Antenatal Based Pilot Psychosocial Intervention to Enhance Mental Health of Pregnant Women Experiencing Domestic and Family Violence in Nepal

Diksha Sapkota^{1,2}, Kathleen Baird^{1,3}, Amornrat Saito^{1,2}, Pappu Rijal⁴, and Debra Anderson^{2,3}

¹ School of Nursing and Midwifery, Griffith University, Queensland, Australia,

² Women's Wellness Research Program, Menzies Health Institute Queensland, Queensland, Australia

³ Faculty of Health, University of Technology Sydney, Australia

⁴ Department of Obstetrics and Gynecology, B.P. Koirala Institute of Health Sciences, Dharan, Nepal

Author Note

Diksha Sapkota <https://orcid.org/0000-0002-2122-8747>

Kathleen Baird <https://orcid.org/0000-0003-0142-6962>

Amornrat Saito <https://orcid.org/0000-0002-9290-719X>

Debra Anderson <https://orcid.org/0000-0001-8996-9624>

This study was registered with the Australian New Zealand Clinical Trials Registry, (Identifier 12618000307202). We have no known conflict of interest to disclose. We received no financial support for the research, authorship, and/or publication of this article. We would like to thank Mrs Rita Pokharel (RP) for helping with data collection, and BPKIHS and their staff for providing administrative support and assistance for the conduct of the study.

Correspondence concerning this article should be addressed to Diksha Sapkota, Griffith University, Logan Campus, 68 University Drive, Meadowbrook, QLD 4131, Phone: +61 (0) 468424923, Email address: diksha.sapkota@griffithuni.edu.au

Abstract

Survivors of domestic and family violence (DFV) report poorer quality of life and worsening mental health. This study evaluated the effect of a counseling and education intervention on mental health and help-seeking behaviors among pregnant women living with DFV. A parallel pilot randomized controlled trial was performed among 140 pregnant women attending an antenatal clinic of a tertiary hospital of Nepal. Using computer-generated random numbers, participants were randomized to the intervention group (a counseling session, an information booklet about DFV, and contact details of the counselor) or a control group (usual care plus a booklet containing contact details of local DFV support services). Outcome measures included mental health, quality of life (QOL), self-efficacy, social support and safety planning behaviors. Analyses followed intention-to-treat, using the generalized estimating equation model. Intervention participants showed significant improvements in anxiety ($\beta=-3.24$, $p<0.001$) and depression ($\beta=-3.16$, $p<0.001$) at post-intervention. Such improvements were also sustained at follow-up assessment ($p<0.001$). Significant group and time interaction for QOL, social support, use of safety behaviors, and self-efficacy ($p<0.05$) revealed a greater increase in these outcome measures among intervention participants at both follow-up assessments compared to the control group. This pilot integrated intervention showed promising outcomes in improving mental health, social support, and the use of safety behaviors among women with DFV. This intervention could be incorporated into regular antenatal care as a strategy to identify and support victims of DFV. Larger controlled trials with longer follow-up are needed to support and expand on the current findings regarding the effectiveness of a psychosocial intervention targeting victims of DFV in resource-constrained settings.

Keywords: domestic violence, randomized controlled trial, counseling, mental health

Antenatal Based Pilot Psychosocial Intervention to Enhance Mental Health of Pregnant Women Experiencing Domestic and Family Violence in Nepal

Over the past decade, there is an increased recognition of importance to address maternal mental health to maximize productivity and reduce health care costs (Howard et al., 2014). Mental health problems such as depression and anxiety are common during pregnancy and following childbirth (Thomas et al., 2019). Compared to high-income countries, the prevalence rates of these morbidities are significantly higher in low- and middle-income countries (LMICs) (Fisher et al., 2012; Howard et al., 2013). All women are at risk of developing mental health disorders during their pregnancy, as it is a period of significant physical, mental and social changes for women (Arora et al., 2019; Howard et al., 2013). Several factors such as experience of violence or hostility from husbands or in-laws, lack of intimate partner or social support, and poor socioeconomic status further increase the risk of mental health conditions among pregnant women (Ludermir et al., 2010).

Within the literature a number of terminologies, such as Intimate Partner Violence (IPV) or Domestic and Family Violence (DFV), are used interchangeably or with slight variations in their meaning. IPV includes physical, sexual, and emotional abuse, and controlling behaviors by an intimate partner, while DFV includes partner violence, as well as abuse by any member of a household (World Health Organization [WHO], 2013). In a Nepalese context, a woman often relocates to her husband's house after marriage and is therefore at risk of violence from the hands of her husband as well as her in-laws due to the culture of extended families living together (Sapkota et al., 2016). Considering this, the broader term '*Domestic and Family Violence*' (DFV) has been used in this study, which included any forms of violence or abuse, such as physical, sexual, and/or emotional, perpetrated against woman by her husband/partners or someone in her husband's family (Ministry of Health et al., 2017; Sapkota, et al., 2016). Despite being considered a global public health issue, DFV around

the time of pregnancy is a major concern in developing countries compared to those in developed ones (27.7% vs 13.3%) (James et al., 2013). From the limited studies available from Nepal, it was found that the prevalence of DFV during pregnancy ranged from 6-29% (Ministry of Health et al., 2017; Rishal et al., 2017).

A well-documented characteristic of DFV is coercive and controlling behaviors from a husband and/or family members. Living under such emotional stress negatively affects the mental wellbeing of victims (Trevillion et al., 2012). Abused women are more likely to suffer from mental health problems such as depression, anxiety, and post-traumatic stress disorders (Devries et al., 2013; Howard et al., 2013). Low confidence and fear of discrimination are common among women in abusive relationships, as they both negatively impact upon their decisions regarding disclosing abusive behaviour and seeking support services (O'Doherty et al., 2016; Rishal et al., 2016). Poor emotional wellbeing has been identified as a barrier in engaging with support services (O'Doherty et al., 2016). In addition, feelings of shame and guilt when combined with the normalization of the DFV contribute to a poorer quality of life (QOL) among abused women (Othman et al., 2014; Tavoli et al., 2016).

Despite the increased vulnerabilities to mental health conditions and DFV at the time of pregnancy (Baird, 2015; Pun et al., 2019), pregnancy is also considered to be an opportune time to interject against DFV. It is a period when a woman is in a regular contact with her health care providers (HCPs) allowing her to develop a relationship of mutual trust, which can facilitate disclosure (Jahanfar et al., 2014; Rishal et al., 2016). Additionally, nurses and midwives are considered some of the best professionals to offer advice and support to victims (Baird, 2015; Rishal et al., 2016). The antenatal clinic (ANC) is considered as an appropriate setting for adopting prevention and intervention strategies against DFV as it offers a confidential environment to safely reach a maximum number of affected women and helps to minimize stigma (Pallitto et al., 2016; Rishal et al., 2017; WHO, 2013).

98 Recently, there has been a global increase in the number of intervention studies on
99 DFV and its consequences to address maternal morbidities and mortalities (Jahanfar et al.,
100 2014; Van Parys et al., 2014). As most of the studies are conducted in few high-income
101 countries (Jahanfar et al., 2014; Van Parys et al., 2014), much of what has been evaluated
102 has limited generalizability to LMICs where the most vulnerable populations reside (James et
103 al., 2013). Furthermore, some interventions, though effective, are rarely scalable to LMICs
104 (for example, use of clinical psychologists, or web-based interactive technology) (Tarzia et
105 al., 2016; Van Parys et al., 2014). A systematic review analyzing interventions targeting
106 abused pregnant women in LMICs found that counseling interventions utilizing an
107 empowerment approach and psychotherapy improved the mental health and use of safety
108 behaviors (Sapkota, Baird, Saito, & Anderson, 2019). Previous studies indicated that assuring
109 a woman that her concerns are listened to and believed, along with providing support to
110 manage her daily stressors has the potential to improve the victim's mental health and ability
111 to take action against DFV (Bryant et al., 2017; Hegarty et al., 2013; Tiwari et al., 2005).

112 Expecting a brief counseling intervention delivered at an individual level to decrease
113 violence in women's lives in the short-term is often problematic (Hegarty et al., 2013), as
114 violence is not solely determined by women's behaviors, rather it depends greatly on the
115 behaviors of perpetrators and broader socio-cultural factors (Ellsberg et al., 2015).
116 Additionally, ending a violent relationship is often not the desired outcome of the victim and
117 they may not be ready to address DFV in their lives directly (Campbell, 2002). Instead, recent
118 studies have increasingly advocated for integrative therapies, such as interpersonal therapy or
119 motivational interviewing or supportive counseling for improving self-efficacy, social
120 support, and mental health including QOL of women having experienced DFV (Hegarty et
121 al., 2013; Saftlas et al., 2014; Tiwari et al., 2005).

The limited availability of intervention studies addressing mental health needs of abused pregnant women in the context of LMICs, coupled with mixed findings regarding their effectiveness, provided the conceptual basis for this study. To date, there have been no counseling programs in Nepal, targeting pregnant women with a history of DFV, that have incorporated a motivational interviewing approach, while being evaluated using an experimental design with mental health as an outcome. In response to this dearth of studies, an integrated intervention including information regarding DFV, facilitated access to community resources, and provision of safety planning advice was implemented in a tertiary hospital of Nepal. This pilot intervention was hypothesized to exert positive changes in women's mental health, self-efficacy, and safety planning behaviors. Moreover, it was hypothesized that the improvements would be sustained over time.

Materials and methods

Study Design and Participants' Characteristics

The design of this study, including data collection tools and techniques, is outlined in more detail in the published protocol paper (Sapkota, Baird, Saito, Rijal, et al., 2019). This paper seeks to describe the quantitative aspect of evaluation of the intervention. An assessor-blinded, 1:1 parallel-group, randomized controlled trial (RCT) was conducted at BP Koirala Institute of Health Sciences (BPKIHS), Nepal between June 2018 and January 2019. The hospital is a large tertiary hospital in Eastern Nepal. Everyday nearly 100-150 pregnant women visit the ANC clinic. Criteria for inclusion into the study were, married women aged 18 years and over, 24-34 weeks of gestation, history of DFV, access to a telephone, and able to understand simple Nepalese language. The five-item Abuse Assessment Screen (AAS) was used to assess whether women were ever afraid of anyone in their family, had experienced emotional and physical violence in their lifetime, physical and sexual violence in the last 12 months, and physical violence in their current pregnancy. Women reporting at least one

positive response in AAS screening questions were classified as victims of DFV (McFarlane et al., 1992), and further asked about the types of perpetrators. This trial conforms to the CONSolidated Standards of Reporting Trials (CONSORT) guidelines (Schulz et al., 2010).

Sample Size

Power calculations using G*Power indicated that 64 participants in each group were sufficient to detect a between-groups effect size of 0.5, with alpha set at 0.05, and power set at 0.80. Due to a lack of previous similar studies, a moderate effect size ($d=0.5$) was used (Cohen, 1988). A 10% attrition rate was anticipated, resulting in a final sample of 140.

Randomization and Blinding

A statistician independent from the trial provided the computer-generated random numbers to assign participants to each condition, using sequentially numbered, opaque, and sealed envelopes. After the baseline data collection, participants were randomized and the intervention nurse (DS) provided either the intervention or a referral list depending on participants' allocation status. The outcome assessor (RP) was blinded to participants' allocation status. Recruitment of participants ceased once the target sample size had been reached.

Intervention

The brief multicomponent intervention was based on the Problem Management Plus (PM+) (WHO, 2016b) and the "*Safe and Sound*" intervention implemented in South Africa (Pallitto et al., 2016). The intervention comprised three interrelated components:

- A single face-to-face counseling session, using an empowerment approach, guided by motivational interviewing (MI) techniques, was used to improve engagement of the participants with the intervention (Saftlas et al., 2014). It aimed to help participants make decisions for themselves and their families that best fit their needs. The intervention was based on social cognitive theory in order to improve self-efficacy

and motivation among participants (Bandura, 2004). Women were encouraged to express their feelings and concerns by asking open-ended questions, and the counselor assisted them by developing plans for managing stress and seeking support services for them.

- Women were provided with an information booklet, which includes DFV and its common mental health impacts, strategies to help them deal with daily stressors, as well as advice on how to improve their safety, and a list of local support organizations against DFV. The development and validation of the information booklet has been described elsewhere (Sapkota, Baird, Saito, Budhathoki, et al., 2020).
- Intervention participants were also provided with the contact details of the counselor and advised that they could contact her at times of need during the study period.

Participants randomized to the control group received a usual care and a booklet including a referral list of local support organizations working against DFV. The booklets provided to participants in the both groups included information regarding pregnancy and postpartum care and had same front cover to decrease any risks to participants by disguising the study as research related to maternal health rather than DFV specifically.

Measures

The participants were interviewed at pre-intervention or baseline (T0); post-intervention or immediate assessment after 4-6 weeks of T0 (T1); and follow-up at 6 weeks post-birth of a baby (T2). The questions were common across all three surveys to maximize comparison of data at different time-points. Interviews were conducted during a woman's antenatal/postnatal visits at the hospital, however, any women, who were unable to visit the hospital were interviewed via telephone. Standard validated tools were selected with rigorous consultation between the research team, and pretesting was carried out to ensure the research instrument was easy for the participants to understand and respond to. Feasibility of the

intervention included an examination of the recruitment rate, randomization, and the attrition rate. Acceptability of the intervention, perceived impacts and recommendations for future implementation of the intervention were explored qualitatively (Sapkota, Baird, Saito, Rijal, et al., 2020).

Hospital Anxiety and Depression Scale (HADS) was used to measure symptoms of anxiety and depression and consists of 14 items, seven items for the anxiety subscale and seven for depression subscale (Zigmond & Snaith, 1983). Each item is scored on a response-scale ranging from 0 to 3. In the present study, the reliability coefficient values (alpha) for anxiety were 0.81 at baseline, 0.74 at post-intervention, and 0.87 at follow-up assessment. Similarly, for depression, Cronbach's alpha were 0.61 at T0, 0.65 at T1, and 0.69 at T2. The WHO Quality of Life Scale – abbreviated version (WHOQOL-BREF) measured quality of life (QOL), and it contains 26-items assessing four domains of QOL- physical, psychological, environmental, and social (WHO, 1998). Each item of the WHOQOL-BREF is scored from 1 to 5 on a response scale. Domain scores are scaled in a positive direction, i.e. higher scores indicate better QOL. Cronbach's alpha for total QOL score were 0.85, 0.92, and 0.93 at baseline, post-intervention, and follow-up respectively.

A 10-items Generalized self-efficacy scale (GSES) measured self-efficacy (Schwarzer & Jerusalem, 1995). Each item of the GSES is scored from 1 to 4 on a response scale, with higher scores indicating higher self-efficacy. Cronbach's alpha for the scale were 0.83, 0.79, and 0.83 at baseline, post-intervention, and follow-up respectively. Social support was assessed with the abbreviated version of the Medical Outcomes Study Social Support Scale (MOS-SSS), which consists of 5 items (Sherbourne & Stewart, 1991). Each item is scored on a response scale ranging from 1 to 5. The values of Cronbach's alpha were 0.77 at T0, 0.84 at T1, and 0.85 at T2. A safety behaviors checklist developed by McFarlane et al. (2002) was modified to fit the study context and the final checklist consisted of 13 items. Socio-

demographic variables included age, ethnicity, educational levels, employment status, residence, family structure (nuclear or joint family), smoking, and alcohol consumption. Caste/ethnicity were categorized as Brahmin/Chettris, Dalits, Terai Madhesi Castes, and Janajatis as previous studies indicated a high proportion of DFV among Dalits and Terai Madhesi (Sapkota et al., 2016; Ministry of Health et al., 2017).

Intervention Fidelity

An intervention guide outlining the objective of the intervention, strategies and processes of conducting it and sample scripts were prepared. Delivering the intervention using this guide and by a single person has ensured consistency in the intervention delivered to all participants. Checklists were completed after each counseling session to ensure all key items were discussed during the counseling. A telephone guide was used to ensure that participants received identical information, which is important to eliminate influences on outcomes.

Data Analysis

Statistical analyses were conducted using the IBM Statistical Package for the Social Sciences, version 25. Socio-demographic characteristics of participants and baseline outcome values across the study groups were compared using the independent-sample Student's t-test or the non-parametric Mann-Whitney U test for continuous variables, and chi-square (χ^2) test for categorical variables. Corresponding p-values and effect sizes are mentioned in the tables. Similarly, the baseline characteristics of dropouts and completers were also compared.

Analyses were based on an intention-to-treat approach, assuming that each individual adhered to their assigned treatment at each time-point. Missing data were substituted using a last-observation-carried-forward (LOCF) approach. Intervention effects were assessed using repeated measures generalized estimating equation (GEE) linear regression models with an unstructured working correlation structure. GEE improves power to detect a treatment effect

by using a single regression model to simultaneously describe treatment effect at all-time points (whilst accounting for the potential correlation between successive within-participant measurements) (Ballinger, 2004). As there were no indications for significant differences between the groups at baseline, GEE models were run without additional adjustment for any covariates. As a measure of intervention effect, the estimated mean difference (β) between groups alongside 95% confidence intervals (CIs) and two-sided p-values were reported, and statistical significance was set at $p < 0.05$. Within-group comparisons were conducted using the paired t-test. The standardized effect sizes were calculated with Cohen's d formula, and were interpreted as small (0.2 to 0.5), medium (0.5 to 0.8), or large (>0.8) (Cohen, 1988).

Ethics

The research ethics committee of the Griffith University, Nepal Health Research Council, and BPKIHS approved this study. Written informed consent was obtained from all participants. Ethical considerations recommended by the WHO (2016a) for conducting intervention research in violence against women were followed throughout the study.

Results

Feasibility Measures

Out of the 625 pregnant women screened, 173 met the inclusion criteria. Of these, 143 women (82.7%) consenting to continue with the trial were recruited in the study. Three women who discontinued the baseline interviews were excluded from the main samples. Over the course of the study, none of the participants recruited in the study refused the intervention or withdrew their consent. The retention rate was 90.7% at T1 and 78.5% at T2. Comparison of socio-demographic variables between the completers and those who were lost to follow-up (LTFU) did not reveal statistically significant differences ($p > 0.05$) (data not shown). Figure 1 depicts the flow of participants through study processes.

[Insert Figure 1 here]

Characteristics of Participants

Participants' age ranged from 18 to 44 years, with a mean of 25.51 ± 5.26 years. Just above half of the respondents (54.3%) in both groups had completed up to secondary level education. Around one-third of the participants were employed, with similar numbers in each group. More than two-third of respondents (70.7%) had never consumed alcohol, and the majority of participants were living in joint family settings. Demographic characteristics and outcome measures were similar between the two groups at baseline ($p > 0.05$) (see Table 1). Similarly, there were no significant differences in the DFV related characteristics, such as types of perpetrators and forms of violence, between the two groups ($p > 0.05$, data not shown).

[Insert Table 1 here]

Intervention Effects

Table 2 and Table 3 illustrates the effects of intervention from T0 to T1, and from T0 to T2 respectively.

[Insert Table 2 and Table 3 here]

Mental Health

There was a greater reduction in anxiety scores from T0 to T1 ($\beta = -3.24$, $p < 0.001$), and from T0 to T2 ($\beta = -3.73$, $p < 0.001$) in the intervention group (IG), compared to the control group (CG). The intervention participants had lower depressive symptoms at T1 ($\beta = -3.16$, $p < 0.001$), and at T2 ($\beta = -3.41$, $p < 0.001$), compared to the control group. Specifically, the IG reported significantly greater improvements than the control group from T0 to T1 in anxiety ($d = 0.75$, $p < 0.001$) and depression symptoms ($d = 0.69$, $p < 0.001$).

Quality of Life

The participants in the IG had a greater increase in mean QOL scores ($\beta = 2.98$, $p < 0.001$) at T1, and ($\beta = 2.45$, $p < 0.001$) at T2 than did those in the CG. Similarly, there were greater increase in scores of QOL in all four domains among the IG compared to CG at T1

and T2 ($p < 0.05$). Within-group analyses revealed significant improvements of QOL in all domain among the IG ($p < 0.001$) at T1 and T2. However, in the CG, except for environmental domain, there were no significant changes in scores of other domains of QOL ($p > 0.05$) at T1. At T2, significant changes in QOL and its subscales were noted in both groups, but the effect sizes seen in the CG were comparatively lower than those observed in the IG.

Self-efficacy

Self-efficacy increased significantly in the IG compared to CG both at T1 ($\beta = 0.40$, $p < 0.001$) and T2 ($\beta = 0.51$, $p < 0.001$). Significant improvements were noted in the mean self-efficacy score from T0 to T1 ($d = 0.91$, $p < 0.001$) and from T0 to T2 ($d = 0.88$, $p < 0.001$) in the IG. Although, there was a significant increment in GSES score from T0 to T1 in the CG ($p < 0.001$), the effect size was smaller than that observed in the IG (0.42 vs 0.91).

Use of Safety Behaviors

The intervention participants had a greater increase in the use of the safety behaviors at T1 ($\beta = 1.91$, $p < 0.001$) and T2 ($\beta = 2.39$, $p < 0.001$), compared to the CG. Significant improvements in the adoption of safety behaviors were identified at both follow-up assessments in the IG ($p < 0.001$). However, in the CG, the mean number of safety behaviors used did not change significantly from T0 to T1 ($p > 0.05$), whilst at T2 there was significant increase in a number of safety behaviors used ($d = 0.36$, $p < 0.05$).

Social Support

A significant group and time interaction ($p < 0.001$, at T1 as well as T2) verified the change in the social support score at different gradients over the time in the two study groups. The perceived social support increased significantly from T0 to T1 in the IG ($d = 1.00$, $p < 0.001$), but not in the CG ($d = 0.10$, $p > 0.05$). Despite significant improvements in social support in both groups at T2, larger effect size was seen in the IG ($d = 0.90$, $p < 0.001$) than the CG ($d = 0.18$, $p < 0.001$).

Discussion

The results from this study revealed for the first time the feasibility and positive outcome of an antenatal based counseling and education intervention to reduce depressive symptoms and anxiety, and improve quality of life (QOL), use of safety behaviors, and self-efficacy in Nepal. In addition, it revealed that improvements in the outcome measures were sustained until 6-weeks post-birth of a baby.

The high participation rate in the study also indicates the general acceptability of the intervention among women. It reflects a positive perception of vulnerable women on disclosing their experiences of DFV to HCPs and adopting strategies to improve their safety and emotional wellbeing, corroborating a similar study (Gupta et al., 2017). Previous studies have shown that women for a varied of reasons have a tendency to hide a history of DFV from HCPs and have a reluctance to initiate a discussion regarding their experience of DFV unless asked specifically by HCPs (Othman et al., 2014). The current study supports the recommendation by WHO (2013) on screening pregnant women against the presence of DFV during their ANC visits. However, integration of DFV enquiry in an ANC care requires a strong system level change including training of HCPs, organizational support, onsite referral services and collaboration with local stakeholders (Arora et al., 2019; Hamberger et al., 2015). This study demonstrates that when provided with the necessary organizational support, intervention delivery protocol, and training, interested HCPs can successfully offer counseling and education interventions in clinical settings.

The findings of the present study are encouraging and are largely consistent with the results reported in the previous literature for improving the mental health and QOL of women experiencing DFV (Gupta et al., 2017; Hegarty et al., 2013; Saftlas et al., 2014; Tiwari et al., 2005). For example, women receiving the intervention utilizing motivational interviewing techniques had shown a decrease in depressive symptoms compared to those in control group

(Saftlas et al., 2014). Similarly, the combination of approaches, such as supportive counseling, safety planning, and referrals, used by Gupta et al. (2017), found short-term improvements in safety planning and mental health QOL. Empowerment based counseling operating at an individual level tends to change a woman's ways of thinking and help her to change help-seeking behaviors (Rivas et al., 2019). In this study, counseling was adapted to the individual needs of the women through the development of a central notion of women-centred care. Without taking into considerations the woman's individual circumstances, there is a greater likelihood of failure of an intervention to produce desired results (Evans et al., 2018). Taking such an individualized approach possibly helped participants to improve their own coping and self-care skills as they built a relationship of trust and satisfaction with the counselor (Sapkota, Baird, Saito, Rijal, et al., 2020).

All participants showed improvements in their QOL, anxiety, and social support over time despite their group allocation. This improvement could represent adequate support and care received by a woman from her parents and/or family during her puerperium. In the Nepalese culture, most women usually go to live with her parents after the birth of their baby for about three to six months to receive nurturing, care, and support for themselves and their babies (Sharma et al., 2016). Though larger effect sizes in the IG indicated greater improvements among intervention participants, further studies with follow-up after return of a woman in her husband's house are recommended.

In this study, participants were advised about DFV and offered techniques to address it as well as being reassured of continual support from the research team. Such encouragement and reassurance might have influenced the participants' self-efficacy; helped them identify additional safety measures; and encouraged them to seek support when it was needed. This is supported by previous studies which indicate that poor self-esteem and social isolation among women in abusive relationships often leads to limited insight into and

recognition of the DFV (Papadakaki et al., 2009). Helping women to understand and identify different forms of DFV is considered a crucial step in altering the trajectory of DFV (Evans & Feder, 2016). Existing literature confirms a greater increase in self-efficacy and perceived social support among women receiving a counseling intervention (Coker et al., 2012; Saftlas et al., 2014), and an important role of consistent and practical support in promoting physical and mental wellbeing of victims (Coker et al., 2012; Hegarty et al., 2013). Though insignificant, other studies from similar settings showed a general trend of a greater number of intervention participants adopting safety behaviors (Cripe et al., 2010; Gupta et al., 2017). Applicability of safety behaviors largely depends on a woman's circumstances; hence, there is no universal list of safety behaviors that should be adopted by all victims. Every study should consider developing a contextual relevant safety behaviors checklist.

The findings of this study should be considered in light of its limitations. First, as participants reported their characteristics using self-reported questionnaires, the results might have been influenced by social desirability bias. However, to minimize this, interviews were conducted at a private place and at a time feasible to the participants. Second, participants were recruited from a single ANC clinic located in a city of Eastern Nepal. While this may limit generalizability, the study provides important findings about the impact of a psychosocial intervention in a vulnerable population for DFV. Thirdly, because of the nature of the intervention, it was not possible for the participants to be blinded to the intervention condition. However, this concern was mitigated to some extent by blinding the outcome assessor to the intervention condition. Finally, due to the financial and time constraints, it was not possible to undertake a longer follow-up; hence, the sustained effects of the intervention could not be guaranteed. Future studies are recommended to determine the long-term outcomes of the intervention.

Despite these limitations, this is the first study to demonstrate the positive effects of a healthcare based psychosocial intervention on the mental health, social support, and self-efficacy in a resource-limited setting. The intervention was developed after rigorous evaluations of available literature and has been adapted to fit the context where it was implemented. This relatively low-resource and brief intervention has a strong potential for translation in similar clinic settings and further exploration of this approach is warranted to establish the efficacy of this intervention. Successful recruitment and retention of a group of vulnerable women in the study, the use of a control group, and use of standardized outcome measures represent significant methodological strengths of this study. Drop-out from the study was consistent with that of other similar trials (Bryant et al., 2017; Gupta et al., 2017), and attrition bias is not of concern as there were no significant differences in socio-demographic characteristics between completers and those who were lost to follow-up.

Conclusions

This novel individual level counseling intervention, delivered by a nurse, has shown beneficial effects in reducing depression and anxiety, and improving self-efficacy and quality of life of victims of DFV in Nepal. This study adds to the evidence about the feasibility of screening pregnant women against DFV and providing counseling and education interventions in antenatal settings in LMICs. The study findings support the provision of brief psychosocial interventions as a viable and effective strategy for supporting victims of DFV, that could be easily implemented in the healthcare settings of Nepal. This model can also be adapted and translated to other resource-constrained settings to elucidate the beneficial components, and more importantly areas for improvements, to optimize the intervention.

References

- Arora, S., Deosthali, P. B., & Rege, S. (2019). Effectiveness of a counselling intervention implemented in antenatal setting for pregnant women facing domestic violence: a pre-experimental study. *BJOG*, *126 Suppl 4*, 50-57. <https://doi.org/10.1111/1471-0528.15846>
- Baird, K. (2015). Women's lived experiences of domestic violence during pregnancy (2). *Pract Midwife*, *18*(9), 37-40.
- Ballinger, G. A. (2004). Using Generalized Estimating Equations for Longitudinal Data Analysis. *Organizational Research Methods*, *7*(2), 127-150. <https://doi.org/10.1177%2F1094428104263672>
- Bandura, A. (2004). Health promotion by social cognitive means. *Health Education & Behavior*, *31*(2), 143-164. <https://doi.org/10.1177/1090198104263660>
- Bryant, R. A., Schafer, A., Dawson, K. S., Anjuri, D., Mulili, C., Ndogoni, L., . . . Shehadeh, M. H. (2017). Effectiveness of a brief behavioural intervention on psychological distress among women with a history of gender-based violence in urban Kenya: A randomised clinical trial. *PLOS Medicine*, *14*(8), Article e1002371. <https://doi.org/10.1371/journal.pmed.1002371>
- Campbell, J. C. (2002). Health consequences of intimate partner violence. *Lancet*, *359*. [https://doi.org/10.1016/S0140-6736\(02\)08336-8](https://doi.org/10.1016/S0140-6736(02)08336-8)
- Cohen, J. (1988). Statistical power analysis for the behavioral sciences. (2nd ed.): Hillsdale, NJ: Lawrence Erlbaum Associates.
- Coker, A. L., Smith, P. H., Whitaker, D. J., Le, B., Crawford, T. N., & Flerx, V. C. (2012). Effect of an In-Clinic IPV Advocate Intervention to Increase Help Seeking, Reduce Violence, and Improve Well-Being. *Violence Against Women*, *18*(1), 118-131. <https://doi.org/10.1177%2F1077801212437908>

- 444 Cripe, S. M., Sanchez, S. E., Sanchez, E., Ayala Quintanilla, B., Hernández Alarcon, C.,
445 Gelaye, B., & Williams, M. A. (2010). Intimate partner violence during pregnancy: a
446 pilot intervention program in Lima, Peru. *Journal of Interpersonal Violence*, 25(11),
447 2054-2076. <https://doi.org/10.1177%2F0886260509354517>
- 448 Devries, K. M., Mak, J. Y., Bacchus, L. J., Child, J. C., Falder, G., Petzold, M., . . . Watts, C.
449 H. (2013). Intimate partner violence and incident depressive symptoms and suicide
450 attempts: a systematic review of longitudinal studies. *PLOS Medicine*, 10(5), Article
451 e1001439. <https://doi.org/10.1371/journal.pmed.1001439>
- 452 Ellsberg, M., Arango, D. J., Morton, M., Gennari, F., Kiplesund, S., & Contreras, M. (2015).
453 Prevention of violence against women and girls: what does the evidence say. *Lancet*,
454 385. [https://doi.org/10.1016/S0140-6736\(14\)61703-7](https://doi.org/10.1016/S0140-6736(14)61703-7)
- 455 Evans, M., Malpass, A., Agnew-Davies, R., & Feder, G. (2018). Women's experiences of a
456 randomised controlled trial of a specialist psychological advocacy intervention
457 following domestic violence: A nested qualitative study. *PLOS One*, 13(11).
458 <https://doi.org/10.1371/journal.pone.0193077>
- 459 Evans, M. A., & Feder, G. S. (2016). Help-seeking amongst women survivors of domestic
460 violence: a qualitative study of pathways towards formal and informal support. *Health*
461 *Expectations*, 19(1), 62-73. <https://doi.org/10.1111/hex.12330>
- 462 Fisher, J., Mello, M. C. d., Patel, V., Rahman, A., Tran, T., Holton, S., & Holmes, W. (2012).
463 Prevalence and determinants of common perinatal mental disorders in women in low-
464 and lower-middle-income countries: a systematic review. *Bulletin of the World Health*
465 *Organization*, 90(2), 139-149. <https://doi.org/10.2471/BLT.11.091850>
- 466 Gupta, J., Falb, K. L., Ponta, O., Xuan, Z., Campos, P. A., Gomez, A. A., . . . Olavarrieta, C.
467 D. (2017). A nurse-delivered, clinic-based intervention to address intimate partner
468 violence among low-income women in Mexico City: findings from a cluster

randomized controlled trial. *BMC Medicine*, 15(1), 128.

<https://doi.org/10.1186/s12916-017-0880-y>

Hamberger, L. K., Rhodes, K., & Brown, J. (2015). Screening and intervention for intimate partner violence in healthcare settings: creating sustainable system-level programs. *Journal of Women's Health*, 24(1), 86-91. <https://doi.org/10.1089/jwh.2014.4861>

Hegarty, K., O'Doherty, L., Taft, A., Chondros, P., Brown, S., Valpied, J., . . . Feder, G. (2013). Screening and counselling in the primary care setting for women who have experienced intimate partner violence (WEAVE): a cluster randomised controlled trial. *The Lancet*, 382(9888), 249-258. [https://doi.org/10.1016/S0140-6736\(13\)60052-5](https://doi.org/10.1016/S0140-6736(13)60052-5)

Howard, L. M., Oram, S., Galley, H., Trevillion, K., & Feder, G. (2013). Domestic violence and perinatal mental disorders: a systematic review and meta-analysis. *PLOS Medicine*, 10(5), Article e1001452. <https://doi.org/10.1371/journal.pmed.1001452>

Howard, L. M., Piot, P., & Stein, A. (2014). No health without perinatal mental health. *Lancet*, 384(9956), 1723-1724. [https://doi.org/10.1016/S0140-6736\(14\)62040-7](https://doi.org/10.1016/S0140-6736(14)62040-7)

Jahanfar, S., Howard, L. M., & Medley, N. (2014). Interventions for preventing or reducing domestic violence against pregnant women. *Cochrane Database of Systematic Reviews*, (11). <https://doi.org/10.1002/14651858.CD009414.pub3>

James, L., Brody, D., & Hamilton, Z. (2013). Risk factors for domestic violence during pregnancy: a meta-analytic review. *Violence Vict*, 28(3), 359-380. <https://psycnet.apa.org/doi/10.1891/0886-6708.VV-D-12-00034>

Ludermir, A. B., Lewis, G., Valongueiro, S. A., de Araujo, T. V. B., & Araya, R. (2010). Violence against women by their intimate partner during pregnancy and postnatal depression: a prospective cohort study. *Lancet*, 376(9744), 903-910. [https://doi.org/10.1016/S0140-6736\(10\)60887-2](https://doi.org/10.1016/S0140-6736(10)60887-2)

- 494 McFarlane, J., Malecha, A., Gist, J., Watson, K., Batten, E., Hall, I., & Smith, S. (2002). An
495 intervention to increase safety behaviors of abused women: results of a randomized
496 clinical trial. *Nursing Research*, 51(6), 347-354. [https://doi.org/10.1097/00006199-](https://doi.org/10.1097/00006199-200211000-00002)
497 [200211000-00002](https://doi.org/10.1097/00006199-200211000-00002)
- 498 McFarlane, J., Parker, B., Soeken, K., & Bullock, L. (1992). Assessing for abuse during
499 pregnancy: severity and frequency of injuries and associated entry into prenatal care.
500 *JAMA*, 267(23), 3176-3178. <https://doi.org/10.1001/jama.1992.03480230068030>
- 501 Ministry of Health, New Era, & ICF International Inc. (2017). *Nepal demographic and health*
502 *survey 2016*. Kathmandu: Nepal.
503 <https://www.dhsprogram.com/pubs/pdf/fr336/fr336.pdf>
- 504 O'Doherty, L., Taket, A., Valpied, J., & Hegarty, K. (2016). Receiving care for intimate
505 partner violence in primary care: barriers and enablers for women participating in the
506 weave randomised controlled trial. *Social Science & Medicine*, 160, 35-42.
507 <https://doi.org/10.1016/j.socscimed.2016.05.017>
- 508 Othman, S., Goddard, C., & Piterman, L. (2014). Victims' barriers to discussing domestic
509 violence in clinical consultations: A qualitative enquiry. *Journal of Interpersonal*
510 *Violence*, 29(8), 1497-1513. <https://doi.org/10.1177/0886260513507136>
- 511 Pallitto, C., Garcia-Moreno, C., Stoeckl, H., Hatcher, A., MacPhail, C., Mokoatle, K., &
512 Woollett, N. (2016). Testing a counselling intervention in antenatal care for women
513 experiencing partner violence: a study protocol for a randomized controlled trial in
514 Johannesburg, South Africa. *BMC Health Services Research*, 16.
515 <https://doi.org/10.1186/s12913-016-1872-x>
- 516 Papadakaki, M., Tzamalouka, G. S., Chatzifotiou, S., & Chliaoutakis, J. (2009). Seeking for
517 risk factors of intimate partner violence (IPV) in a Greek national sample: The role of

- 518 self-esteem. *Journal of Interpersonal Violence*, 24(5), 732-750.
519 <https://doi.org/10.1177%2F0886260508317181>
- 520 Pun, K. D., Rishal, P., Darj, E., Infanti, J. J., Shrestha, S., Lukasse, M., & Schei, B. (2019).
521 Domestic violence and perinatal outcomes—a prospective cohort study from Nepal.
522 *BMC Public Health*, 19(1), 671. <https://doi.org/10.1186/s12889-019-6967-y>
- 523 Rishal, P., Joshi, S. K., Lukasse, M., Schei, B., Swahnberg, K., & ADVANCE Team. (2016).
524 'They just walk away'- women's perception of being silenced by antenatal health
525 workers: a qualitative study on women survivors of domestic violence in Nepal.
526 *Global Health Action*, 9(31838). <https://doi.org/10.3402/gha.v9.31838>
- 527 Rishal, P., Pun, K. D., Darj, E., Joshi, S. K., Bjørngaard, J. H., Swahnberg, K., . . .
528 ADVANCE Study Group. (2017). Prevalence and associated factors of domestic
529 violence among pregnant women attending routine antenatal care in Nepal.
530 *Scandinavian Journal of Public Health*, 46(8), 785-793.
531 <https://doi.org/10.1177/1403494817723195>
- 532 Rivas, C., Vigurs, C., Cameron, J., & Yeo, L. (2019). A realist review of which advocacy
533 interventions work for which abused women under what circumstances. *Cochrane*
534 *Database of Systematic Reviews*(6).
535 <https://doi.org/10.1002/14651858.CD013135.pub2>
- 536 Saftlas, A. F., Harland, K. K., Wallis, A. B., Cavanaugh, J., Dickey, P., & Peek-Asa, C.
537 (2014). Motivational interviewing and intimate partner violence: a randomized trial.
538 *Annals of Epidemiology*, 24(2), 144-150.
539 <https://doi.org/10.1016/j.annepidem.2013.10.006>
- 540 Sapkota, D., Bhattarai, S., Baral, D., & Pokharel, P. K. (2016). Domestic violence and its
541 associated factors among married women of a village development committee of rural
542 Nepal. *BMC Research Notes*, 9(1), 178. <https://doi.org/10.1186/s13104-016-1986-6>

- 543 Sapkota, D., Baird, K., Saito, A., & Anderson, D. (2019). Interventions for reducing and/or
544 controlling domestic violence among pregnant women in low-and middle-income
545 countries: a systematic review. *Systematic Reviews*, 8(1), 79.
546 <https://doi.org/10.1186/s13643-019-0998-4>
- 547 Sapkota, D., Baird, K., Saito, A., Rijal, P., Pokharel, R., & Anderson, D. (2019).
548 Counselling-based psychosocial intervention to improve the mental health of abused
549 pregnant women: a protocol for randomised controlled feasibility trial in a tertiary
550 hospital in eastern Nepal. *BMJ Open*, 9(4), Article e027436.
551 <https://bmjopen.bmj.com/content/9/4/e027436>
- 552 Sapkota, D., Baird, K., Saito, A., Budhathoki, S. S., Pokharel, R., Basnet, S., & Anderson, D.
553 (2020a). Development and Validation of an Information Booklet Aimed at Promoting
554 Mental Health for Pregnant Women with a History of Abuse. *Journal of Nepal Health*
555 *Research Council*, 17(4), 456.
556 <http://jnhrc.com.np/index.php/jnhrc/article/view/2017/866>
- 557 Sapkota, D., Baird, K., Saito, A., Rijal, P., Pokharel, R., & Anderson, D. (2020b). ‘We don’t
558 see because we don’t ask’: Qualitative exploration of service users’ and health
559 professionals’ views regarding a psychosocial intervention targeting pregnant women
560 experiencing domestic and family violence. *PLOS One*, 15(3), Article e0230069.
561 <https://doi.org/10.1371/journal.pone.0230069>
- 562 Schulz, K. F., Altman, D. G., Moher, D., & Group, C. (2010). Consort 2010 statement:
563 Updated guidelines for reporting parallel group randomized trials. *Annals of Internal*
564 *Medicine*, 152(11), 726-732. [https://doi.org/10.7326/0003-4819-152-11-201006010-](https://doi.org/10.7326/0003-4819-152-11-201006010-00232)
565 [00232](https://doi.org/10.7326/0003-4819-152-11-201006010-00232)
- 566 Schwarzer, R., & Jerusalem, M. (1995). Generalized self-efficacy scale. [https://userpage.fu-](https://userpage.fu-berlin.de/health/engscal.htm)
567 [berlin.de/health/engscal.htm](https://userpage.fu-berlin.de/health/engscal.htm)

- 568 Sharma, S., van Teijlingen, E., Hundley, V., Angell, C., & Simkhada, P. (2016). Dirty and 40
569 days in the wilderness: Eliciting childbirth and postnatal cultural practices and beliefs
570 in Nepal. *BMC Pregnancy and Childbirth*, 16(1), Article 147.
571 <https://doi.org/10.1186/s12884-016-0938-4>
- 572 Sherbourne, C. D., & Stewart, A. L. (1991). The MOS social support survey. *Social Science*
573 *& Medicine*, 32(6), 705-714. [https://doi.org/10.1016/0277-9536\(91\)90150-B](https://doi.org/10.1016/0277-9536(91)90150-B)
- 574 Tarzia, L., Murray, E., Humphreys, C., Glass, N., Taft, A., Valpied, J., & Hegarty, K. (2016).
575 I-DECIDE: An Online Intervention Drawing on the Psychosocial Readiness Model
576 for Women Experiencing Domestic Violence. *Women's Health Issues*, 26(2), 208-
577 216. <https://doi.org/10.1016/j.whi.2015.07.011>
- 578 Tavoli, Z., Tavoli, A., Amirpour, R., Hosseini, R., & Montazeri, A. (2016). Quality of life in
579 women who were exposed to domestic violence during pregnancy. *BMC Pregnancy*
580 *and Childbirth*, 16(1), 19. <https://doi.org/10.1186/s12884-016-0810-6>
- 581 Thomas, J. L., Lewis, J. B., Martinez, I., Cunningham, S. D., Siddique, M., Tobin, J. N., &
582 Ickovics, J. R. (2019). Associations between intimate partner violence profiles and
583 mental health among low-income, urban pregnant adolescents. *BMC Pregnancy*
584 *Childbirth*, 19(1), 120. <https://doi.org/10.1186/s12884-016-0810-6>
- 585 Tiwari, A., Leung, W. C., Leung, T. W., Humphreys, J., Parker, B., & Ho, P. C. (2005). A
586 randomised controlled trial of empowerment training for Chinese abused pregnant
587 women in Hong Kong. *BJOG*, 112(9), 1249-1256. [https://doi.org/10.1111/j.1471-](https://doi.org/10.1111/j.1471-0528.2005.00709.x)
588 [0528.2005.00709.x](https://doi.org/10.1111/j.1471-0528.2005.00709.x)
- 589 Trevillion, K., Oram, S., Feder, G., & Howard, L. M. (2012). Experiences of domestic
590 violence and mental disorders: a systematic review and meta-analysis. *PLOS One*,
591 7(12), Article e51740. <https://doi.org/10.1371/journal.pone.0051740>

- 592 Van Parys, A.-S., Verhamme, A., Temmerman, M., & Verstraelen, H. (2014). Intimate
593 partner violence and pregnancy: A systematic review of interventions. *PLOS One*,
594 9(1). <https://doi.org/10.1371/journal.pone.0085084>
- 595 World Health Organization. (1998). *WHOQOL user manual: Programme on mental health:*
596 World Health Organization. <https://apps.who.int/iris/handle/10665/77932>
- 597 World Health Organization. (2013). *Responding to intimate partner violence and sexual*
598 *violence against women: WHO clinical and policy guidelines*. Geneva: World Health
599 Organization.
- 600 World Health Organization. (2016a). *Ethical and safety recommendations for intervention*
601 *research on violence against women: Building on lessons from the WHO publication*
602 *Putting Women first: ethical and safety recommendations for research on domestic*
603 *violence against women*. Geneva: World Health Organization.
- 604 World Health Organization. (2016b). *Problem Management Plus (PM+): Individual*
605 *psychological help for adults impaired by distress in communities exposed to*
606 *adversity. (Generic field-trial version 1.0)*. Geneva: World Health Organization.
- 607 Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta*
608 *Psychiatrica Scandinavica*, 67(6), 361-370. [https://doi.org/10.1111/j.1600-](https://doi.org/10.1111/j.1600-0447.1983.tb09716.x)
609 [0447.1983.tb09716.x](https://doi.org/10.1111/j.1600-0447.1983.tb09716.x)
- 610

Table 1*Socio-demographic Characteristics and Outcome Measures at Baseline compared by Groups*

Socio-demographic variables		Total M (SD)/ n (%)	Intervention M (SD)/ n (%)	Control M (SD)/ n (%)	p- value/ES
Educational qualification	Age in years	25.51 (5.26)	24.70 (4.74)	26.31 (5.65)	0.07/0.31 ^a
	Up to primary level	19 (13.6)	10 (14.3)	9 (12.9)	0.79/0.06 ^b
	Up to secondary level	76 (54.3)	36 (51.4)	40 (57.1)	
Ethnicity	Higher Secondary level and above	45 (32.1)	24 (34.3)	21 (30.0)	
	Brahmins/Chhetris	40 (28.6)	20 (28.6)	20 (28.6)	0.94/0.05 ^b
	Dalits	21 (15.0)	11 (15.7)	10 (14.3)	
	Terai Madhesi Castes	20 (14.3)	11 (15.7)	9 (12.9)	
Personal source of income	Janajatis	59 (42.1)	28 (40.0)	31 (44.3)	
	Yes	52 (37.1)	26 (37.1)	26 (37.1)	1.00/0.00 ^b
Source of income	No	88 (62.9)	44 (62.9)	44 (62.9)	
	Service	7 (10.9)	4 (12.1)	3 (9.7)	0.54/0.18 ^b
Smoking status	Business/Shops/Cattle rearing	39 (60.9)	19 (57.6)	20 (64.5)	
	Daily wages labor	6 (9.4)	2 (6.1)	4 (12.9)	
	Has now left	12 (18.8)	8 (24.2)	4 (12.9)	
	Current smoker	5 (3.6)	3 (4.3)	2 (2.9)	0.12/0.17 ^b
Alcohol consumption habit	Past smoker	7 (5.0)	1 (1.4)	6 (8.6)	
	Never	128 (91.4)	66 (94.3)	62 (88.6)	
	Current consumer	18 (12.9)	9 (12.9)	9 (12.9)	0.51/0.10 ^b
Family structure	Past consumer	23 (16.4)	14 (20.0)	9 (12.9)	
	Never	99 (70.7)	52 (74.3)	47 (67.1)	
	Nuclear family	47 (33.6)	21 (30.0)	26 (37.1)	0.37/0.08 ^b
Anxiety	Joint family	93 (66.4)	49 (70.0)	44 (62.9)	
		9.05 (4.65)	9.61 (4.95)	8.49 (4.29)	0.20/0.11 ^c
Depression		6.50 (3.89)	6.90 (3.67)	6.10 (4.09)	0.20/0.11 ^c
	Physical QOL	14.29 (2.73)	14.30 (2.65)	14.27 (2.82)	0.94/0.01 ^a
Psychological QOL		13.50 (2.64)	13.27 (2.56)	13.73 (2.72)	0.30/0.17 ^a
	Social Relationships QOL	13.90 (3.26)	13.50 (3.23)	14.29 (3.27)	0.18/0.11 ^c
Environmental QOL		13.31 (2.66)	12.99 (2.56)	13.64 (2.74)	0.14/0.24 ^a
	Overall QOL	13.72 (2.16)	13.50 (2.02)	13.93 (2.28)	0.25/0.20 ^a
GSES		2.96 (0.63)	2.88 (0.69)	3.04 (0.55)	0.18/0.11 ^c
	Use of safety behaviors	6.35 (2.65)	6.03 (2.67)	6.67 (2.60)	0.15/0.12 ^c
Social support		3.54 (0.89)	3.40 (0.90)	3.68 (0.87)	0.05/0.17 ^c

QOL = quality of life; ES = effect size; ^a Values obtained from independent t-test; ^b Values obtained from Pearson or Likelihood ratio chi-square test; ^c Values obtained from Mann-Whitney-U test

Table 2*Effectiveness of Intervention on Outcome Measures From Baseline to Post-Intervention*

Outcome variable	G	Pre-intervention (T0)	Post-intervention (T1)	T×G interaction ^a	Within-group changes (T0-T1)	
		M(SD)	M(SD)	β (95% CI)	MD (95% CI)	d
Anxiety	IG	9.61 (4.95)	5.77 (3.58)	-3.24 (-4.78, -1.71)***	3.84 (2.62, 5.07) ***	0.75
	CG	8.49 (4.29)	7.89 (4.08)		0.60 (-0.39, 1.59)	0.15
Depression	IG	6.90 (3.67)	3.94 (3.44)	-3.16 (-4.50, -1.82) ***	2.96 (1.94, 3.98) ***	0.69
	CG	6.10 (4.09)	6.30 (4.08)		-0.20 (-1.12, 0.72)	0.05
Physical QOL	IG	14.30 (2.65)	17.04 (2.66)	2.63 (1.65, 3.60) ***	-2.74 (-3.42, -2.07) ***	0.97
	CG	14.27 (2.82)	14.38 (2.91)		-0.12 (-0.85, 0.62)	0.04
Psychological QOL	IG	13.27 (2.56)	16.68 (2.59)	3.38 (2.39, 4.37) ***	-3.41 (-4.09, -2.73) ***	1.23
	CG	13.73 (2.72)	13.76 (2.99)		-0.03 (-0.79, 0.73)	0.01
Social Relationships QOL	IG	13.50 (3.23)	16.57 (3.34)	2.91 (1.57, 4.26) ***	-3.07 (-3.94, -2.19) ***	0.83
	CG	14.29 (3.27)	14.44 (3.91)		-0.15 (-1.21, 0.91)	0.03
Environmental QOL	IG	12.99 (2.56)	16.90 (2.57)	3.01 (1.98, 4.04) ***	-3.91 (-4.71, -3.12) ***	1.17
	CG	13.64 (2.74)	14.55 (2.66)		-0.91 (-1.59, -0.22) *	0.32
Overall QOL	IG	13.50 (2.02)	16.85 (2.34)	2.98 (2.13, 3.83) ***	-3.34 (-3.96, -2.72) ***	1.29
	CG	13.93 (2.28)	14.29 (2.50)		-0.36 (-0.98, -0.25)	0.14
Self-efficacy	IG	2.88 (0.69)	3.45 (0.49)	0.40 (0.21, 0.58) ***	-0.57 (-0.72, -0.43) ***	0.91
	CG	3.04 (0.55)	3.22 (0.53)		-0.18 (-0.29, -0.06) *	0.38
Use of safety behaviors	IG	6.03 (2.67)	8.30 (2.60)	1.99 (1.16, 2.81) ***	-2.27 (-2.87, -1.68) ***	0.92
	CG	6.67 (2.60)	6.96 (2.87)		-0.29 (-0.89, 0.32)	0.11
Social support	IG	3.40 (0.90)	4.26 (0.92)	0.77 (0.48, 1.06) ***	-0.86 (-1.06, -0.66) ***	1.00
	CG	3.68 (0.87)	3.77 (0.92)		-0.09 (-0.31, 0.12)	0.10

QOL= quality of life; MD = mean difference; *d* = effect size; M(SD) = mean(standard deviation); IG = intervention group; CG =

control group; T = time; G = group; ^a Results are presented as mean differences with 95% CI at post-intervention calculated using

GEEs with baseline value and control group as reference categories; **p* < .05, ****p* < .001.

Table 3*Effectiveness of Intervention on Outcome Measures From Baseline to Follow-up*

Outcome variable	G	Pre-intervention (T0)	Follow-up (T2)	T×G interaction ^a	Within group changes (T0-T2)	
		M(SD)	M(SD)	β (95% CI)	MD (95% CI)	<i>d</i>
Anxiety	IG	9.61 (4.95)	4.33 (3.84)	-3.73 (-5.42, -2.04) ***	5.29 (4.10, 6.47) ***	1.06
	CG	8.49 (4.29)	6.93 (4.87)		1.56 (0.30, 2.82) *	0.30
Depression	IG	6.90 (3.67)	3.51 (3.46)	-3.41 (-4.84, -1.99) ***	3.39 (2.52, 4.24) ***	0.94
	CG	6.10 (4.09)	6.13 (3.68)		-0.03 (-1.20, 1.15)	0.20
Physical QOL	IG	14.30 (2.65)	17.68 (2.56)	2.15 (1.02, 3.28) ***	-3.38 (-4.05, -2.71) ***	1.19
	CG	14.27 (2.82)	15.50 (3.11)		-1.23 (-2.17, -0.29) *	0.31
Psychological QOL	IG	13.27 (2.56)	16.88 (2.51)	2.67 (1.53, 3.81) ***	-3.61 (-4.33, -2.89) ***	0.71
	CG	13.73 (2.72)	14.68 (2.33)		-0.94 (-1.86, -0.03) *	0.25
Social Relationships QOL	IG	13.50 (3.23)	16.86 (3.60)	2.74 (1.36, 4.13) ***	-3.35 (-4.22, -2.48) ***	0.93
	CG	14.29 (3.27)	14.90 (3.71)		-0.61 (-1.73, 0.51)	0.13
Environmental QOL	IG	12.99 (2.56)	17.20 (2.59)	2.44 (1.42, 3.47) ***	-4.21 (-4.97, -3.46) ***	1.34
	CG	13.64 (2.74)	15.41 (2.82)		-1.77 (-2.50, -1.04) ***	0.58
Overall QOL	IG	13.50 (2.02)	17.22 (3.00)	2.45 (1.51, 3.39) ***	-3.71 (-4.31, -3.12) ***	1.49
	CG	13.93 (2.28)	15.19 (2.77)		-1.26 (-2.01, -0.51) **	0.40
Self-efficacy	IG	2.88 (0.69)	3.46 (0.52)	0.51 (0.30, 0.72) ***	-0.58 (-0.73, -0.42) ***	0.88
	CG	3.04 (0.55)	3.11 (0.48)		-0.07 (-0.21, 0.07)	0.13
Use of safety behaviors	IG	6.03 (2.67)	9.50 (2.63)	2.41 (1.43, 3.40) ***	-3.47 (-4.17, -2.77) ***	1.18
	CG	6.67 (2.60)	7.74 (2.42)		-1.06 (-1.78, -0.33) **	0.36
Social support	IG	3.40 (0.90)	4.31 (0.94)	0.73 (0.39, 1.06) ***	-0.91 (-1.15, -0.67) ***	0.90
	CG	3.68 (0.87)	3.86 (0.90)		-0.18 (-0.43, -0.06) **	0.18

QOL = quality of life; MD = mean difference; *d* = effect size; M(SD) = mean (standard deviation); IG = intervention group; CG =

control group; T = time; G = group; ^a Results are presented as mean differences with 95% CI at follow-up calculated using GEEs with

baseline value and control group as reference categories; **p* < .05, ***p* < .01, ****p* < .001.

Figure 1. CONSORT flow diagram outlining the study processes

Authors Biographies

Diksha Sapkota, MPH, is a doctoral student in School of Nursing and Midwifery, Griffith University. She has more than five years of experience in tutoring medical and nursing students. Her areas of interest include intervention studies, reproductive health issues, lifestyle-diseases, and domestic violence.

Kathleen Baird, PhD, is a Professor in the School of Nursing and Midwifery, University of Technology, Sydney. She is an adjunct Professor at the School of Nursing and Midwifery, Griffith University. Her main research interests centre around midwifery models of care and family violence, with a focus on violence during pregnancy.

Amornrat Saito, PhD, is a Lecturer in School of Nursing and Midwifery, Griffith University. Dr Saito's areas of expertise are intimate partner violence, social support and mental health nursing. She has several years of experience in quantitative research, including data management and analysis.

Pappu Rijal, MD, is an Additional Professor in BPKIHS, Nepal. He is also a Deputy Hospital Director of BPKIHS. He has several years of experiences in using quantitative methodology including RCTs in the field of gynecological cancers and women's health.

Debra Anderson, PhD, is the Assistant Dean (Research) in University of Technology, Sydney and an adjunct Professor at the Menzies Health Research Institute, Griffith University. She is a Director and Founder of the Women's Wellness Research Program. She has been continually involved in the development, piloting and evaluation of lifestyle interventions in the area of women's global health.