

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

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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

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50 Over the past decade, there is an increased recognition of importance to address
51 maternal mental health to maximize productivity and reduce health care costs (Howard et al.,
52 2014). Mental health problems such as depression and anxiety are common during pregnancy
53 and following childbirth (Thomas et al., 2019). Compared to high-income countries, the
54 prevalence rates of these morbidities are significantly higher in low- and middle-income
55 countries (LMICs) (Fisher et al., 2012; Howard et al., 2013). All women are at risk of
56 developing mental health disorders during their pregnancy, as it is a period of significant
57 physical, mental and social changes for women (Arora et al., 2019; Howard et al., 2013).
58 Several factors such as experience of violence or hostility from husbands or in-laws, lack of
59 intimate partner or social support, and poor socioeconomic status further increase the risk of
60 mental health conditions among pregnant women (Ludermir et al., 2010).

61 Within the literature a number of terminologies, such as Intimate Partner Violence
62 (IPV) or Domestic and Family Violence (DFV), are used interchangeably or with slight
63 variations in their meaning. IPV includes physical, sexual, and emotional abuse, and
64 controlling behaviors by an intimate partner, while DFV includes partner violence, as well as
65 abuse by any member of a household (World Health Organization [WHO], 2013). In a
66 Nepalese context, a woman often relocates to her husband's house after marriage and is
67 therefore at risk of violence from the hands of her husband as well as her in-laws due to the
68 culture of extended families living together (Sapkota et al., 2016). Considering this, the broader
69 term '*Domestic and Family Violence*' (DFV) has been used in this study, which included any
70 forms of violence or abuse, such as physical, sexual, and/or emotional, perpetrated against
71 woman by her husband/partners or someone in her husband's family (Ministry of Health et al.,
72 2017; Sapkota, et al., 2016). Despite being considered a global public health issue, DFV around

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

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

88 Despite the increased vulnerabilities to mental health conditions and DFV at the time
89 of pregnancy (Baird, 2015; Pun et al., 2019), pregnancy is also considered to be an opportune
90 time to interject against DFV. It is a period when a woman is in a regular contact with her
91 health care providers (HCPs) allowing her to develop a relationship of mutual trust, which
92 can facilitate disclosure (Jahanfar et al., 2014; Rishal et al., 2016). Additionally, nurses and
93 midwives are considered some of the best professionals to offer advice and support to victims
94 (Baird, 2015; Rishal et al., 2016). The antenatal clinic (ANC) is considered as an appropriate
95 setting for adopting prevention and intervention strategies against DFV as it offers a
96 confidential environment to safely reach a maximum number of affected women and helps to
97 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).

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

133 **Materials and methods**

134 **Study Design and Participants’ Characteristics**

135 The design of this study, including data collection tools and techniques, is outlined in
136 more detail in the published protocol paper (Sapkota, Baird, Saito, Rijal, et al., 2019). This
137 paper seeks to describe the quantitative aspect of evaluation of the intervention. An assessor-
138 blinded, 1:1 parallel-group, randomized controlled trial (RCT) was conducted at BP Koirala
139 Institute of Health Sciences (BPKIHS), Nepal between June 2018 and January 2019. The
140 hospital is a large tertiary hospital in Eastern Nepal. Everyday nearly 100-150 pregnant
141 women visit the ANC clinic. Criteria for inclusion into the study were, married women aged
142 18 years and over, 24-34 weeks of gestation, history of DFV, access to a telephone, and able
143 to understand simple Nepalese language. The five-item Abuse Assessment Screen (AAS) was
144 used to assess whether women were ever afraid of anyone in their family, had experienced
145 emotional and physical violence in their lifetime, physical and sexual violence in the last 12
146 months, and physical violence in their current pregnancy. Women reporting at least one

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

150 **Sample Size**

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

155 **Randomization and Blinding**

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

163 **Intervention**

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

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

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

176 • Women were provided with an information booklet, which includes DFV and its
177 common mental health impacts, strategies to help them deal with daily stressors, as
178 well as advice on how to improve their safety, and a list of local support organizations
179 against DFV. The development and validation of the information booklet has been
180 described elsewhere (Sapkota, Baird, Saito, Budhathoki, et al., 2020).

181 • Intervention participants were also provided with the contact details of the counselor
182 and advised that they could contact her at times of need during the study period.

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

188 **Measures**

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

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

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

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

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

227 **Intervention Fidelity**

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

235 **Data Analysis**

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

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

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

256 **Ethics**

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

261 **Results**

262 **Feasibility Measures**

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

271 [Insert Figure 1 here]

272 **Characteristics of Participants**

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

281 [Insert Table 1 here]

282 **Intervention Effects**

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

285 [Insert Table 2 and Table 3 here]

286 ***Mental Health***

287 There was a greater reduction in anxiety scores from T0 to T1 ($\beta = -3.24$, $p < 0.001$),
288 and from T0 to T2 ($\beta = -3.73$, $p < 0.001$) in the intervention group (IG), compared to the control
289 group (CG). The intervention participants had lower depressive symptoms at T1 ($\beta = -3.16$,
290 $p < 0.001$), and at T2 ($\beta = -3.41$, $p < 0.001$), compared to the control group. Specifically, the IG
291 reported significantly greater improvements than the control group from T0 to T1 in anxiety
292 ($d = 0.75$, $p < 0.001$) and depression symptoms ($d = 0.69$, $p < 0.001$).

293 ***Quality of Life***

294 The participants in the IG had a greater increase in mean QOL scores ($\beta = 2.98$,
295 $p < 0.001$) at T1, and ($\beta = 2.45$, $p < 0.001$) at T2 than did those in the CG. Similarly, there were
296 greater increase in scores of QOL in all four domains among the IG compared to CG at T1

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

302 *Self-efficacy*

303 Self-efficacy increased significantly in the IG compared to CG both at T1 ($\beta = 0.40$,
304 $p < 0.001$) and T2 ($\beta = 0.51$, $p < 0.001$). Significant improvements were noted in the mean self-
305 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
306 IG. Although, there was a significant increment in GSES score from T0 to T1 in the CG
307 ($p < 0.001$), the effect size was smaller than that observed in the IG (0.42 vs 0.91).

308 *Use of Safety Behaviors*

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

315 *Social Support*

316 A significant group and time interaction ($p < 0.001$, at T1 as well as T2) verified the
317 change in the social support score at different gradients over the time in the two study groups.
318 The perceived social support increased significantly from T0 to T1 in the IG ($d = 1.00$,
319 $p < 0.001$), but not in the CG ($d = 0.10$, $p > 0.05$). Despite significant improvements in social
320 support in both groups at T2, larger effect size was seen in the IG ($d = 0.90$, $p < 0.001$) than the
321 CG ($d = 0.18$, $p < 0.001$).

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Discussion

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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.

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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.

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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

347 (Saftlas et al., 2014). Similarly, the combination of approaches, such as supportive
348 counseling, safety planning, and referrals, used by Gupta et al. (2017), found short-term
349 improvements in safety planning and mental health QOL. Empowerment based counseling
350 operating at an individual level tends to change a woman's ways of thinking and help her to
351 change help-seeking behaviors (Rivas et al., 2019). In this study, counseling was adapted to
352 the individual needs of the women through the development of a central notion of women-
353 centred care. Without taking into considerations the woman's individual circumstances, there
354 is a greater likelihood of failure of an intervention to produce desired results (Evans et al.,
355 2018). Taking such an individualized approach possibly helped participants to improve their
356 own coping and self-care skills as they built a relationship of trust and satisfaction with the
357 counselor (Sapkota, Baird, Saito, Rijal, et al., 2020).

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

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

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

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

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

408

Conclusions

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

418

419

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- 610

611 **Table 1**612 *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
	Age in years	25.51 (5.26)	24.70 (4.74)	26.31 (5.65)	0.07/0.31 ^a
Educational qualification	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)	
	Higher Secondary level and above	45 (32.1)	24 (34.3)	21 (30.0)	
Ethnicity	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)	1.00/0.00 ^b
	Yes No	52 (37.1) 88 (62.9)	26 (37.1) 44 (62.9)	26 (37.1) 44 (62.9)	
Source of income	Service	7 (10.9)	4 (12.1)	3 (9.7)	0.54/0.18 ^b
	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)	
Smoking status	Current smoker	5 (3.6)	3 (4.3)	2 (2.9)	0.12/0.17 ^b
	Past smoker	7 (5.0)	1 (1.4)	6 (8.6)	
	Never	128 (91.4)	66 (94.3)	62 (88.6)	
Alcohol consumption habit	Current consumer	18 (12.9)	9 (12.9)	9 (12.9)	0.51/0.10 ^b
	Past consumer	23 (16.4)	14 (20.0)	9 (12.9)	
	Never	99 (70.7)	52 (74.3)	47 (67.1)	
Family structure	Nuclear family	47 (33.6)	21 (30.0)	26 (37.1)	0.37/0.08 ^b
	Joint family	93 (66.4)	49 (70.0)	44 (62.9)	
Anxiety		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

613 QOL = quality of life; ES = effect size; ^a Values obtained from independent t-test; ^b Values614 obtained from Pearson or Likelihood ratio chi-square test; ^c Values obtained from Mann-

615 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)	<i>d</i>
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)			
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)			
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)			
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)			
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)			
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)			
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)			
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)			
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)			
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)			

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.

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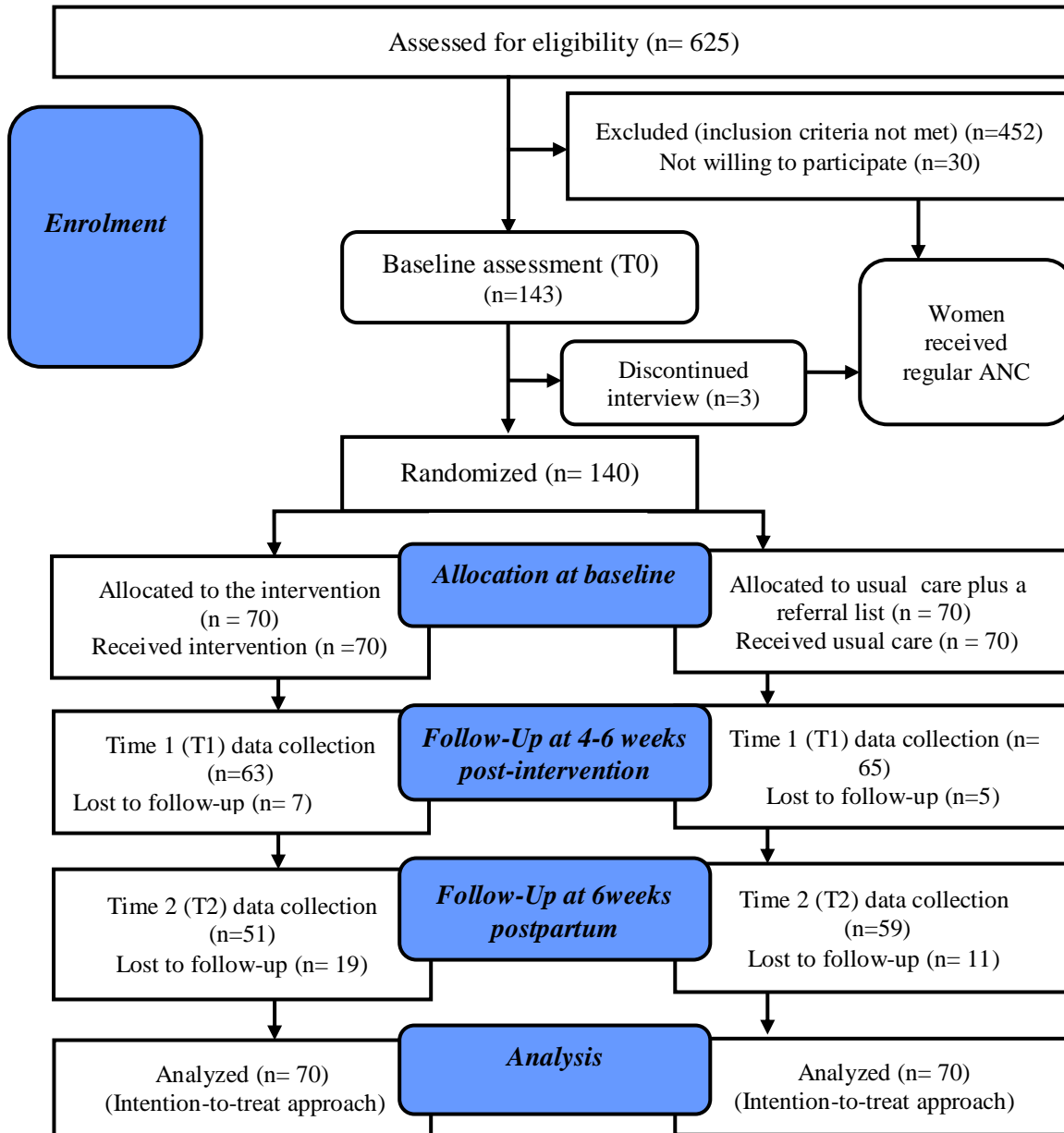


Figure 1. CONSORT flow diagram outlining the study processes

Authors Biographies

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