framework

Theoretical framework

The Udaan study will combine three theoretical approaches. First, complexity theory, which in health systems research recognizes that outcomes are the result of interactions between individual and among groups of providers, and that changes in outcomes are the result of a process of continuous feedback loops and adaptation [22]. Second, theories of gender and power dynamics in health systems research [23, 24], which recognize that providers own gender attitudes, and their position within the structure of health systems influence gender-sensitive/woman-centred care for survivors of violence. And third, the Theoretical Domains Framework [TDF] which integrates several behaviour change theories to provide a simplified framework for understanding HCPs performance [25]. This study will contribute to advancing complexity theory to consider gender power relations and behaviour change approaches for improving health worker performance and creating gender-sensitive health systems more broadly (see Fig. 2).

Data collection, sampling, measurement, and analysis

Research Objective #1: Test the efficacy of a combined CHW and health systems strengthening intervention on reducing domestic violence

To address this research objective, we will implement a baseline and an endline (i.e.18 months) survey of women attending health facilities in the intervention and control arm as two cross-sectional surveys for comparison. In addition to measuring basic socio-demographic and intervention-exposure questions, the cross-sectional survey will measure self-reported frequency of experience of domestic in the past 6-month based on the standard WHO

multi-country measure for violence against women [4] and attitudes regarding acceptability of violence as per the Demographic Health Survey (NFHS- 5, 2019-21). In the intervention arm, 4,160 facility-attending women will be surveyed, per data collection time point. In the control arm, 4,968 facility-attending women will be surveyed, per data collection time point. Thus, a total of approximately18,256 surveys will be completed (9,128 from baseline and 9,128 from endline).

The Udaan study assumes a conservative estimate of reductions in prevalence compared to other studies, because it does not follow a cohort that is directly receiving the interventions for ethical and feasibility reasons. Ethical reasons are based on the fact that women who disclose violence to health workers do so in confidence, it is not safe to conduct follow up interviews or track them and invite them for interviews at home. Feasibility is a challenge because the geographic area in these blocks is vast and comprises of 400 villages dispersed and not easily accessible. Mobile phones are not widely used in this region, especially by women who may not have individual access. Therefore, to track women who directly received the intervention from health workers over 18 months is expensive and would require enormous human resources. To overcome the challenge of measuring impact on reducing prevalence directly among those receiving the intervention, we instead propose to measure prevalence reduction among women attending health facilities which may include some who receive direct interventions and others who experienced the intervention through diffusion effects. This study is powered to detect a 25% difference in the prevalence of domestic violence (20% to 15%) with 80% power at $p=0.05$ significance level, assuming a 5% intraclass correlation.

Regression analysis using Generalized Linear Models (GLM) to estimate both the risk difference and relative risk for primary analysis will allow adjustment for correlation due to clustering / repeated measures across time periods. The Null Hypothesis that proportions are equal in the two arms over the two periods (baseline versus end-line) will be tested against the Alternative Hypothesis that they are not equal, adjusting for potential correlation between observations within each cluster of sites.

Research Objective #2: Explore the influence of health systems interventions and community health worker intervention on uptake of services and women's perceptions of quality of care

To address this research objective, we will examine survivors' perceptions of the intervention through in-depth interviews conducted 18-months post-training of health workers. In-depth interviews will explore topics related to perceptions of quality of care and expectations from health workers, including what enabled or hindered their ability to disclose violence to their health workers. Survivors will also be asked about their willingness to return for services and/or refer others to the facilities for violence services, as well as their approaches to help-seeking and coping. A minimum of 15 survivors who sought counselling no earlier than 3-months prior to endline will be interviewed.

Data analysis for qualitative data, including those relevant to Research Objective #2, will be conducted in two steps, applying a collaborative process that is grounded in thematic analysis, which is relevant when working in a team [26]. In the first phase, a data analysis workshop will be held with the in-country research team to facilitate a review of the data. Prior to the workshop, the research team will review a sub-set of the data, using open coding to apply deductive categories and identify inductive concepts in the data [27]. The team will map connections between categories and concepts during the workshop. This mapping will enable the agreement of axial codes, reflecting the major patterns in the data. These patterns in data will also be reviewed against or mapped to the theory of change to see if there are any further refinements to be made to the coding in order to analyse pathways to change that are hypothesized as potential explanations.

Based on findings from the analysis workshop, the research team will develop a draft codebook. Two coders from the in-country research team will conduct line-by-line coding on a sub-set of transcripts, compare coding schemes, resolve any discrepancies, and refine the codebook based on this process. The constant comparison method and co-coding will be used to refine the codebook [28]. Final thematic analysis of the qualitative data will be conducted by the in-country research team using AtlasTi or similar qualitative data analysis software.

Additionally, quarterly aggregated reports of facility registers, which will be filled by trained health workers will be analysed over the duration of the study, to analyse trends in identification and self-disclosures of domestic violence, and in the types of care being provided to women. Descriptive analysis of types of domestic violence, relationship to perpetrators, and clinical signs and symptoms linked to domestic violence identification will also be analysed over the duration of the study. These data will help triangulate qualitative findings on perceptions of services with uptake of services. It is expected that if trends in identification and self-disclosed violence increase over time, it reflects a greater trust of health workers by women in disclosing violence and improved skills of health workers in identification and response.

Research Objective #3: Determine what factors lead to improvements in health workers' skills and clinical practice in identifying and responding to women survivors of domestic violence and CHWs' skills in integrating prevention health promotion

In order to address this research objectives, changes in health worker readiness to support women who have experienced domestic violence, and the number of women identified and supported, will be assessed through a baseline (pre-training and immediately post-training) and an endline (18-months post-training) survey of health workers' knowledge, attitudes and skills/practices (KAP) in the intervention and control arms. A minimum of 124 health workers will be surveyed across the 17 intervention facilities and 147 health workers across the 19 control facilities. For the additional component related to CHWs, their KAP related to domestic violence prevention will also be assessed at baseline (pre-training), immediately post-training, and endline (18 months post-training). All ASHA workers in intervention and in control sites attached to PHCs will be surveyed, estimated to be about 400 CHWs per arm.

Both versions of the KAP survey, for health workers and CHWs, will assess knowledge related to domestic violence as a health issue and attitudes towards acceptability of domestic violence. The health workers KAP survey will also ask about attitudes towards asking about domestic violence in the context of a health facility, perceived preparedness to identify and respond to survivors, and numbers of women identified and responded to in a 3-month time frame prior to the survey. The CHW KAP survey will assess perceived preparedness to respond to survivors who voluntarily disclose, numbers of women referred to services, and number of community outreach events to in a 3-month time frame prior to the survey.

Given the findings of the previous study, we powered this study to detect a 20% difference in primary outcomes among health workers with 80% power at $p = 0.05$ significance level, assuming a 5% intraclass correlation coefficient, and allowing for 10% attrition. The feasibility study conducted on similar population of health workers [18] observed 49% of health workers reporting identification at baseline and 72% at endline – i.e. a change in about 20% in clinical practice.

In-depth interviews, with a maximum of 20 health workers in the intervention arm, and focus-group discussions, with a minimum of four groups of six to 10 health workers in the intervention arm, will also be conducted 18-months post-training. Health worker will be asked to reflect on their perceptions of the intervention to support uptake and quality of care for survivors. Topics will include health workers' beliefs, attitudes, and motivations to provide care to survivors. We will also explore health workers' perceptions of relevance of the intervention components, whether the intervention was found acceptable and feasible to implement, and any unintended effects of the intervention.

Additionally, qualitative and quantitative analytic approaches will be triangulated to assess (i) socio-demographic factors of health workers and CHWs that may influence changes in knowledge, attitudes and practices, (ii) triangulation of qualitative and quantitative data to assess and confirm potential pathways of intervention impact and (iii) coding and interpretation of qualitative process evaluation data using Extended Normalization Process Theory [29], to identify processes through which a complex intervention is adapted and incorporated into clinical practice.

Research Objective #4: Identify what factors lead to improvements in health facility readiness to deliver care to women survivors of domestic violence

To address this research objective, we will examine changes in health facility readiness through analysis of baseline and endline (i.e. 18-months post-training) health facility checklist completed in the 16 intervention facilities and the 19 control facilities. Through responses from health workers and managers, the health facility readiness checklist will assess: service delivery and provision; health workforce, infrastructure and medical product, leadership, governance and accountability mechanisms; budget and financing considerations; multi-sectoral coordination and community engagement activities, and; information, monitoring and evaluation mechanism.

Analysis of the health facility readiness will involve a simple comparison of baseline and endline data and, if sample size allows, to stratify the analysis by facility level (i.e. number of beds) as it is expected that the readiness will vary by the level of health facility (i.e. primary health facility, first referral facilities/secondary, and sub-district or district hospitals/tertiary facilities). The sample sizes of the health facilities will not lend itself to multivariate analysis but will provide additional triangulation of information to see whether, in addition to changes in health workers KAP, there were changes in health facility readiness in intervention facilities.

Research Objective #5: Identify the most relevant questions/ items to measure changes health workers' including CHWs' knowledge, attitudes practices/skills and in health facility readiness

Examining the KAP survey instruments and health facility readiness checklist will involve psychometric analysis of the respective longitudinal data from each instrument and across each arm. We will use both Classical Test Theory (CTT) and Item Response Theory (IRT) [30] approaches to examine each instrument's reliability and validity. Tests of measurement invariance analysis or differential item functioning may also be conducted to examine appropriateness of the tools across groups (incl. country, provider type, gender, etc.). This combined approach will offer a nuanced understanding of item and person interactions, especially valuable for adaptive testing and cross-cultural assessments.

Research Objective #6: Establish a costing of the health intervention to respond to domestic violence

The costing component of the study will be established by filling out the WHO One Health costing tool template adapted for clinical care for responding to violence against women. The major cost element in this template is related to health workers salary apportioned to the time spent in responding to domestic violence. The data for time spent in responding to domestic violence a question KAP survey of health workers, on time spent per client/patient at baseline as well as endline to obtain estimates on staff costs. Other intervention related costs including those related to trainings; improvements in health system readiness (e.g., related to privacy and confidentiality (e.g. curtains, cupboards with lock and key), information, education and communication materials, essential medicines, job aids for providers, facility registers and time spent in coordinating referrals with other sectors or supervision and mentoring, salaries for counsellors) will be documented as part of the project Udaan costs by the implementing partner. Facility registers will be aggregated on a monthly basis over the 18-month study period to establish the need for services over time.

Ethical considerations

Women who experience violence are often stigmatised, and are particularly vulnerable to adverse physical, mental and psychosocial outcomes. Researching violence against women can potentially result in unintentional risks to participants, researchers, and health care providers or other personnel involved in the research, if ethical and safety measures are not incorporated into the study design and training exercises. The study will follow strict ethical and safety guidelines, based on the WHO recommendations in *Putting women first: ethical and safety*

recommendations for research on domestic violence against women [31]. All ethical and safety procedures follow these standard guidelines and were utilised effectively in the first pilot phase of this study in tertiary hospitals. Participation in the study will be entirely voluntary, with informed consent required for each component of data collection to ensure participants' autonomy. Participants will be told explicitly that they can stop the interviews at any point, and they will be assured that their refusal to participate will not in any way impact any care they receive. Interviews and surveys will be conducted in private spaces, including within health facilities, where a separate room will be designated to protect participants' confidentiality. Note that across all study tools, respective participants will be informed of mandated reporting requirements in the case of disclosure of previous or ongoing sexual violence against minors. Site-specific referrals will also be available, as relevant, for all participants.

The research protocol was reviewed as part of the funding process by the Independent Advisory Board of the What Works to Prevent Violence Against Women and Girls programme, an external, non-commercial funding initiative. In addition, the research proposal underwent review by the Research Proposal Review Panel of the World Health Organization.

The intervention team will actively monitor the community environment to track any unintended consequences resulting from the intervention activities. This approach will include monthly monitoring and reporting to ensure early identification and response to potential unanticipated harms. This will include monitoring any backlash to CHWs or health workers and also discussing with the committees at village level to decide what can be done to mitigate backlash.

Dissemination plans

The findings from this study will be disseminated as follows: (1) Planned manuscripts for peer reviewed publication will be discussed with the site-specific partners at the outset, (2) Interim study findings will be disseminated on a periodic basis to policy makers at the study site and at national levels, (3) Study findings will be disseminated on an ongoing basis in national and international forums through webinars, conference submissions, United Nations meetings, academic and civil society forums, (4) Dissemination will be led by in-country partners including those who implement the interventions as well as researchers, (5) All manuscripts will have in-country research team and implementing partners as co-authors with every effort made to ensure that they are lead and last authors in relevant manuscripts. Authorship of manuscripts will be discussed and distributed transparently in line with the recommendations of the International Committee of Medical Journal Editors, and (6) The research team including data collectors and the implementation team will be acknowledged as a collective in the manuscript as appropriate. Aggregated findings will be made available to participants via presentations and report briefs, available in local languages. Communication of their availability will be shared at facility level to promote accessibility of health workers, managers, and survivors.

In line with WHO's open access policy, study findings will be made available in an open-access publications. Following the WHO Policy for "Sharing and reuse of health-related data for research purposes: WHO policy and implementation guidance", at the close of the study, study meta-data including data dictionary of the analytic data file will made available and instructions to request for anonymized analytic data for future research will be included.

Beyond the peer reviewed journals, in-country teams will be developing and implementing a stakeholders engagement plan to ensure that the results of the study will feed into sectoral policies and advocacy through community organizations. The health sector at the local level operationalises implementation at scale through state level project implementation plans (PIP) that are submitted to the state health missions for funding health programmes and services in Maharashtra. In-country partners have long histories of working with government public health sectors in Maharashtra in the area of domestic violence and are part of networks of civil society organizations in India that advocate for gender-responsive health systems that provide quality health care to women including for domestic violence. Therefore, through their access to local and national policy makers and civil society advocates, efforts will be made to facilitate uptake of findings. Furthermore, WHO through its

country office in India works directly with the Ministry of Health and Family Welfare of India and they will be engaged as a key stakeholder from the beginning of this study with the view to facilitate the uptake of the findings through its technical support at national and state level in the Reproductive and Child Health, and the ASHA/CHW Programmes.

Discussion

This paper describes a study protocol of the Udaan study, research which aims to test the effectiveness of implementation of WHO's evidence-based guidelines to strengthen a health systems' response and the efficacy of the combined health systems response inclusive of an added CHW component on reducing domestic violence in primary health settings in India. The Udaan study builds on an earlier study (Phase 1) that focused on tertiary health facilities, which showed that a health systems response was feasible and acceptable to implement in low resource settings, improved health workers' skills in identification of domestic violence and response and uptake of care by survivors. It did not aim to reduce domestic violence and therefore the present Udaan study builds upon Phase 1 by incorporating in a prevention component.

While there is evidence on the importance of training health workers to respond to domestic violence, there is less evidence on sustainable approaches to deliver such training especially at scale. This includes limited evidence on ideal training methods, length, core content, and sustaining and measuring skills and competencies post-training and other outcomes such as women's satisfaction with care, improvements in quality of care. A systematic review of training programs for health workers on responding to domestic violence reported some evidence on participatory techniques of training [32]. The evidence that informed the WHO recommendations on training was based on a systematic review that suggested that there are positive outcomes of training on health workers' awareness, attitudes towards women and readiness to respond to the women facing domestic violence. However, studies on effectiveness of training of health workers have mostly relied on perceived or self-reported outcomes by health workers, rather than shifts in clinical practice or the impacts on women's perceptions of quality of care well-being [33]. Therefore, the proposed study will provide much needed evidence to understand not only the potential impact of training on health workers skills and practices, but also how training may (or may not) contribute to improving women's perceptions of quality of care and wellbeing.

In the Udaan study, a central component is the perceptions of survivors of violence about quality of care received from health workers. Improved understanding of the expectations and needs of women who are experiencing domestic violence, especially in LMICs, from health workers and services are critical to improving quality of care [34]. A mixed-methods exploration of help-seeking and preferences for intervention following violence experience in Mumbai, India indicated that while few women had been screened for violence in a health-care setting, more than two-thirds of participants in the study reported willingness to disclose violence and interest in receiving information or assistance from health workers [35]. However, much less is known regarding women's trajectory after receiving care from health providers, particularly in terms of their perceptions of quality of care and wellbeing, highlighting an important gap that needs to be filled. The Udaan study will address this gap by capturing uptake of care as a proxy for women's satisfaction with care and more directly through qualitative data in the process evaluation phase, focusing on their perceptions of the care they received and how it helped them subsequently.

Additionally, ASHA workers constitute a critical component of health systems in this context, forming a bridge between facility-based service delivery and community-outreach and engagement. In the Udaan study, they are expected to raise awareness about the harmful effects of domestic violence and generate critical reflections about the acceptability of such violence. The study hypothesizes that this will contribute to shifting norms in community and improving women's uptake of services. Evidence from other studies that have implemented interventions through the health sector highlight that when health workers, including CHWs, raise conversations about the impacts of domestic violence, for many women it is the first time recognizing that what is happening to them

is violence and that it is not acceptable. This in turn contributes to prevention or reduction in domestic violence [36].

Strengths

The strength of the proposed Udaan study is that it takes comprehensive health systems approach to scale in primary health care settings by including intervention activities across six WHO health systems building block components and extending it to leverage community outreach and health promotion through CHWs for prevention. Another strength is for its potential to identify sustainable interventions that can be taken to scale in low resource and stretched public health systems by integrating domestic violence prevention and response into services that are routinely accessed by women at the community level. The study has the potential for positive spillover effects on overall quality of care provided to women through its approach on woman-centered response. The study will gather data on cost elements of delivering a health systems intervention which will be valuable for policy makers to understand whether the interventions can be feasibly included in the local, state and national health budgets. Another added value is that it is employs a robust cluster randomized design as compared to other study designs that have utilised pre-post designs without comparison groups, a cross-sectional design or have used qualitative methods to document findings.

Limitations

In part to minimize the burden to participants, as well as in response to the complexity and potential ethical challenges of following women over time in this context, this study uses two cross-sectional surveys rather than a longitudinal design to examine changes in domestic violence among health care-seeking women. Because women attending the facilities participate in only a single survey without follow-up, the study cannot track individual changes in experiences of violence over time. However, the study can still assess the impact of the intervention by comparing the prevalence of domestic violence between intervention and control groups at the two points in time (baseline and 18-monhts post-baseline). Additionally, a dose-response analysis will help determine whether greater exposure to intervention activities—such as engagement with CHWs, IEC materials, or direct receipt of LIVES and additional counselling from health workers or counsellors—correlates with reductions in violence. The strength of causal inference will be further enhanced by triangulating findings from the cross-sectional surveys with qualitative interviews with survivors and facility data on service utilization.

A limitation of the costing component in this study is the reliance on self-reported estimates of time spent by health workers and CHWs in responding to survivors, rather than using objective time-tracking methods. Given that staff costs are expected to be the largest cost element, this approach introduces potential recall bias and variability in responses. The study will collect this data through the KAP surveys administered to health workers and CHWs, rather than direct observation or time-motion studies. Self-reporting was chosen over objective time-tracking methods to minimize disruptions to workflow and service provision. Additionally, direct observation or time-motion studies could compromise provider and patient privacy, making self-reported estimates a more ethically appropriate and less intrusive approach to data collection.

Other limitations are that as a combined intervention package comprising of several components and only two arms, it will not be possible to disaggregate whether there are specific components that are more likely to impact the outcomes than others. It would have been preferable to randomise units at the PHC facility level rather than the block level for more robust design. However, given that health seeking patterns in the communities are not fixed to the nearest PHCs but based on different considerations; to avoid contamination, randomization was conducted at the block level, where homogeneity between the blocks add to internal validity but may limit generalizability to diverse populations.

Despite these limitations, the findings are expected to provide actionable insights for policy makers, especially on how the health as one of the largest scalable platforms, can contribute to response and prevention of violence

against women within a multi-sectoral context. Furthermore, taking an approach of systems strengthening and enhancing collaborations between health and other sector services has the potential for sustaining intervention impacts beyond the study period. Ultimately, this research has the potential to advance global efforts to reduce violence against women and promote health equity through evidence-based, contextually relevant strategies.

Abbreviations

CEHAT	Centre for Enquiry Into Health and Allied Themes
CHWs	Community Health Workers
CTT	Classical Test Theory
HIV	Human Immunodeficiency Virus
ICMJE	International Committee of Medical Journal Editors
IEC	Information Education and Communication
IRT	Item Response Theory
KAP	Knowledge, attitude and practice
M&E	Monitoring and Evaluation
NCRB	National Crime Record Bureau
NGOs	Non- Government Organisations
NFHS	National Family Health Survey
PHC	Primary Health Centre
SC	Scheduled Caste
ST	Scheduled Tribe
TOC	Theory of Change
UN	United Nation
VAW	Violence against women
WHO	World Health Organisation
WHO-SRH- HRP	World Health Organisation- Sexual and Reproductive Health – Human Reproduction Programme

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1186/s12913-026-15586-9.

Acknowledgements We would like to acknowledge Dr. Manisha Gupte, Dr. Ramesh Awasthi, Dr. Padma Bhate- Deosthali and Dr. Suniti Neogy for their inputs on protocol. We gratefully acknowledge the efforts of Abhijit Kumbharkar, Yogesh Dhende, and Rajeeta Chavhan for providing assistance on gathering data essential for development of protocol.

Author contributions The project was conceptualised and designed by SA, SR, SM, ST and AA with refinements made by ME MM and KJ. SA, SR, SM, AM and ST led the phase 1 of the project which contributed in development of UDAAN protocol. ST designed the process of data collection, estimated sample size and developed statistical analysis plan. The intervention is designed and will be implemented by KJ. SA, MM and SM prepared the first draft of manuscript. All authors read and approved the final version of the manuscript.

Funding This work was funded by the Government of the United Kingdom's Foreign, Commonwealth and Development Office (Contract #3680) through the Global Women's Institute at the George Washington University. The time of some of the authors (SM, SST, MM and AA) was covered by funding provided by the UNDP/UNFPA, UNICEF/World Bank/WHO Special Programme of Research on Human Reproduction (HRP) housed at the World Health Organization (WHO) Department of Sexual and Reproductive Health and Research. The findings and opinions are those of the authors and not the Government of the United Kingdom or of the WHO.

Data availability No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate Study procedures have been reviewed and approved by (i) CEHAT's Program Development Committee (ii) Anusandhan Trust Ethics Committee which is an independent review committee of research ethics experts and is registered with Department of Health and Family Welfare, Ministry of Health, India (Reference number: IEC36/2024), (iii) an independent technical review panel of HRP, Research Project Review Panel [RP2]; (iv) the World Health Organization's Ethics Review Committee [ERC], which reviews all human subjects research conducted or supported by WHO, and (v) the Institutional Review Boards (IRBs) by the Office of Human Research (OHR for the George Washington University (GWU), which reviews all human subjects research conducted or supported by GW. All respondents will provide informed consent prior to participating in interviews, focus groups discussions, and surveys.

Competing interests The authors declare no competing interests.

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