Dialogues in Health 2 (2023) 100126

Contents lists available at ScienceDirect

Dialogues in Health

journal homepage: www.elsevier.com/locate/dialog

Adherence to behavioural intervention in RCT study by the women experiencing domestic violence and attending ANC in a public hospital in India-an analysis

Meerambika Mahapatro, Sudeshna Roy *, Poonam Nayar, Suruchi Panchkaran, Ashwini Jadhav

National Institute of Health and Family Welfare, New Delhi 110067, India

ARTICLE INFO

Keywords:
Adherence
Impeding factor
Facilitating factor
ANC
India
Intervention
Domestic violence

ABSTRACT

Background: The paper aims to identify the factors for effective implementation and adherence to the behavioural intervention package by women experiencing domestic violence (DV) and attending ANC in a public hospital.
Methods: A qualitative study was undertaken with 211 pregnant women experiencing DV and attending antenatal care (ANC) at the LN Hospital, New Delhi. The intervention was given to women recruited under the RCT study. The narratives were analysed under two broad themes, impeding and facilitating factors, with nine sub-themes.
Findings: Impeding factors are external factors generated by the structural interaction of the participants, whereas facilitating factors are supplied internally in the trial to eliminate the influence of impeding factors and singulate the factors under study. Our results show that despite the plethora of impeding factors (nine), the overall sum impact of impeding factors falls short of the positive impact of facilitating factors (nine), which were minor adjustments but reinforce participation in the trial and adherence with 97% follow-up rates.
Interpretation: Our study findings are expected to reset the treatment protocol, which entails converting impeding factors into facilitating factors for appropriate adherence and compliance and adequate access and utilization of public services. The sensitization of healthcare providers to the impact of the quality of human interaction on the patient and its impact on the uptake of healthcare services and adherence is needed, particularly in the public hospitals of India.
Funding: Funds received for the research are from the Indian Council of Medical Research (ICMR), New Delhi, Government of India.

1. Introduction

Domestic violence (DV) against women can be physical, sexual, or psychologically perpetrated by a husband or family members, leading to increased long-term physical, sexual, and mental health consequences. The prevalence of DV during pregnancy increases manifold [1]. Treatment at hospitals does not address the health needs of the women experiencing domestic violence (WEDV), especially their mental health. Many studies have been conducted to assess the prevalence of DV in pregnancy. It was found that 12.9% of 481 women at an antenatal assessment in Ireland [2], 18% of 2199 women during their last pregnancy in India [3], 49.5% of 921 women during the antenatal care (ANC) period in India [4], and 27.7% of 612 pregnant women in Uganda [5] during that pregnancy reported to have experienced DV. ANC allows the healthcare provider to screen for and diagnose DV. Several studies have found that providing intervention promotes self-empowerment and resilience in women to protect them from future abuse [6].

Even when practices were targeted, conducting a randomized controlled trial (RCT) and clinical practises within a hospital setting is problematic [7]. “Contextual” elements such as the hospital environment, management, work systems, and current health policies [8] influence the clinical trial implementation of integrated therapies [9,10]. The interventions tested have generally combined women's economic empowerment with or without some other elements, including gender-focused ones. It was found that providing the participants with incentives and a courteous telephone connection with them aided in better follow-up and retention [11]. Along with the evaluation of the RCT [12], it was recommended to collect information about the elements that facilitate or pose barriers to implementing interventions, as this aids in identifying the unwanted challenges in clinical trials [13–15]. Although RCTs are considered the

Abbreviations: ANC, Antenatal care; BIP, Behavioural intervention package; OPD, Outpatient department; DV, Domestic violence; WEDV, Women experiencing domestic violence.

* Corresponding author.
E-mail address: sudeshna.jnu@gmail.com (S. Roy).

http://dx.doi.org/10.1016/j.dialog.2023.100126
Received 23 August 2022; Received in revised form 17 March 2023; Accepted 17 March 2023
Available online 20 March 2023

"gold standard" in evaluating healthcare interventions, finding subjects for such studies is difficult [11]. It becomes complicated if the study focuses on screening women who have experienced DV and recruiting for an RCT [16].

Furthermore, pregnant women's reluctance to participate in RCTs stems from their fear and perception of risk to their fetuses and health [17,18]. Literature shows that there is a hesitation to conduct and encourage clinical research among pregnant women [19–24]. The significant reasons are concerns about health and safety, difficulty in recruitment, and retention of pregnant women [23].

As a result, a few interventions to reduce DV have been tested in various settings [6]. Therefore, treatments that consider the context and complexity of their lives and are tailored to their particular circumstances, priorities, and needs will benefit women in abusive relationships. One of the critical recommendations of a study is that evaluations of "complex" interventions must pay attention to disparities across women, analyse differential impacts across subgroups, and explore who, how, and why expected changes occur or do not occur in addition to the "main effects" [25]. A contextualized understanding of interventions is essential for successful implementation and scale-up.

Although early screening and identification of DV were crucial in improving responsive efforts towards it and were highly recommended by several medical organisations [26], many factors together affect the missed opportunity in screening potential DV cases. Because of a lack of training and standard guidelines [27,28], a lack of knowledge about referral resources [29], and an underestimation of the effects of DV [30,31], most healthcare providers are hesitant to get involved in patient family matters. The socio-cultural background, upbringing, and belief systems of healthcare workers [32] and their attitudes [33] often pose barriers to screening patients for DV. Studies have revealed that although women who have experienced violence want to disclose their situation to trusted healthcare providers and access support services [34], a higher proportion of these women do not disclose their condition "on the spur of the moment" during initial "clinical consultations" [35]. Factors such as humiliation, fear of retaliation from abusers, and the perception that healthcare workers' or doctors' proactive role in probing patients prevent abused or battered women from seeking help from healthcare providers [36,37]. The sensitivity of the issue of DV makes the initial response of the healthcare provider crucial in determining the extent of disclosure from the patient and the subsequent 'course of action' taken by the patient [38,39].

Trial-specific qualitative research is crucial for interpreting trial results and extending our understanding of how contextual barriers and opportunities may affect results [40]. If the intervention is effective, understanding from qualitative research can guide implementation and help the researcher be "sensitive to the human beings who participate in trials" [41]. In addition, qualitative studies help understand the context, interpret the results of trials, and enhance external validity. An intervention study was critical for comprehensively evaluating complex interventions because it helped develop a more contextualized and nuanced understanding of intervention processes, impacts, and group variations on outcomes. A qualitative study helps to identify outcomes most valued by participants and explore barriers and facilitators to adherence to the intervention [40].

2. The context and the problem

This paper is the outcome of a trial to assess the impact of the behavioural intervention package (BIP) on pregnant women facing DV who are attending ANC at Lok Nayak (LN) Hospital. The BIP was implemented for each recruited WEDV for seven months. The multipronged approach of BIP ensures that every aspect of the victim's life is adequately analysed and dealt with. This involved a series of interactions to work through the initial stages of hesitation on developing a rapport and implementing the individual care plan, taking regular feedback to monitor progress and identify the problems faced in adherence. The feedback helped ensure that the research team adequately addressed any new challenges. Therefore, the research question was, what factors affect compliance and adherence among women from low socio-economic backgrounds attending ANC in a public hospital? The paper aims to identify the impeding and facilitating factors for effective implementation, completion, and adherence to the BIP by the WEDV attending ANC at a tertiary care hospital in New Delhi.

3. About behavioural intervention package

Different national and international guidelines [42] were reviewed, and the BIP was developed based on those existing guidelines, which are context-specific. This intervention aims to empower women to attain better physical and mental health. The BIP consists of five components. These components were focused on i. Understanding the depth of the problem and assessing the need with empathy and rapport; ii. Analysing her strengths and available resources (emotional, medical, and physical resources) for utilization and navigating a better outcome; iii. Self-regulation mechanisms of the body's internal system through yoga-based methods (chanting, meditation, and exercise); iv. Individual counselling for effective communication and better interpersonal relations; and v. Developing better awareness and creating opportunities for alternative livelihoods.

The research team had adequate time to establish rapport and trust so women could speak uninhibitedly about their healthcare service delivery experience. The intervention was executed during the pilot project within the same hospital-based set-up with a smaller sample in 2015. Based on participant feedback and open-ended qualitative questions about the BIP and each of the sessions, including how much they liked or disliked practising BIP, how much time they spent on each session, and other feedback on the effect of the BIP, the research team was able to revise the BIP. Additionally, observation by the research team regarding the women's reactions to specific sessions helped revise the BIP. The actual project was started in October 2018. The expected outcome of the intervention was that there would be a change in the women's physical and mental health components, which were measured by the SF-36 scale. The pilot study was essential to conducting the RCT study.

4. Methods

4.1. Domain 1: Research team and reflexivity

Seven highly qualified and competent women researchers from various professions, including psychology, demography and social geography, social medicine and community health, yoga, gynecology, and anthropology, interacted with the WEDV in various roles and capacities. A one-week training programme was provided to the researchers to help them understand the study's goal, build a shared perspective, and assure a two-year commitment to the project's data collection and interaction with the participants. They were also taught how to use the tools and questionnaires, the meanings of each question, and the entire methodology, to ensure that the data and responses were uniform and of high quality.

4.2. Domain 2: Study design

This study was part of a larger RCT research project. It was conducted using a narrative inquiry, qualitative method to gain an in-depth understanding of the participants' everyday environments and the social meanings associated with being part of a particular family culture. The narrative inquiry was used to construct the meanings of patients' lived experiences expressed through stories. The individual stories were used as a unit of study to make sense of the complexity of seeking health services, unique constraints, and their consequences. The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was used for detailed and comprehensive reporting of qualitative data. Ethical approval was obtained from the Institutional Review Board (IRB), National Institute of Health and Family Welfare (NIHFW), New Delhi, in 2018. The trial registration number is CTRI/2019/01/017009.

4.2.1. Participants

The inclusion criteria to consider the participants for the study were as follows: i. all married pregnant women (first contact of pregnancy confirmation, i.e., 18–20 weeks) attending the Obstetrics Outpatient Department (OPD) of LN hospital for antenatal registration; ii. both primigravida and multigravida; iii. Signed the informed consent form; iv. screened positive for DV in the previous year using an abuse assessment screening tool; v. staying with the husband and in-laws (family) for at least two years; vi. likely to stay in the area till delivery and attend the LN hospital OPD for ANC; vii. Willing to visit the hospital for follow-up as per schedule; and viii. Willing to allow study staff to visit her home for contact if needed. At the same time, those who had previously registered a medical-legal case (MLC) for abuse and mentally challenged women who could not comprehend and comply with the intervention were excluded. The women were recruited at 20 weeks of pregnancy to ensure their long-term interaction with the hospital and plan their delivery at the same hospital. In Indian culture, many pregnant women go to their mothers' houses for childbirth. They were more likely to continue their ANC and childbirth later in gestation or pregnancy.

4.2.2. Setting

The study was undertaken at the ANC OPD of the Department of Reproductive Medicine of the LN Hospital, a prime public tertiary care hospital in the central district of Delhi. Most women seeking ANC and treatment from this hospital belong to the lower socio-economic strata (Table 1).

4.2.3. Instruments/interview guide/questions

Based on the objective of the study, the interview schedule was prepared with two broad, open-ended questions, i.e., “describe what made your hospital visit comfortable or good” and “describe what made your hospital visit distressful.” We also asked the women about their level of satisfaction during ANC, the need for privacy during consultations, their experience of interacting with the healthcare providers and the research team, etc. The observation of the researcher on the interactions of the participants with the research team and the system was essential to getting insight.

Table 1
Socio-demographic background of the women experiencing domestic violence.

Characteristics	N	%
Age (in years)		
≤20	23	10.9
21–25	111	52.6
≥26	77	36.5
Education		
Illiterate	18	8.5
Primary Schooling	27	12.8
Middle Schooling	42	19.9
High School /Higher Secondary Schooling	78	37.0
Graduate/ P.G./ Professional Degree	46	21.8
Religion		
Hindu	74	35.1
Muslim	137	64.9
Caste		
General	72	34.1
Other Backward Caste (OBC)	117	55.5
Scheduled Caste (SC)	20	9.5
Scheduled Tribe (ST)	2	0.9
Family Type		
Nuclear	45	21.3
Joint	166	78.7
Employment Status		
Employed	10	4.7
Housewife/Unemployed	201	95.3
Monthly Household Income (in Rs)		
<10,000	99	46.9
10,000–20,000	57	27.0
20,001–40,000	31	14.7
>40,000	24	11.4
Total	211	100

4.3. Domain 3: Analysis and findings

In the OPD area, where the women were waiting to consult the doctor, we were given a separate room for conducting the research and the BIP intervention. The room where the routine OPD activities were conducted was separate from where we did the intervention. The first step was to establish a dedicated space with sufficient seclusion in which women could converse freely without being overheard by their accompanying families. The room was divided into sections with adjustable dividers to ensure that all the women had privacy. The area was kept clean, organised, and well-aired to provide a welcoming and joyful setting where the participants could relax and express their feelings, including refreshments.

A total of 921 cases for routine ANC check-ups were screened for DV. Of them, 211 cases of pregnant WEDV were identified and recruited for the study, and they were randomly allocated into the study group and the control group (Fig. 1). Written consent was taken from the participants before the data collection. The confidentiality of the respondent was maintained during and after the data collection. As per programme need, there are four routine ANC check-ups. In the study for the follow-ups with the women, eleven sessions were carried out over seven months, of which four coincided with the routine ANC check-up. Within the rushed, overcrowded, and impersonal hospital atmosphere, one intervention component was establishing a space where individuals could receive empathy, care, respect, and support. The researchers and the participants gained trust and understanding of the phenomenon.

In-depth, open-ended interviews were conducted with the women to explore their experiences and the meanings they attribute to them. Women were encouraged to narrate the issues pertinent to the open-ended questions in the interview. The same question was asked in different ways, keeping the meaning intact. The researcher attempted to understand the participants' daily lives and the social implications connected with belonging to a specific family culture. Feedback from women patients was gathered regarding the challenges they faced while participating in the trial, and their suggestions to improve the implementation and adherence were noted. Observations of the interactions of pregnant women with healthcare staff, the interaction of healthcare staff among themselves, and the dialogue of women with the research team were also noted.

4.4. Data analysis and reporting

The verbatim narration follows as the women share their life experiences, thoughts, feelings, and responses, which were recorded and transcribed. Transcribing the data involves repeated, careful listening, which was done by the researchers involved in collecting the data. The data was understood within the context, as each woman had a unique pattern of life circumstances. The words and phrases used were identified and coded. The manually coded data were entered into the NViVO 12 Plus software to develop themes, sub-themes, and sentiments. The two broad themes were: (i) impeding factors and (ii) facilitating factors. Nine sub-themes emerged from the analysis. Impeding factors were pre-existing structural and functional problems in the hospital environment and the participants' interactions. The facilitating factors comprised educational/informational, behavioural, emotional, and cognitive interventions, which were part of the BIP, converting impeding factors into facilitating factors. The descriptive mini-quotes were presented under the themes and sub-themes.

5. Results

5.1. Background information of the respondents

The women respondents had low education and socioeconomic status (Table 1). Half of the women respondents were in the age group of 21–25 years; a quarter of them had completed 10 or 12 years of schooling; about 65% of the women respondents were Muslim, and 55% belonged to the other backward caste. Seventy-nine percent belong to joint families, 95% are homemakers, and 47% have a monthly household income of less

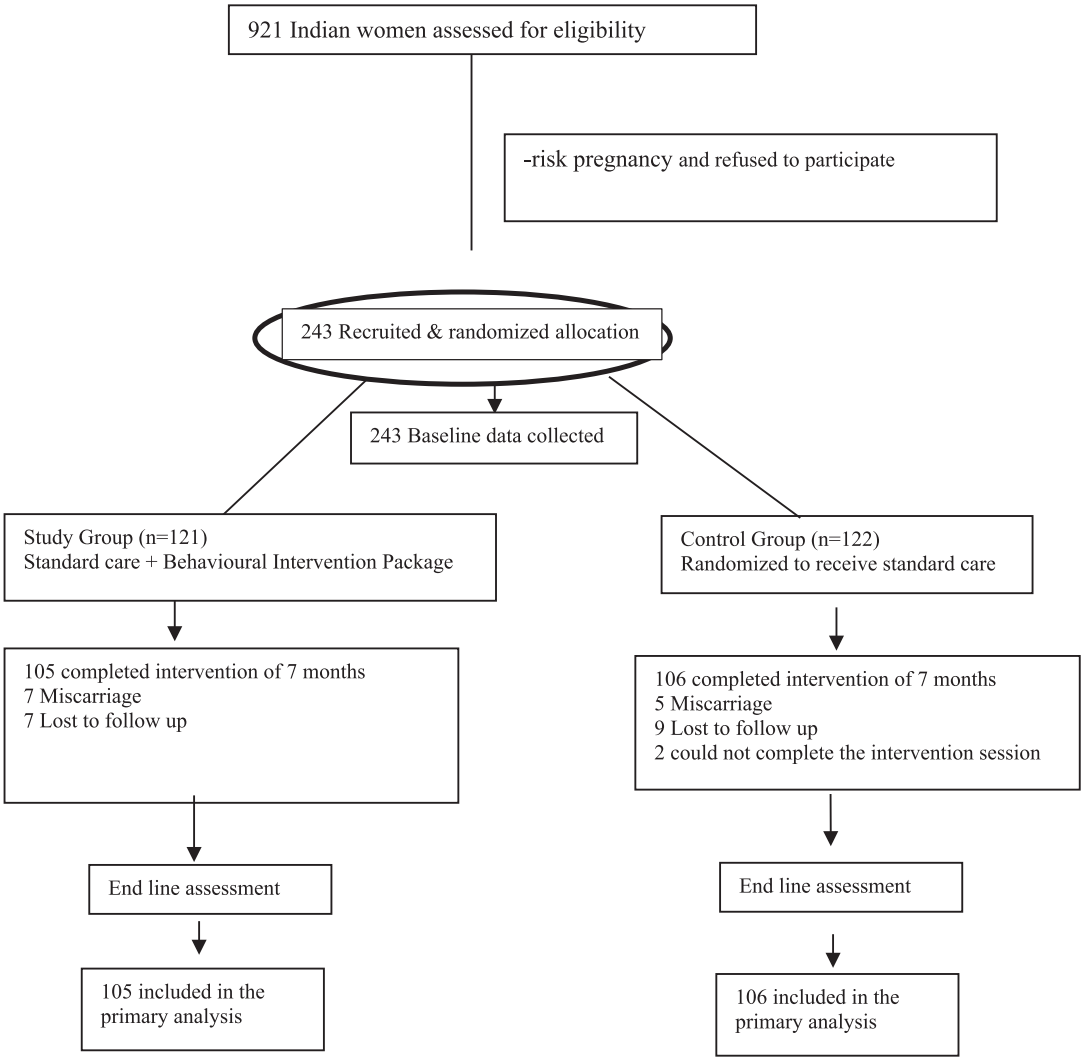

Fig. 1. Flow of participants through the study.

than Rs. 10,000. It was observed that 18% of the women were anemic, about 3% were previously known hypertensives, 9% had vaginal bleeding, about 21% had urinary tract infections, 34% had the hypertensive disorder, and 16.6% were newly detected gestational diabetics (Table 2).

5.2. Adherence and compliance

Out of the 921 women who were screened, 211 were enrolled in the study and completed the intervention for seven months. The follow-up visits were performed by 97% of the women. The follow-up period was 28 weeks from the time of recruitment. Each woman visited the hospital for longer than their scheduled follow-up to interact with the research team. The number of missed follow-ups was used to calculate the loss-to-follow-up rate, which was only 1.2%, with 1.8% having miscarriages or high-risk pregnancies.

5.3. Thematic interpretation

Two main themes were impeding factors and facilitating factors. There were nine sub-themes: i. Inadequate space and infrastructure for screening, ii. Space provided for empathetic listening at the hospital, iii. Difficulties in establishing trust and maintaining confidentiality, iv. The time commitment for routine ANC and follow-up visits; v. Barriers to women's psychosocial conditioning, attitudes, and beliefs; vi. A lack of sensitization of healthcare providers; vii. Information asymmetry and instrumental support services; viii. Difficulty in obtaining legal services; ix. Intervention to develop emotional resilience. These nine sub-themes were analysed in terms of converting impeding factors into facilitating factors.

Table 2
Baseline pregnancy health indicators of the women experiencing domestic violence.

Health Indicators	N	%
Haemoglobin level (mg%)		
<10	38	18.0
>10	173	82.0
Hypertensive disorders		
Any hypertensive drug in use	6	2.8
Any hypertensive drug not in use	205	97.2
Vaginal Bleeding		
Yes	19	9.0
No	192	91.0
Urinary Tract Infection (UTI)		
Yes	44	20.9
No	167	79.1
Blood Pressure		
<140/90	139	65.9
>140/90	72	34.1
Gestational Diabetes		
Yes	35	16.6
No	176	83.4
Total	211	100

1. Inadequate space and infrastructure for screening.

Impeding factor:

It was challenging to find a separate room where privacy and confidentiality could be maintained in the crowded OPD of government hospitals where women could communicate their problems to enable the healthcare staff to screen for DV. They were not at ease due to the presence of family members and their fear of being inflicted with more violence. One of the women victims stated, *"During my consultation in a small room, I was surrounded by a minimum of 10 to 15 women, including my mother-in-law. I did not dare to open up and talk about my problem at home."*

Facilitating factor:

We were allotted a separate room inside the OPD waiting area for our project. The women were screened. The researchers kept the accompanying family members out of the consultation room to maintain privacy and confidentiality. There were instances where inquisitive women and visitors came into the screening room using false excuses to probe into the actual happenings within the room. If they learned that their wrongdoings were exposed, they would prevent the victim from coming to the hospital, even for a routine ANC, further endangering their health and putting their lives at risk. The women were repeatedly reassured of complete confidentiality and our support in all aspects of the ANC check-up within the hospital. The accompanying relatives were also assured about the support and help they would receive for their routine ANC consultation. At a low cost, the room was decorated with happy baby photographs and schematics with crucial information on diet, the mother-child bond, and the father's responsibility in caring for and nurturing his child. The research team took the initiative to involve a group of students in a discussion on pregnancy and maternal care. This was done purposefully to depict the mother's natural and relatable sentiments. Patients' interpretation of written communications was impeded by their lack of education; thus, these pictorial representations were easy to understand.

2. Space provided for empathetic listening at the hospital

Impeding factor:

Because public hospitals had a high patient-to-doctor ratio (on average, 150 patients per doctor per day, as reported informally), doctors and healthcare providers were pressed for time to attend to all OPD patients besides routine inquiries. They need more time to engage in the emotional aspects of a patient's personal life after completing the necessities of ANC check-ups.

Facilitating factor:

The research team showed an interest in creating empathetic relationships with the participants. Women were welcomed to sit calmly in the room and were offered light refreshments. The research team explored and tried to understand the concerns of the women.

3. Difficulties in establishing trust and maintaining the confidentiality

Impeding factor:

The patients were not ready for disclosure because they did not know if this was the right place to disclose and if sharing the information would be helpful. Also, they feared retaliation by the abuser as family members accompanied her and were present during the consultation. One of the respondents said, "*I am scared that if I reveal being abused at home and if they find out from the doctor, I will be beaten up severely at home*." Furthermore, women were also discouraged by the humiliating nature of the information.

Facilitating factor:

The women needed to understand the intention and rationale behind the administration of BIP to participate in the intervention. Repeated interaction and follow-up with the women for seven months—listening empathetically to their problems given sufficient time and active listening to their narration—allowed them to start expressing their concerns, fears, and hopes, which helped establish trust.

4. The time commitment for routine ANC and follow-up visits

Impeding factor:

Due to the family pressure and burden of domestic chores, child care, and sometimes home-based paid work, the women were mainly hurrying to head back home and committing less time beyond routine ANC check-ups in the hospital. Pestering calls from home and the fear of eliciting suspicion among the family members in the wake of taking up more time at the hospital create more pressure on the women not to interact beyond the required essentials.

Facilitating factor:

i. The behavioural intervention process was spaced in such a manner between the usual waiting periods to ensure the patient's routine ANC check-up was not hampered, extra time was not taken up, and the patient did not miss their turn or any medical consultation. However, they reached the hospital with their family members for follow-up visits. As per the session schedule, we requested the family members to wait outside or return after 45 min and explained the need for and importance of the session for the unborn child's health.
ii. Providing refreshments to help them re-energize: The women were given refreshments as part of the trust-building process, which proved helpful. It also revitalizes and boosts their spirits. The food items were also chosen to represent women's healthy dietary options. They needed a haven from the hectic, overcrowded, and impersonal medical environment.
iii. Reimbursement with remuneration: They were reimbursed for a tiny portion of their transportation costs. Reimbursement of transportation costs is part of the ethical guidelines of the ICMR. It was a considerable aid to women who came from lower-income families and needed money. It promoted trust-building, provided proper financial support during pregnancy, and paid the women for their time commitment to the trial. However, in the future, this may hinder the programme's sustainability.

5. Barriers to women's psychosocial conditioning, attitudes, and beliefs.

Impeding factor:

Women's beliefs regarding DV as a private matter involving family respect, belief in the normalization of abuse as a man's right, permission to take from the family or husband for decision-making, and passive acceptance prevented the women from opening up and disclosing these issues with the healthcare provider. Adding to their belief in the normalization of violence, there were many challenges to disclosing their problem to the healthcare providers, resulting in a low health status reflected in their maternal health indicators (Table 2).

Facilitating factor:

During counselling and self-regulation, providing them with group support helped them slowly regain confidence and start working towards finding solutions to their problems. They started sharing their life experiences with the research team.

6. Lack of sensitization of healthcare providers.

Impeding factor:

According to the researcher's observations and the verbatims of the women respondents, the healthcare providers were unconcerned about women's problems. Some women also said, *"The hospital staff scolded us for not getting the medical reports; we did not know where to get them... we kept asking at the reception—nurses, female guards, and doctors—on how to proceed, and it was very frustrating and time-consuming."*

Poor or inadequate sensitization of healthcare providers to adopting a client-centred approach to patient care was reflected in many ways daily. There was a lack of sensitization of the healthcare staff about the profound, long-lasting, and intergenerational harmful effects of DV.

The women in this study and during the screening process revealed that they had experienced the rude behaviour of healthcare providers.

Disrespect at the hands of hospital staff during ANC visits had eroded their trust in the system as a whole. It also burdens women already in a turbulent, unhealthy, unstable family situation.

Facilitating factor:

One of the focus areas of BIP is establishing confidence in accessing legal and societal support. The research team learned about the problems with accessing and using hospital facilities from the women. Further, the low education levels of most women in the study made it difficult for them to understand the administrative paperwork. The research team provided help to the women in understanding the hospital procedures, and when needed, actual handholding was also done for some of the women.

7. Information asymmetry and instrumental support services.

Impeding factor:

There was a lack of effective interlinkage between health and financial subsidies and schemes run by the Government of India, such as the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (a national public health insurance fund that aims to provide free access to health insurance coverage for low-income earners), the Janani Suraksha Yojana (a safe motherhood intervention implemented to reduce maternal and neonatal mortality by promoting institutional delivery among poor pregnant women), the Pradhan Mantri Matru Vandana Yojana (a conditional cash transfer scheme for pregnant and lactating mothers), etc. To access and avail of these schemes, they need more guidance. Irregular information dissemination and information asymmetry hinder the smooth operation of disbursing healthcare benefit schemes. Even all the healthcare staff needed to be made aware of government schemes or any modifications to these schemes to help the poor and needy patients. Lack of familiarity with resources for helping poor patients results in low uptake of their entitlements.

Facilitating factor

An essential component of BIP was enabling women to effectively and efficiently utilize the existing government programmes and schemes for promoting reproductive and child health. All the impeding factors were converted into enabling factors with improved awareness and seamless backward-forward linkages of public services and schemes.

8. Difficulty in obtaining legal services

Impeding factor:

The institution gives no guidelines or awareness regarding how to deal with cases of DV in the ANC setup. Although the hospital has a one-stop centre (where the victim receives all the support, including legal, health, counselling, etc., under one roof) within its premises, women did not know about it. This procedure makes it impossible to take decisive action when confronted with DV issues. It is difficult, to say the least, for WEDV, who are already in a disturbed frame of mind, to navigate the complex legal system. Most of the women were afraid of involving the police alone; many narrated their experiences of being exploited by the corrupt system. There is a genuine lack of instrumental support services at the healthcare facility, helping women to reach out for legal and police support to deal with DV.

Facilitating factor:

The research team provided information regarding the rights and entitlements of women. It provided a few written documents on the helpline number, family counselling centre, one-stop centre, and DV Act. For creating income opportunities and skill development, the research team facilitated linkages with the schemes and programmes of the government, private agencies, and NGOs working on livelihood and microfinance.

9. Intervention to develop emotional resilience.

Impeding factor:

There were no such activities for developing emotional resilience in the hospital setting.

Facilitating factor:

Apart from modifying the existing problem, the research team was instrumental in developing emotional resilience skills. They learn to manage their stress levels and confront the hard facts of life, which leads to change. Relaxation techniques, sharing their life experiences, and participating in group activities with other women gave them a new perspective from which they could reconstruct their lives. The women respondents liked yoga-based techniques such as physical exercise, breathing exercises, and chanting. They knew they had found a spot in the hospital where they would be welcomed with open arms and given hope for their unborn child's future. This environment enabled them to endure and go through the therapeutic processes, which included significant relearning and progress.

6. Discussion

Findings have documented the barriers pregnant women face that make managing DV more challenging, including a lack of support services and a perceived lack of options at the hospital. The study highlights the level of emotional distress, competing contextual issues, and lack of support from healthcare providers as essential factors in the health and well-being of the WEDV. In addition, it focuses on the plight of terrified, disturbed pregnant women who were dealing with DV at home while attempting to do regular ANC in an overcrowded, impersonal hospital with limited resources. It also offers crucial insights into the elements influencing the intervention's adherence and compliance. In addition, the study emphasizes both the external barriers and internal factors provided by BIP that need to be in place for a DV survivor to engage with and benefit from intervention [43]. Facilitating factors were supplied internally in the trial to reduce the influence of impeding factors and singulate the factors under study. The researchers successfully built rapport with the participants and won their trust and confidence. The assurance of culturally competent and empathic care, problem-solving guidance, and regular interactions all contributed to developing trust and confidence.

Despite the abundance of restrictive variables, the aggregate cumulative impact of impeding factors falls short of the positive impact of facilitating factors, which provide little comfort yet support participation in the trial and BIP adherence. Counselling, empathic listening, and a small transport reimbursement have all been beneficial in encouraging women to follow through on their appointments, with a 97% follow-up rate. Each woman visited the hospital for longer than their scheduled follow-up to interact with the research team. It demonstrates that the women required attentive listening and emotional catharsis from healthcare providers.

The neglect of the patient's emotional needs was frequently reflected in the overworked, overloaded healthcare personnel's abrupt, hurried attitude when faced with acute occupational stressors [44–46]. The results reported that BIP was an essential and helpful part of the intervention and contributed new insight that helps to create a more contextualized and nuanced understanding of intervention processes and impacts. Adopting research approaches capable of evaluating differential effects, processes, and group differences in outcomes is essential for conducting rigorous evaluations of complex interventions [39,42].

Women, in particular, reported that the intervention provided them with the time and space provided by the healthcare providers to think through their risks and strengthen their self-confidence (aspects of positive mental health) to deal with the violence in the best possible ways [47]. As a result, they were very compliant. Women's narratives suggest that an intervention comprising aspects of therapy, education, behaviour modification, and emotional support helped them cope with the emotional and psychological effects of DV and had the potential for long-term improvement. Studies reported elsewhere corroborate these findings [39,48]. Therefore, hearing the voices of DV survivors is essential in designing and implementing interventions and services.

This study is the first of its kind in an Indian hospital setting to determine the levels of adherence and compliance. Strengths of the study include repeat interviews conducted with each participant over a seven-month period, which provided insights into short-term and long-term outcomes. The study establishes the critical elements of BIP as individualized, women-centered, and respectful care and provides added value to address WEDV during pregnancy.

The limitation of the study is that the healthcare professionals were not part of the study design and that it, therefore, lacks holistic, contextual factors, which may be considered in future studies. These intervention effects have been applied only to the low socio-economic group of women attending ANC at a public hospital. Testing this intervention in other socio-demographic groups would be essential to show whether the results can be generalized.

7. Conclusion

The implementation of this study demonstrates a strong need for interventions to convert impeding factors into facilitating factors for appropriate adherence and compliance. Women experiencing DV who attended ANC at a hospital and were exposed to BIP as a facilitating factor have enhanced mental health and their ability to attend the follow-up. In order to improve adherence and compliance with healthcare services, healthcare practitioners must be made more aware of the impact of the quality of human connections. Human connection in the client-centered approach takes no additional time; instead, it benefits the patient and the medical team by minimizing time and burnout and maximizing trust. Thus, BIP interventions create co-benefits for women, medical professionals, and the government at large. Therefore, intervention should be embedded in the health system to provide support and continuity of provisions to women experiencing domestic violence.

Research in context

Evidence before this study

A few observational and cross-sectional studies were conducted in India on the incidence, prevalence, and health consequences of domestic violence (DV). Also, these studies have highlighted the level of awareness among healthcare providers about DV and how to deal with women facing violence. Since there is a high number of patients, this results in non-disclosure of the problem. These studies are insufficient to conclude the factors that might be associated with better or worse outcomes for women experiencing domestic violence (WEDV) in a hospital setting in the cultural context of India.

Added value of this study

This study was part of a larger randomized controlled trial (RCT) study. It is the first RCT of its kind among pregnant women who were facing DV and attending antenatal care (ANC) at a tertiary care hospital in India. The strength of the study lies in the fact that it accounts for the first-hand observations and evidence experienced by the researchers and participants in the hospital setting. The particular objectives in this study were explored with the help of qualitative analysis methods. The women coming to the public hospital for ANC check-ups are diverse religious and socio-cultural background. We found that the behavioural intervention package (BIP) developed in the Indian cultural setting was tested on WEDV for adherence, resulting in a 97% follow-up rate and a significant association with counselling, empathetic listening, and yoga, among other things. We can ascertain that the quality and extent of interaction by the healthcare providers give overall health benefits and other possible clinical benefits to the patients.

Implications of all the available evidence

This study helps identify the impeding and facilitating factors that influence the quality and extent of human interaction centred on the implementation and adherence to an intervention package by the women seeking ANC at the public hospitals in India. The study emphasizes the need for reforms and arrangements in healthcare service provision for pregnant WEDV-seeking ANC and guides policies for healthcare practitioners. We identified several contextual factors associated with an increased adherence rate to the intervention in patients. These findings have implications for patients and healthcare providers who will face difficult decisions during the ANC and in dealing with DV. The current policy may be influenced by this standardised BIP adopted by integrating it with the ANC to address pregnancy-related health outcomes.

Ethical consideration

Informed written consent was obtained from the patient as per the ICMR 2018 ethical guidelines. Confidentiality of information was maintained throughout along with data storage.

Author contributions

MM: contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript. SR: data collection, analysis, and writing paper. PN: data collection, analysis and writing. SP: data collection. AJ: data collection.

Declaration of competing interest

We declare no conflict of interest.

Acknowledgement

We acknowledge the support of Prof. Sudha Prasad and her team from the Obstetrics and Gynecology department at LN hospital to give us the opportunity to carry out the project on the issue.

Funding

This work is supported by funding from the Indian Council of Medical Research (ICMR).

References

[1] Marié T, O'Shea CC, Riain AN, Daly M. Domestic violence during Pregnancy –GP survey report. Dublin: Irish College of General Practitioners; 2016.
[2] McDonnell E, Holohan M, Reilly MO, Warde L, Collins C, Geary M. Acceptability of routine enquiry regarding domestic violence in the antenatal clinic. Ir Med J. 2006 Apr;99(4):123–4. [PMID: 16972587].
[3] Ahmed S, Koenig MA, Stephenson R. Effects of domestic violence on perinatal and early-childhood mortality: evidence from North India. Am J Public Health. 2006 Aug;96(8):1423–8. https://doi.org/10.2105/AJPH.2005.066316.
[4] Mahapatro M, Nayar P, Roy S, Jadhav A, Suruchi Panchkaran S. Domestic violence during pregnancy as risk factors for stress and depression: the experience of women attending ANC at a tertiary care hospital in India. Women Health. 2022;62(2):124–34. https://doi.org/10.1080/03630242.2022.2029670.
[5] Kaye DK, Mirembe FM, Bantebya G, Johansson A, Ekstrom AM. Domestic violence during pregnancy and risk of low birthweight and maternal complications: a prospective cohort study at Mulago hospital. Uganda Trop Med Int Health. 2006 Oct;11(10):1576–84. https://doi.org/10.1111/j.1365-3156.2006.01711.x. [PMID: 17002732].
[6] Evans M, Malpass A, Agnew-Davies R, Feder G. Women's experiences of a randomised controlled trial of a specialist psychological advocacy intervention following domestic violence: a nested qualitative study. PLoS One. 2018;13(11):e0193077.
[7] Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet. 2003;362:1225–30. https://doi.org/10.1016/S0140-6736(03)14546-1.
[8] Luker JA, Craig Louise E, Bennett Leanne, Ellery Fiona, Langhorne Peter, Olivia Wu, et al. Implementing a complex rehabilitation intervention in a stroke trial: a qualitative process evaluation of AVERT. BMC Med Res Methodol. 2016;16:52. https://doi.org/10.1186/s12874-016-0156-9.
[9] Bradley F, Smith M, Long J, O'Dowd T. Reported frequency of domestic violence. Cross sectional survey of women attending general practice. Br Med J. 2002;324:271. https://doi.org/10.1136/bmj.324.7332.271.
[10] Shiell A, Hawe P, Gold L. Complex interventions or complex systems? Implications for health economic evaluation. Br Med J. 2008;336:1281–3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2413333/.
[11] Dickson S, Logan J, Hagen S, Stark D, Glazener C, McDonald AM, et al. Reflecting on the methodological challenges of recruiting to a United Kingdom-wide, multi-Centre, randomised controlled trial in gynaecology outpatient settings. Trials. 2013;14:389. https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-14-389.
[12] Glasgow R, Emmons K. How can we increase translation of research into practice? Types of evidence needed. Annu Rev Public Health. 2007;28:1311–2. https://doi.org/10.1146/annurev.publhealth.28.021406.144145.

[13] Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. Lancet. 2009;374:86–9. https://doi.org/10.1016/S0140-6736(09)60329-9.
[14] Chan A, Song F, Vickers A, Jefferson T, Dickersin K, Gøtzsche P, et al. Increasing value and reducing waste: addressing inaccessible research. Lancet. 2014;383:257–66. https://doi.org/10.1016/S0140-6736(13)62296-5.
[15] Chalmers I, Bracken MB, Djulbegovic B, Garattini S, Grant J, Gülmezoglu A, et al. How to increase value and reduce waste when research priorities are set. Lancet. 2014;383:156–65. https://doi.org/10.1371/journal.pone.0190045.
[16] Mahapatro M. Domestic violence and health Care in India: Policy and practice. Singapore: Springer Nature; 2018.
[17] Mohanna K, Tunna K. Withholding consent to participate in clinical trials: decisions of pregnant women. Br J Obstet Gynaecol. 1999;106(9):892–7. https://obgyn.onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.1999.tb08426.x.
[18] Ballantyne A, Pullon S, Macdonald L, Barthow C, Wickens K, Crane J. The experiences of pregnant women in an interventional clinical trial: research in pregnancy ethics (RIPE) study. Bioethics. 2017;31(6):476–83. https://doi.org/10.1111/bioe.12361.
[19] Van der Zande ISE, Van der Graaf R, Hooft L, Van Delden JJM. Facilitators and barriers to pregnant women's participation in research: a systematic review. Women Birth. 2018;31(5):350–61. https://doi.org/10.1016/j.wombi.2017.12.009.
[20] Tooher RL, Middleton PF, Crowther CA. A thematic analysis of factors influencing recruitment to maternal and perinatal trials. BMC Pregnancy and Childbirth. 2008;8:36. https://doi.org/10.1186/1471-2393-8-36.
[21] Blehar MC, Spong C, Grady C, Goldkind SF, Sahin L, Clayton JA. Enrolling pregnant women: issues in clinical research. Womens Health Issues. 2013;23:e39–45. https://doi.org/10.1016/j.whi.2012.10.003.
[22] Brandon AR, Shivakumar G, Inrig SJ, Sadler JZ, Craddock Lee SJ. Ethical challenges in designing, conducting, and reporting research to improve the mental health of pregnant women: the voices of investigators and IRB members. Am J Bioethics Empirical Bioethics. 2014;5:25–43. https://doi.org/10.1080/23294515.2013.851128.
[23] Madan A, Tracy S, Reid R, Henry A. Recruitment difficulties in obstetric trials: a case study and review. Aust New Zealand J Obst Gynaecol. 2014;54:546–52. https://doi.org/10.1111/ajo.12233.
[24] Haas DM, Wunder K, Wolf JG, Denne SC. Women's health care providers' attitudes toward research in pregnancy. J Reprod Med. 2010;55:108–14. https://pubmed.ncbi.nlm.nih.gov/20506670/.
[25] Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350:h1258.
[26] Cole TB. Is domestic violence screening helpful? JAMA. 2000;284:551–3. https://doi.org/10.1001/jama.284.5.551.
[27] Gutmanis I, Beynon C, Tutty L, Wathen CN, MacMillan HL. Factors influencing identification of and response to intimate partner violence. A survey of physicians and nurses. BMC Public Health. 2007;7:12–22. https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-7-12.
[28] Taft A, Broom D, Legge D. General practitioner management of intimate partner abuse and the whole family: a qualitative study. Br Med J. 2004;328:618–21. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381135/.
[29] McCall-Hosenfeld JS, Weisman CS, Perry AN, Hillemeier MM, Chuang CH. I just keep my antennae out: how rural primary care physicians respond to intimate partner violence. J Interpers Violence. 2014;29(14):2670–94. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4121375/.
[30] Elliott L, Nerney, Jones M, Friedmann PD. Barriers to screening for domestic violence. J Gen Intern Med. 2002;17(2):112–6. https://link.springer.com/article/10.1046/j.1525-1497.2002.10233.x.
[31] Nagham N, Alsafy Entisar S, Alhendal Shurooq H, Alhawaj Medhat K, El-Shazly Mohamed I, Kamel. Knowledge of primary care nurses regarding domestic violence. Alexandria J Med. 2011;47:173–80. https://doi.org/10.1016/j.ajme.2011.02.002.
[32] Alotaby IY, Alkandari Bader A, Alshamali Khalil A, Kamel Mohamed I, El-Shazly Medhat K. Barriers for domestic violence screening in primary health care centers. Alexandria J Med. 2013;49:175–80. https://doi.org/10.1016/j.ajme.2012.07.005.
[33] Maiuro RD, Vitaliano PP, Sugg NK, Thompson DC, Rivara FP, Thompson RS. Development of a health care provider survey for domestic violence. Psychometric properties. Am J Prev Med. 2000;19:245–52. https://doi.org/10.1016/s0749-3797(00)00230-0.
[34] Feder GS, Hutson M, Ramsay J, Taket AR. Women exposed to intimate partner violence. Expectations and experiences when they encounter health care professionals: a meta-analysis of qualitative studies. Arch Intern Med. 2006;166:22–37. https://doi.org/10.1001/archinte.166.1.22.
[35] Richardson J, Coid J, Petruckevitch A, Chung WS, Moorey S, Feder G. Identifying domestic violence. Cross sectional study in primary care. Br Med J. 2002;324:274–7. https://doi.org/10.1136/bmj.324.7332.274.
[36] McCauley J, Yurk RA, Jenckes MW, Ford DE. Inside "Pandora's box": abuse women's experiences with clinicians and health services. J Gen Intern Med. 1998;13(8):549–55. https://doi.org/10.1046/j.1525-1497.1998.00166.x.
[37] Hamberger LK, Ambuel B, Marbella A, Donze J. Physician interaction with battered women. JAMA. 1998;7:576–82. https://doi.org/10.1001/archfami.7.6.575.
[38] Overstreet NM, Quinn DM. The intimate partner violence stigmatization model and barriers to help-seeking. Basic Appl Soc Psychol. 2013;35(1):109–22.
[39] Liebschutz J, Battaglia T, Finley E, Averbuch T. Disclosing intimate partner violence to health care clinicians - what a difference the setting makes: a qualitative study. BMC Public Health. 2008;8:229. https://bmcpublichealth.biomedcentral.com/articles/https://doi.org/10.1186/1471-2458-8-229.
[40] Ford-Gilboe M, Varcoe C, Scott-Storey K, et al. Longitudinal impacts of an online safety and health intervention for women experiencing intimate partner violence: randomized controlled trial. BMC Public Health. 2020;20:260.
[41] Pedersen JS, Malcoe LH, Pulkingham J. Explaining aboriginal/non-aboriginal inequalities in Postseparation violence against Canadian women. Violence Against Women. 2013;19(8):1034–58.
[42] Parker B, McFarlane J, Soeken K, Silva C, Reel S. Testing an intervention to prevent further abuse to pregnant women. Res Nurs Health. 1999;22:59–66.
[43] Feder G, Agnew-Davies R, Baird K, Dunne D, Eldridge S, Griffiths C, et al. Identification and referral to improve safety (IRIS)of women experiencing domestic violence with a primary care training and support programme: a cluster randomised controlled trial. Lancet. 2011;378(9805):1788–95.
[44] Portoghese I, Galletta M, Campagna M. Burnout and workload among health care workers: the moderating role of job control. Saf Health Work. 2014;5(3):152–7. https://doi.org/10.1016/j.shaw.2014.05.004.
[45] McVicar A. Workplace stress in nursing: a literature review. J Adv Nurs. 2003;44:633–42. https://doi.org/10.1046/j.0309-2402.2003.02853.x.
[46] Marine A, Ruotsalainen JH, Serra C, Verbeek JH. Preventing occupational stress in healthcare workers. Cochrane Database Syst Rev. 2006;4. https://doi.org/10.1002/14651858.CD002892.pub2. Art. No. CD002892.
[47] Varcoe C, Ford-Gilboe M, Scott-Storey K, Wuest J, Perrin N. Women's experiences with an online intervention: The complexity of women's lives dealing with intimate partner violence and implications for engagement and design; 2019.
[48] Trevillion K, Howard LM, Morgan C, Feder G, Woodall A, Rose D. The response of mental health services to domestic violence: a qualitative study of service users' and professionals experiences. J Am Psychiatr Nurses Assoc. 2012;18:326–36. pmid:22989418.