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The effect of a behavioural intervention package on quality of life of pregnant women experiencing domestic violence: a randomised controlled trial

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Abstract

Background Domestic violence during pregnancy is especially concerning due to its significant detrimental impact on a woman's health and that of her unborn child. The study aims to evaluate the effects of a behavioural intervention package (BIP) delivered during pregnancy on the quality of life (QOL), domestic violence (DV), and reproductive and child health (RCH) of women experiencing DV.

Methods A randomised controlled trial was conducted on 211 pregnant women recruited between 18 and 20 weeks of pregnancy and randomly assigned to one of two groups: intervention ($n = 105$) or control ($n = 106$). The intervention group received BIP and standard care, while the control group received only standard care for 28 weeks. Study tools included socio-demographic variables, a short-form health survey, an abuse assessment screening tool, and an RCH checklist. The tools were completed once before the intervention and again at 6 weeks postnatal. The tools and their subscales were compared pre- and post-intervention using a paired *t*-test, or Wilcoxon signed test as appropriate to estimate the effect size at baseline and post-intervention.

Results Post-intervention, the QOL scores were found to be significant, with a positive effect favouring the intervention as compared to the control group. The BIP intervention, which was found to be significantly effective ($P \leq 0.001$) in reducing DV for pregnant women experiencing DV, was higher in the intervention group than in the control group.

Conclusion The BIP may be an appropriate method for treating pregnant women experiencing DV from low socio-economic strata who attend public hospitals in India to improve their QOL. The approach may offer an intervention that healthcare institutions or other organizations in contact with women at risk of violence can implement.

Trial registration Indian Registry of Clinical Trials CTRI/2019/01/017009. Registered on 09/01/2019.

Keywords Domestic violence, Quality of life, Behavioural intervention, RCT, Post-intervention

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Background

The global burden of domestic violence (DV) during pregnancy has been well documented in the literature [1, 2]. DV during pregnancy is especially concerning due to its significant detrimental impact on a woman's health and that of her unborn child [3–5]. A meta-analysis reports that a higher proportion of DV occurs during

pregnancy in developing countries than in developed countries [3]. In India, the incidence of DV against pregnant women is reported to be 63% psychological violence, followed by 26% physical violence and 22% sexual violence [6]. DV can take many forms, among which physical, psychological, and sexual violence are the main types [7]. These repercussions are not only physical but also mental and can result in poor health choices, premature birth, recurrent miscarriages, poor quality of life (QOL), and developmental delays [8, 9]. In addition, mental health consequences such as anxiety, depression, and post-traumatic stress disorder (PTSD) [10, 11] are the contributors to maternal morbidities [12].

Further untreated mental illness during the perinatal period poses a dual risk of adverse physical and emotional outcomes for women and their developing foetus or infant. Experts in the field advocate for more IPV screening and intervention to take place among women who are at high risk for DV. A timely intervention might reduce the risk of future IPV, improve treatment utilization, and reduce mental health symptoms [8]. Further, the presence of DV increases the likelihood of disengagement from treatment, which could compromise the ability of women with DV to effectively use essential facilities and resources necessary for better healthcare for themselves and their children [7].

Several interventions aimed at addressing DV and comorbid health conditions have expanded globally in the last decade. Thus, it requires women-centric intervention and institutional architecture that increases access to knowledge, resources, and decision-making power during a crisis. A review of DV interventions found a variety of DV interventions, ranging from brief, one-session individualised consultation to multiple therapy sessions during pregnancy, with some even extending postpartum [13, 14]. DV screening, accompanied by critical therapeutic interventions such as counselling, psychotherapy, and education, has shown some encouraging results [15, 16]. A study on empowerment intervention specially designed for Chinese abused pregnant women was effective in reducing interpersonal violence and improving the health status of the women [17]. A number of interventions have been developed in recent years; however, the generalizability of their findings is problematic as a disproportionately high number of the studies stemmed from high-income countries (HICs), and most of them have not considered DV in the context of pregnancy [15, 16, 18, 19]. Because violence is a contextual issue influenced by financial constraints, insufficient human resources, cultural barriers, social norms, and government policy, the applicability and efficacy of a specific intervention may differ in different settings [20, 21]. There are limited studies on the effects of a women-centric approach on the QOL of abused pregnant women in India. Moreover, without control over their environment, women are subjugated by unequal medical treatment, preventing them from taking control of their lives and the lives of their children. Consequently, women continue to suffer in the vicious cycle of violence.

Pregnancy presents a unique opportunity to identify victims and offer support because of repeated interactions with health care providers (HCPs) from early pregnancy to postpartum [5, 22]. The risk of violence and the ability to prevent and cope with it are different for pregnant women, and reviews failed to provide conclusive recommendations about any one intervention that can be adopted within the antenatal care (ANC) context. Hospitals are more effective settings for targeted case identification and intervention. Thus, considering the high prevalence of DV among pregnant women, the harsh outcomes of violence during pregnancy, its impact on the QOL of pregnant women, and the absence of similar studies conducted in India, the present study was conducted. The study aims to evaluate the effects of a behavioural intervention package (BIP) delivered during pregnancy on the quality of life (QOL), domestic violence (DV), and reproductive and child health (RCH) of women experiencing DV.

Methods

Trial design, setting, and participants

The study was a randomised controlled trial (RCT) with two groups (intervention and control) among pregnant women experiencing DV. The study was conducted from January 2019 to June 2020 at a tertiary-care LN hospital in New Delhi. The study was approved by the institutional review board of the National Institute of Health and Family Welfare (NIHFW), New Delhi. Since the respondents are the patients of the hospital, ethical compliance was obtained from the Ethical Committee of MAMC, New Delhi. The LN hospital is a government hospital that provides free services and caters to people of low and middle socio-economic status.

The inclusion criteria comprised all married pregnant women (preferably between 18 and 20 weeks of pregnancy) attending the obstetrics OPD of LN hospital for antenatal registration; in the age group of 18–37 years, primigravida and multigravida were considered. Further, having been screened positive for DV during the year using the Abuse Assessment Screening Tool (AAST) [23], continuing to stay with the husband or in-laws (family) for at least two years, being likely to continue the treatment till delivery, and being willing to come to the hospital for follow-up as per schedule were other inclusion criteria. Consent was sought for participation in the study by taking signatures on the informed consent

form. Women excluded from this study were those who had already been registered as medicolegal cases (MLCs) related to abuse, those who were in a high-risk group (conditions that may pose a risk to the pregnancy), and those who were intellectually challenged to comprehend and comply with the intervention.

Intervention

A study was carried out in 2016 to assess the feasibility of the behavioural intervention package (BIP) [24], which was then applied in the study. The BIP and standard care were administered to each woman in the intervention group. The control group did not receive the BIP. Standard care was provided alone. The BIP consisted of five components focusing 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 internal system of the body through yoga-based methods (chanting, meditation, and exercise); (iv) individual counselling for effective communication and better interpersonal relations; and (v) developing better awareness for safety planning, problem-solving, and creating opportunities for alternate livelihoods. The standard of care focused on the routine care provided by the health professional at the antenatal clinic includes antenatal care (ANC), postnatal care (PNC), and child care components. It also includes promoting health and well-being via education and support for nutrition, substance abuse cessation, family planning uptake, recognition of danger signs, birth preparedness, etc. The standard care intervention was given to each woman in both groups. The interaction and discussion focused on healthy development and the well-being of the foetus and mother. Although it is part of routine care, the research team reiterated this information in individual-centered care.

The intervention was administered by senior researchers trained in clinical psychology, community medicine, gynaecology, anthropology, and yoga. The sessions were held periodically and distributed over 11 months. Each one-to-one session for administering the intervention package lasted about 45–70 min in an excluded room near OPD without the male partner or other family members being present. After each intervention session, the woman was given the next session's time and date. The entire intervention package was administered, i.e. 6 weeks postnatal, and 11 sessions were conducted with each woman over 28 weeks. The control group received the standard care intervention, which consisted of 11 sessions with the researcher, similar to the study group. Participants were reimbursed for their travel expenses per ICMR guidelines [25] after each session to comply with ethical issues and ensure compliance. A qualitative study was carried out, which helped to identify outcomes most valued by participants and explore barriers and facilitators to adherence to the intervention [26].

Study outcomes

The primary outcome of the present study was QOL measured through a short-form survey (SF-36) [27]. The secondary outcome was the recurrence of DV measured by the Abuse Assessment Screening Tool (AAST) [24]. The outcomes were measured at baseline and post-intervention. Reproductive Child Health (RCH) indicators using the checklist and feedback mechanisms were also recorded to assess the effect of BIP.

Sample size

In a previous study by Tiwari and colleagues [17], an outcome indicator, general health, was considered for sample size calculation. It assumed that the general health is 53 ± 7.5 in the experiment group and 50 ± 7 in the control group; a minor change is expected. It was further, assuming α (type I error) of 5% and power taken as 80%, that a sample of 184 cases was required to be enrolled. It was rounded to hundreds to achieve the figure of 200. Assuming a non-compliance rate of 20%, considering the probability of abortion due to genetic markers and culture-specific reasons for dropouts, the required sample size was 220.

Recruitment and consent

All the pregnant women who met the eligibility criteria were screened using the ASST, and the respondents who answered "yes" within the last year were considered and enrolled in the study. The participants were explained about the study's purpose, potential risks and benefits, instruments, administration time, and follow-up schedules and approached with the subject information sheet (SIS) for consent. If a participant agreed to participate, written informed consent was obtained, and the participant was enrolled in the study.

Randomisation and blinding

To avoid any bias in selection, eligible participants were randomised to either the intervention or the control group at a 1:1 ratio. The list was generated by a computer, concealed in consecutively numbered, sealed envelopes, and recorded by an investigator who was not involved in the study. Outcome assessors and research assistants who entered and analysed the data were recruited after data collection in the third phase and, therefore, did not know the study hypotheses or design and were blinded to group assignment. The person administering the

intervention and standard care packages differed for the groups and were not interchangeable.

Questionnaire measures and data collection tools

The Socio-Economic and Demographic Schedule (SEDS), the AAST, the RCH checklist, the SF-36, and the feedback interview schedule were administered to participants of both groups at baseline and post-intervention after the entire intervention had been completed.

1. The SF-36 is composed of eight multi-item scales (35 items) assessing physical function (PF-10 items), role physical (RP-4 items), bodily pain (BP-2 items), general health (GH-5 items), vitality (VT-4 items), social functioning (SF-2 items), role emotional (RE-3 items), and mental health (MH-5 items) [27].
2. The ASST, which has 15 items developed and validated in Indian culture, was used to screen. A comprehensive assessment tool for DV, having 43 items, was used to evaluate the type, frequency, duration, abuser-relationship fabric, and severity of violence [23].
3. Reproductive Child Health Checklist- Based on OPD investigation information, an RCH checklist on reproductive and child health was used. Maternal health data was related to the pregnancy duration, pregnancy outcome, and sex of the children. The current reproductive health status of the women included their height and weight, planned and unplanned pregnancies, haemoglobin (Hb), blood pressure (BP), preterm labour, hypertensive disorders, drug use, premature rupture of membranes, intrauterine growth retardation, and intrauterine death (IUD) of the foetus, as well as the child's sex. Child health data focused on the baby's birth weight and immunization per the national immunization schedule [24].
4. Socio-Economic and Demographic Schedule (SEDS): The schedule includes information regarding age, education, caste, religion, family type, and income.
5. Feedback on BIP: The research team collected feedback using a semi-structured interview schedule covering all five domains of the BIP, including safety planning, problem-solving, daily yoga practice, maintenance of a diet chart, and coping mechanisms. Some questions were asked to be maintained daily in charts/handouts, some quarterly in open-ended responses, and a few on completing the intervention using a 5-point Likert scale [24].

The researcher telephoned the respondent twice, two days before and a day before, to remind her of the date and time for the follow-up session to enhance her participation. If the participant could not come to the hospital for some reason, the researcher fixed up another convenient time after discussing it with the participant. It was ensured that the participants got preferential care and respect in the hospital with the facilitation of the investigator. This was not the standard or the norm of the hospital setting. However, it was an essential part of the research study to improve compliance.

Data analysis

Statistical analysis was conducted using SPSS 20 software. The SEDS and RCH indicators were calculated with frequency and chi-square. Data are expressed as frequencies and percentages. Continuous data is represented as the mean ± SD or median (IQR) as appropriate. The severity of DV was compared pre and post-intervention by McNemar test separately for intervention and control groups. Chi-square trend analysis was used to compare trends among the ordinal data separately for pre and post-intervention. An independent t-test/ student *t*-test was applied to compare continuous normally distributed data, and the Mann-Whitney test (QOL data) was used for non-normal distribution.

Data of the AAST, QOL scale, and their subscales were compared using a paired t-test or Wilcoxon signed test as appropriate (normality/nonnormality) to estimate the effect size (Cohen's *d*) at baseline and post-intervention. Besides this, with 95% CI, in terms of (1) between-group differences (primary analysis), (2) within-group change from baseline, and (3) between-group difference in change from baseline in the outcomes. Although 243 women entered the study, baseline information was collected for all. However, for various reasons, 211 respondents completed the intervention session, and therefore, an analysis was conducted on 211.

Results

Participants

Overall, 921 pregnant women were screened, of whom 678 also had DV but were not eligible for or excluded from the study. 243 women were randomised into either the intervention (n = 121) or control (n = 122) group. Thirty-two women (13.2%) were not included in the analysis, and the major reasons were that women (n = 12) had miscarriages after recruitment, were lost to follow-up (n = 16), and could not complete the intervention session (n = 4) (Fig. 1). Most of them attended all the sessions of the intervention. All the participants were enumerated, and there was no missing data. There were no reports of adverse events or harm arising from participation in the study.

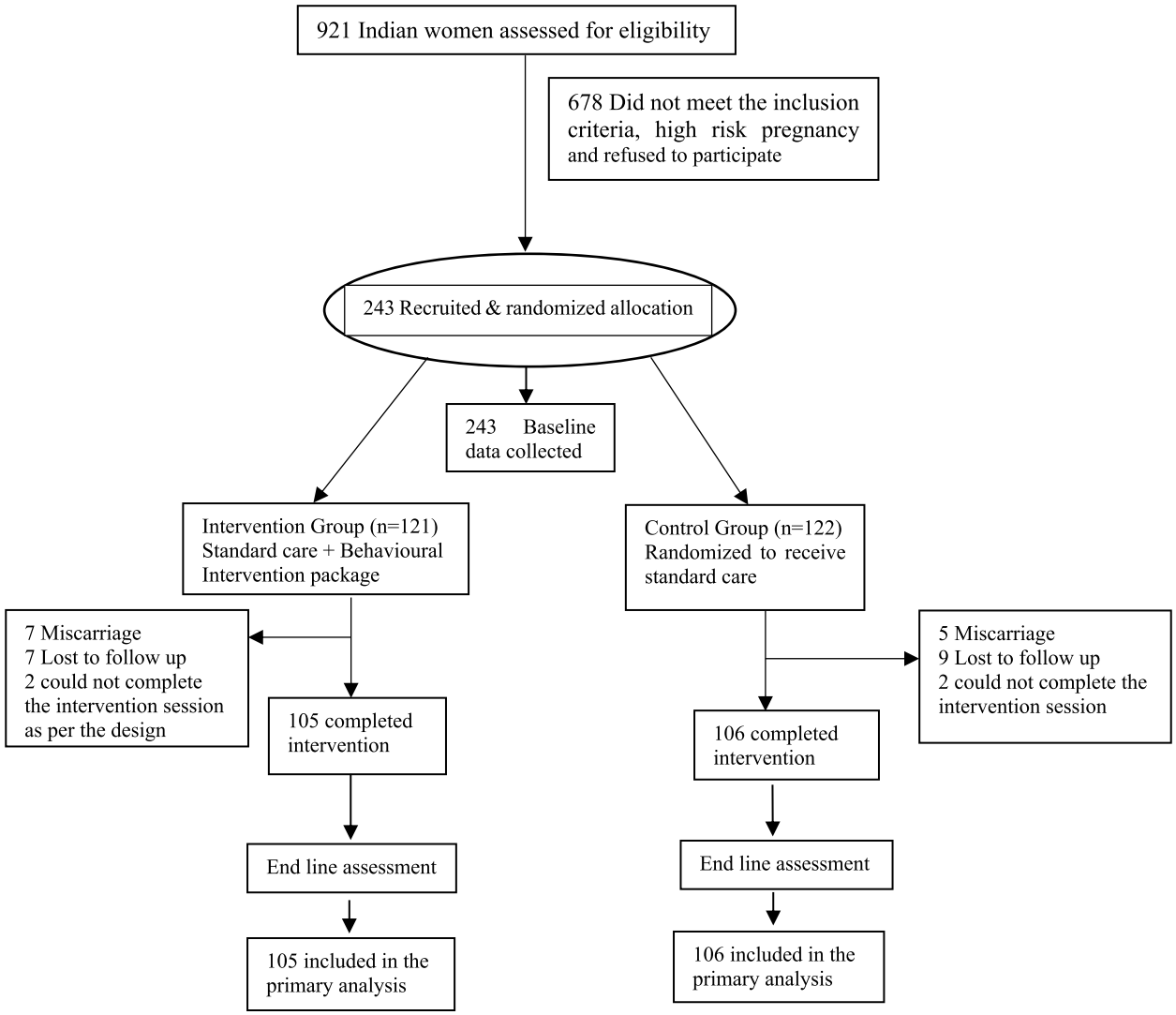

Fig. 1 Flow of participants through the study

Preliminary analysis

The socio-demographic characteristics of the women respondents are shown in Table 1. The mean (SD) of the women's age in the intervention group was 25.3 (3.6) years, and in the control group, it was 24.5 (3.6) years. About 18% of the women in the intervention group and 25% in the control group had 12 years of schooling or more. Women were predominantly housewives (95%) and belonged to a lower economic category. The percentage of women who belonged to Hindu is less compared to Muslims in both groups. The reason may be that the participation of Muslim women in the study is an outcome of the hospital being located in an area dominated by religion. It does not draw religion and domestic violence interpretation. The caste system in India has been scheduled into four categories: General, Other Backward Caste (OBC), schedule caste, and schedule tribe based on socio-political and economic conditions. Other than the general caste group, the other three underprivileged groups receive reservation benefits depending on various factors. Irrespective of the caste categories, facilities in public hospitals are free for all pregnant women. The participants in both groups mostly belonged to the general caste category (about 34%) and (OBC) (about 55%). At baseline, the intervention and control groups were comparable on all but one of the characteristics—specifically, more women were living in joint families in the control group (about 87%) than in the intervention group (about 70%). In India, a joint family can be viewed as having conflict and stress, with women deprived of decision-making

Table 1 Comparison of socio-demographic variable data in intervention and control groups

Variables		Control group $N = 106$	Intervention group $N = 105$	*P*-value
Age (in years)*		24.5 ± 3.6	25.3 ± 4.2	0.14
Caste	General	36 (34.0)	36 (34.3)	0.487
	Other Backward Caste (OBC)	60 (56.6)	57 (54.3)	
	Others	10 (9.4)	12 (11.4)	
Religion	Hindu	40 (37.7)	34 (32.4)	0.999
	Muslim	66 (62.3)	71 (67.6)	
Women education	Illiterate	10 (9.4)	8 (7.6)	0.318
	Primary	17 (16.0)	10 (9.5)	
	Middle	16 (15.1)	26 (24.8)	
	High-school	44 (41.5)	34 (32.4)	
	Above higher-secondary school	19 (17.9)	27 (25.7)	
Husband education	Illiterate	12 (11.3)	12 (11.4)	0.227
	Primary	11 (10.4)	8 (7.6)	
	Middle	27 (25.5)	29 (27.6)	
	High-school	32 (30.2)	33 (31.4)	
	Above higher-secondary school	24 (22.6)	23 (21.9)	
Women occupation	House-wife	101 (95.3)	100 (95.2)	0.999
	Working	5 (4.7)	5 (4.8)	
Husband occupation	Organized sector	58 (54.7)	68 (64.8)	0.460
	Self-employed	30 (28.3)	15 (14.3)	
	Unemployed	18 (17.0)	22 (21.0)	
Type of family	Nuclear	14 (13.2)	31 (29.5)	0.754
	Joint	92 (86.8)	74 (70.5)	
Total family income (in Rs per month)*		22,845.3 ± 28,706.6	20,599.0 ± 23,795.2	0.545

Values are expressed as mean ± SD or frequency (%)

**t*-test was used

power and a sense of security from the members of the family due to the collectiveness of the group.

The intervention effects on QOL

The primary outcome, QOL, was measured using the SF-36, which includes eight domains. At baseline, the groups were similar concerning the QOL and its components. Post-intervention, there were significant mean changes in the intervention group in QOL subscales for all eight domains ($p < 0.001$) compared to the baseline (Fig. 2). After 28 weeks, the between-group difference indicated a statistically significant increase ($p < 0.001$) in the QOL for all the sub-scales in the intervention group in comparison to the control group: PF (5.086 vs. − 0.415), RP (2.13 vs. 0.14), RE (1.67 vs. 0.13), MH (2.555 vs. − 2.632), VT (1.048 vs. − 3.157), BP (0.448 vs. − 0.883), GH (0.874 vs. − 4.423), SF (1.25 vs. − 0.13) (Fig. 3). However, there were improvements in the few QOL subscales after follow-up in the control group. In the present study, the highest subscale scores were associated with physical functioning in the intervention group.

The intervention effects on violence

The intervention and control groups were compared using chi-square (χ^2) trend analysis. The data analysis reports that in the control group, a third of the women fell into each of the mild, moderate, and severe categories of facing DV prior to intervention. In contrast, 40% of women in the intervention group fell into the moderate category, followed by 38% in the severe category (Table 2).

The DV was 2. 89 and 2.86 times more in the moderate and severe categories than in the mild categories, respectively. There was a reduction of 31% in moderate cases and 90.2% in severe cases as compared to mild cases. The McNemar test shows a statistically significant value ($P = .02$) in the control group and intervention group ($P \leq 001$). Post-intervention, the difference in severe cases is more in the intervention group from the baseline. The severe and the moderate cases are less than in the control group. The intervention group has more mild cases (69.5%) than the control group (47.1%). The higher the number of mild cases, the lower the incidence of severe and moderate cases.

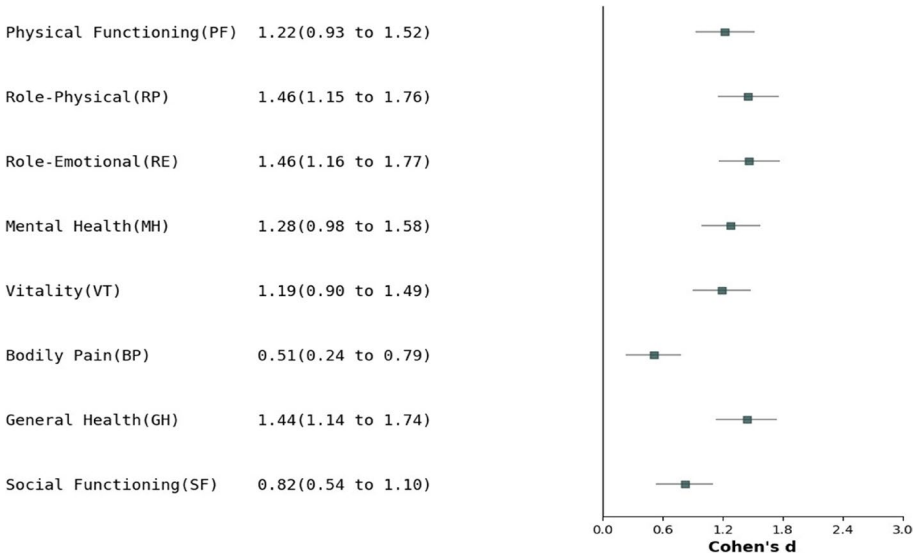

Fig. 2 Standarsied mean difference of QOL within the group from baseline to post-intervention

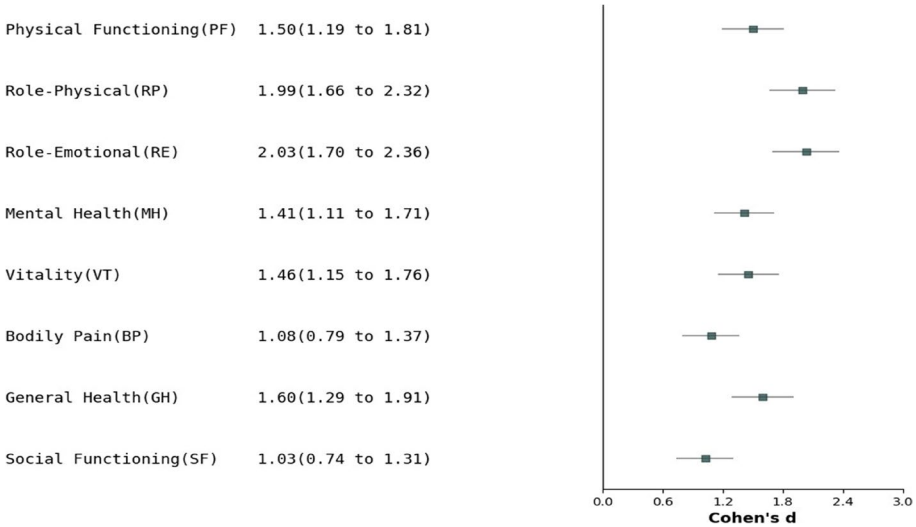

Fig. 3 Standarsied mean difference of QOL between Intervention and control group

Table 2 Comparison of domestic violence pre- and post-intervention between intervention and control group

Domestic violence		Intervention group $N = 105$ Frequency (%)	Control group $N = 106$ Frequency (%)	OR	χ^2 trend analysis in proportion
Pre-intervention	Mild	34 (32.1)	16 (15.2)	1	3.97
	Moderate	36 (34.0)	49 (46.7)	2.89	
	Severe	36 (34.0)	40 (38.1)	2.36	
Post-intervention	Mild	50 (47.2)	73 (69.5)	1	19.34
	Moderate	28 (26.4)	28 (26.7)	0.685	
	Severe	28 (26.4)	4 (3.8)	0.098	
Between group (McNemar)		60.89	7.78		
	P-value	0.020	0.000		

The intervention effects on RCH indicators

The association of RCH indicators between the intervention and control groups using chi-square is presented in Table 3. The distribution of women in percentage with BP > 140/90 mmHg (37.7 vs. 31.5), IUD (1.9 vs. 0.0), women in preterm labour (2.8 vs. 0.0), and low birth weight of the baby (< 2.5 kg) (34.6 vs. 32) is marginally higher in the control group compared to the intervention group (Table 3), though not statistically significantly associated.

Feedback from the respondent to assess the BIP

Assessment of BIP through feedback has been advocated as a means of improving intervention progress and outcomes. It also helped to understand the translation of the parameters in real-life circumstances. Some information was collected daily, while some were collected every quarter. For example, handouts for dietary charts and yoga practices were given to respondents to complete daily, and the research team used to review them in the following session with the respondent.

Questions like this were asked quarterly: "What was most useful for helping in your life situation?". The respondents said, "The doctors in the hospital are kind and considerate. They listen to our problems and we try to find solutions together. It was very comforting as nobody else has given this time and attention in the hospital ever." "Were you able to better understand the resources you have that are available free of cost? Are you able to utilize them now? Respondent said, "They did not know about various entitlements provided by the government, such as a free food distribution system, health insurance scheme, family counseling cells in the hospital providing civil rights to women experiencing DV, and other resources." The researcher checked the handouts of yoga-based methods and dietary practices for compliance. They were motivated to continue right through if they could not do it. Did you find chanting, exercising, breathing, and communicating with the baby helpful? Based on their feedback, they were encouraged and motivated. They were also told alternate ways to continue if they had any problems during the exercises. For example, one woman said she could not sit on the floor. She was told to sit comfortably on a chair and practice. They also narrated their novel ways to cope with the family situation. At the end of the intervention, the respondents were asked to rate the discussion and interaction with the researcher/doctor. The responses were noted on a 5-point scale (ranging from 1, not helpful, to 5, extremely helpful). Overall, the women found this discussion and interaction with the researcher extremely helpful.

Table 3 Comparison of reproductive and child health indices in intervention and control groups

Reproductive health indicators	Intervention group ($N = 105$)		Control group ($N = 106$)		P-value (χ^2 test)
	N	%	*N*		%
Hb (gm%)					
< 10	18	17.2	20	0.228	19.1
≥ 10	45	42.9	57		54.8
BP (mmHg)					
< 140/90	72	68.5	66	0.446	62.3
> 140/90	33	31.5	40		37.7
Preterm Labor					
Yes	0	0.0	3	0.121	2.8
No	105	100.0	103		97.2
Use of hypertensive drug					
Yes	3	2.9	3	0.991	2.8
No	102	97.1	103		97.2
Intrauterine death of fetus					
Yes	0	0.0	2	0.246	1.9
No	105	100.0	104		98.1
Birth weight of baby					
less than 2.5 kg	34	32.0	36	0.768	34.6
Greater or equal to 2.5 kg	72	67.9	68		65.4
Immunization status					
Yes	102	97.1	103	0.991	97.1
No	3	2.9	1[a]		0.9

[a] In two cases there was an intrauterine death of foetus

Discussion

Overall, the study showed the potential of BIP intervention, which was found to be significantly effective in increasing the QOL and reducing the recurrence of DV for pregnant women who experienced DV during their ANCs in a clinical setting in India. Post-intervention, the QOL scores were found to be significant, with a positive effect favouring the intervention as compared to the control group. This result was consistent with studies conducted in other Asian countries and worldwide [28–30]. Furthermore, the intervention improves the control group's quality of life from baseline to post-intervention. The significance of a few subscales of QOL in the control group may be attributed to external factors such as time, awareness, and fear of administration. The possible reason was the interaction of the study researcher with the women and providing standard care in a respectful manner, which is generally not expected in a hospital setting. The challenges faced by pregnant women in hospital settings have been reported [26].

Post-intervention, a statistically significant change was observed within and between the intervention and control groups in the recurrence of DV. There was a reduction of DV of 31% in moderate cases and 90.2% in severe cases compared to mild cases, which was statistically significant. Consistent with the findings of this study, similar results were reported from RCT studies conducted elsewhere [8, 17]. There are likely other factors; for example, women were more focused on self-care with increasing gestational age, and family members and spouses were less likely to commit severe forms of violence. Despite their poor reproductive and child health indices and the challenges of an overwhelmed healthcare system, we demonstrated the effectiveness of a BIP intervention.

The objectives of the BIP are empowerment and developing plans to achieve better health. It seems that women who underwent this type of intervention could work on regulating the internal systems of the body, emotions, and thoughts through improved self-care, including yoga, enhancement of positive self-perception, and an improvement in awareness. In line with this research, previous RCTs have shown that mind-body interventions such as cognitive counselling and anger management training are effective approaches to reducing DV and increasing the quality of life of women [31–33]. Further, the feedback mechanism was useful to understand the effect on women's overall lives. It also helped to understand that even if ready-made solutions were not available, giving time to the women was very helpful. It was hopeful to see women embrace life again. The overall feedback indicated that BIP intervention works satisfactorily to help women experiencing DV.

Strengths and limitations

To our knowledge, this is the first RCT to examine the effects of a BIP intervention on the QOL of pregnant women who have experienced DV in India. The retention rate and compliance to intervention in this study appear remarkable [26]; previous trials involving abused women have also reported a high retention rate [17, 34]. We demonstrated the utility and feasibility of using an innovative, integrated approach. The effects of this intervention would have been even more significant if the women had come from a better socioeconomic background.

This study has a few limitations. All measures were self-reported, subject to memory errors and conscious or unconscious distortions of what was reported. Also, the initial responses of the women may vary with the post-intervention level of rapport establishment and trust due to a higher level of trust with the researcher. The assessment was done at the baseline and post-intervention; however, measuring the outcome in between would have been a helpful guide to the intervention. Focusing on women's efforts to cope with DV without taking their partners' actions into account is also a limitation. Without knowing the context in which DV occurs, the actions of both the perpetrators and the survivors cannot be fully understood. Finally, these intervention effects have been applied only to the low socioeconomic group of women attending ANC at a public hospital. Testing this intervention in other socio-demographic groups would be important to show whether the results can be generalized.

Conclusion

The BIP may be an appropriate method for treating pregnant women experiencing domestic violence from low socioeconomic strata who attend public hospitals in India to improve their QOL. The approach may offer an intervention that healthcare institutions or other organizations in contact with women at risk of violence can implement. It is recommended that India, with its diversified culture, multi-centre study, and similar studies conducted on non-pregnant women, would be better. If women in the intervention group retain the skills learned during the intervention, this could assist them in maintaining their behavioural gains for a more extended period. In future studies, we recommend following the mothers for longer intervals to measure sustained effects. To safeguard the health of pregnant women, screening for domestic violence and its management using BIP may be included in the antenatal services in different settings.

Abbreviations

ANC Antenatal care
BIP Behavioural intervention package

RCT Reproductive child health
QOL Quality of life
DV Domestic violence

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-07966-5.

Supplementary Material 1.

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Protocol available
https://www.ctri.nic.in/Clinicaltrials/pdf_generate.php?trialid=29984&EncHid=&modid=&compid=%27%2729984det%27.

Authors' contributions
Prof. Meerambika Mahapatro—conceived the project and executed it, conceived the idea for the paper, supervised the findings and wrote the manuscript. Dr. Sudeshna Roy—collected data, entered the data into the software and supported in writing the manuscript. Dr. Poonam Nayar—collected data and supported in writing the manuscript. Mr. Divyanshu Srivastava—analysed the data. Ms. Suruchi Panchkaran—collected data. Dr. Ashwini Jadhav—collected data. Prof. Sudha Prasad—managed the project at the hospital. Prof. Neera Dhar—supported in report writing.

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Availability of data and materials
Owing to the conditions of the ethical approval for the project, and the sensitive nature of the data and concerns, the raw data analysed here are not available for a deposit.

Declarations

Ethics approval and consent to participate
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.

Consent for publication
It is the mandate for the Principal Investigator to publish the research findings.

Competing interests
The authors declare that they have no competing interests.

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