

Two-year follow up of a cluster randomised controlled trial for women experiencing intimate partner violence: effect of screening and family doctor-delivered counselling on quality of life, mental and physical health and abuse exposure

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ABSTRACT

Objectives This was a 2-year follow-up study of a primary care-based counselling intervention (weave) for women experiencing intimate partner violence (IPV). We aimed to assess whether differences in depression found at 12 months (lower depression for intervention than control participants) would be sustained at 24 months and differences in quality in life, general mental and physical health and IPV would emerge.

Design Cluster randomised controlled trial. Researchers blinded to allocation. Unit of randomisation: family doctors.

Setting Fifty-two primary care clinics, Victoria, Australia.

Participants Baseline: 272 English-speaking, female patients (intervention n=137, doctors=35; control n=135, doctors=37), who screened positive for fear of partner in past 12 months. Twenty-four-month response rates: intervention 59% (81/137), control 63% (85/135).

Interventions Intervention doctors received training to deliver brief, woman-centred counselling. Intervention patients were invited to receive this counselling (uptake rate: 49%). Control doctors received standard IPV information; delivered usual care.

Primary and secondary outcome measures Twenty-four months primary outcomes: WHO Quality of Life-Brief dimensions, Short-Form Health Survey (SF-12) mental health. Secondary outcomes: SF-12 physical health and caseness for depression and anxiety (Hospital Anxiety Depression Scale), post-traumatic stress disorder (Check List-Civilian), IPV (Composite Abuse Scale), physical symptoms (≥ 6 in last month). Data collected through postal survey. Mixed-effects regressions adjusted for location (rural/urban) and clustering.

Results No differences detected between groups on quality of life (physical: 1.5, 95% CI -2.9 to 5.9; psychological: -0.2, 95% CI -4.8 to 4.4.; social: -1.4, 95% CI -8.2 to 5.4; environmental: -0.8, 95% CI -4.0 to 2.5), mental health status (-1.6, 95% CI -5.3 to 2.1) or secondary outcomes. Both groups improved on primary outcomes, IPV, anxiety.

Strengths and limitations of this study

- Well-designed cluster randomised controlled trial of primary care intervention for women experiencing intimate partner violence (IPV), addressing a major gap in existing evidence to guide practice.
- Long-term follow-up, rarely reported in this population, tested whether outcomes from an IPV intervention were sustained at 2 years or emerged over this extended time period.
- Two-year retention rates (~60%) were similar across groups and acceptable for the population under study; low rate of active withdrawal (18%); and no reporting of adverse events, indicate no harm from either the intervention or study participation.
- A low counselling intervention dose was delivered overall, with 49% of intervention group women taking up the invitation to attend counselling sessions, and the majority only attending only one session.
- Socially disadvantaged women, younger women and women of non-English speaking background were under-represented in the sample limiting generalisability for these populations.

Conclusions Intervention was no more effective than usual care in improving 2-year quality of life, mental and physical health and IPV, despite differences in depression at 12 months. Future refinement and testing of type, duration and intensity of primary care IPV interventions is needed.

Trial registration number ACTRN12608000032358.

INTRODUCTION

Intimate partner violence (IPV) is a common issue among women attending primary healthcare services, and a leading cause of morbidity and mortality for women of



childbearing age.¹² Research suggests that around 13% of women attending a family doctor in Australia have experienced fear of their partner or ex-partner in the past 12 months,³ and 30% at some point in their lives.⁴ Similarly, a study of female patients attending general practice in the UK found that 17% had experienced physical violence from a partner or ex-partner in the past 12 months.⁵ IPV is often associated with physical and psychological health damage, including depression, anxiety, chronic pain, gynaecological and general health issues.^{16,7} In such situations, the presenting condition may be unresponsive to treatment unless the impact of IPV is also addressed. Furthermore, family doctors may be the first or only point of contact for many women experiencing IPV, and hence are in a unique position to assist.⁸ It is, therefore, imperative that family doctors are equipped to identify and respond to IPV.^{9–11}

Despite the important role family doctors have to play in identifying and responding to IPV, there have been limited trials in primary care settings to guide effective interventions.^{8,12} Reviews of IPV interventions found that most primary care-based trials have been in reproductive health or pregnancy contexts, rather than broader family practice settings, and none of the studies tested doctor-delivered interventions.^{12,13} Another recent systematic review in 2017 also revealed limited evidence to base guidance for general practitioners and family doctors.¹⁴ Hence, WHO and others have called for more evidence on interventions following identification of IPV.^{8,11,12}

In response to this need for IPV intervention trials in primary care settings, Hegarty *et al* undertook the weave trial.^{15,16} Fifty-two family doctors/clinics were recruited, along with 272 of their female patients who had experienced fear of a partner or ex-partner in the past 12 months. Family doctors assigned to intervention were trained to deliver woman-centred counselling by offering up to six, 30 min sessions using motivational interviewing or non-directive problem-solving techniques depending on the patient's readiness to change.^{16,17} The control group received usual care. At 6-month follow-up, more women in the intervention group than the control group had been asked by their doctor about their safety and that of their children. At 12-month follow-up, rates of depression were lower for the intervention group than the control group. However, there were no significant differences at either time point on quality of life or general mental health status or safety planning, which were primary outcomes. Only half of the intervention group took up the invitation to attend the counselling sessions,^{15,18} and many of these women only attended one session.

This paper reports results of the 24-month follow-up of the weave trial. First, we were interested in whether group differences in quality of life and general mental health would emerge by 24 months post baseline. Quality of life is a complex, multifaceted construct which may take time to develop,¹⁹ and it is possible the initial 12-month follow-up period was insufficient for improvements to be detected in the intervention group. Similarly, it is plausible that

it may take longer for overall mental health status to show an effect. Any small improvements the intervention group had made on these primary outcomes by 12-month follow-up had been matched by improvements in the control group. This could have been due to common aspects of study involvement, such as survey completion and reminder calls, prompting positive changes for both groups, or due to both groups accessing other support services outside of primary care.^{15,20} The 24-month follow-up allowed us to test whether this pattern would continue once contact with participants was less frequent.

Second, we were interested in whether rates of depression would remain lower for the intervention group than control group at the 24-month time point. This would help assess whether the impact of family doctor-delivered counselling on depression could persist over an extended time, once the counselling intervention has ceased. Third, we were interested in whether levels of IPV, post-traumatic stress disorder (PTSD) and physical symptoms would be lower for the intervention group than the control group by 24 months. Based on prior theory and research,^{21,22} it was anticipated that any external reduction in IPV would take longer to emerge and improve PTSD symptoms than internal changes such as reduced depression.¹⁶

Specifically, we investigated whether, at 24 months after the counselling invitation, there was a difference between intervention and control groups (on the individual participant level) for:

- ▶ Quality of life dimensions (physical, psychological, social, environmental) and general mental health status (primary outcomes).
- ▶ Physical health status and caseness for IPV, depression, anxiety, PTSD and physical symptoms (secondary outcomes).

We also explored within-groups effects, to determine if groups had changed on these outcomes from baseline to 24 months.

METHODS

Study design and participants

Our protocol, trial methods, baseline characteristics, intervention and 6-month and 12-month response rates and outcomes are published elsewhere.^{3,15,16,23,24} Briefly, we undertook a cluster randomised controlled trial with family doctors and their female patients who had been fearful of a partner or ex-partner in the past 12 months. The trial reporting conformed to Consolidated Standards of Reporting Trials guidelines.²⁵

As described elsewhere,^{15,16} family doctors from urban and rural practices in Victoria, Australia were recruited (one doctor per practice; between 31 January 2008 and 18 January 2010). All female patients aged 16–50 years who had attended that doctor in the past 12 months were mailed a brief health and lifestyle screening survey (20/100 patients from 55 doctors in total).³ Female patients were eligible for trial participation if they spoke English, screened positive for fear of a partner or ex-partner in the

past 12 months and provided contact details. Researchers telephoned eligible patients to reconfirm eligibility and invite their participation in the trial. Those who agreed to participate were mailed a baseline survey to their nominated safe address, along with an information leaflet and resource card. As described in detail elsewhere,^{15 26} protocols to protect participant safety were followed throughout the trial and harm was systematically monitored using an adapted version of the Consequences of Screening Tool²⁷ and a harm–benefit Visual Analogue Scale (0=harmful to 100=beneficial). A data monitoring committee monitored the trial's integrity and reviewed outcome and harm data.¹⁵

Randomisation and masking

Once baseline data had been collected, doctors with participating patients were randomised to intervention or control groups (between 22 September 2008 and 18 June 2010).¹⁵ Patients were assigned to the same trial group as their doctor. Randomisation was by an independent statistician who generated a coded allocation sequence using the computer random number generator in Stata V.12.²⁸ Randomisation was stratified by urban and rural practice location with random permuted block sizes of two and four within each stratum and an equal allocation ratio for two study arms.¹⁵ After baseline data had been collected, the trial coordinator (not involved in recruitment of participants) randomly selected one of the two codes as the intervention arm and held the code key in a secure location. All other researchers and research personnel, including those who recruited doctors and women and those who undertook analyses, were blinded to study arm allocation until results had been interpreted and preliminary write-up undertaken. The trial coordinator was responsible for notifying doctors of their assigned study arm. It was not possible to mask doctors and patients after randomisation, as doctors needed to receive training and women were offered counselling.

Intervention

As described in detail in previous publications,^{15 16 23} the study intervention consisted of training doctors, notifying doctors of women who screened positive for fear of a partner, and inviting women for brief counselling with their doctor for relationship and emotional issues. The intervention was based on the psychosocial readiness model, which describes both internal and external factors in the process of change for IPV survivors.^{21 23} Internal factors in the psychosocial readiness model include awareness that the perpetrator's behaviour is abuse, perceived support from others and self-efficacy or perceived power.²¹ The doctor training was delivered as a Healthy Relationships Training programme, consisting of a 6-hour distance learning package, and a 1-hour interactive practice visit delivered by a clinician academic.²³ The training aimed to equip doctors to respond to women experiencing IPV and to deliver a brief counselling intervention. It used a patient-centred care approach, emphasising active

listening, motivational interviewing, problem-solving techniques, validating women's experiences and feelings, assessing readiness for change, and supporting decisions. Following this training, patients in the intervention group were mailed a letter from their weave doctor, inviting them to attend counselling sessions. Patients could attend between one and six counselling sessions, over a 6-month period, at no cost to the patient. Just under half of the intervention group attended counselling (49%, n=67), with most only taking up one session.^{15 18} In both intervention and control groups, doctors received a basic IPV information pack and continuing professional development points and patients received a list of resources with each survey. Women in the control group received standard care from their doctor if they attended during the study period.

Data collection

Trial outcomes were measured at the individual level, at baseline, 6 months, 12 months and 24 months, using postal surveys sent to each participating woman's nominated safe address. The current study focuses on 24-month outcomes of the trial, collected from 15 March 2011 to 1 November 2012. Primary outcomes measured at 24 months were quality of life dimensions (physical, psychological, social and environmental on the WHO Quality of Life Brief Version)²⁹ and Short Form Health Survey (SF-12) mental health status.³⁰ Secondary outcomes were IPV caseness (score ≥ 7 on the Composite Abuse Scale),³¹ depression and anxiety caseness (score ≥ 8 on the Hospital Anxiety Depression Scale),³² PTSD caseness (score ≥ 50 on the PTSD Check List-Civilian version; this cut-off score has shown sound sensitivity and specificity in previous studies)^{33 34}; physical symptoms caseness (sum ≥ 6 in last month) and SF-12 physical health status.³⁰

Statistical analyses

We calculated that a minimum sample size of 136 women from 34 doctors (four women per doctor) would be needed to detect the prespecified effect size of half an SD difference on primary outcomes, with 80% power ($\alpha=5\%$, two-sided test).¹⁵ This was based on a two-sample t-test, allowing for a design effect of 1.08, due to clustering.³⁵ Further details on sample size calculations for initial screening and recruitment phases are published elsewhere.^{15 16} It was anticipated that around 60% out of the 272 trial participants would return their 24-month survey, and thus the required sample size would be exceeded.

Analyses were performed in Stata V.12,²⁸ using mixed effects linear regression for continuous outcomes and mixed effects logistic regression for binary outcomes, with robust standard errors.³⁶ Study group was fitted as a fixed effect and change over time from baseline as a random effect. Analyses adjusted for location (rural vs urban) and clustering of data by practice and were conducted according to intention-to-treat principles. All available data were included from all participants who had completed baseline, regardless of whether they had



completed all follow-up time points, and for intervention group participants, regardless of whether they had attended the counselling intervention. In order to assess whether uptake of the intervention affected 24-month findings, supplementary subgroup analyses were performed which excluded intervention group participants who had not attended the counselling intervention.

Patient and public involvement

The weave study was designed with input from a reference group consisting of community organisation representatives and medical professionals, including a family doctor. The data monitoring committee also included a representative from a community organisation that provides IPV-related services and information.

FINDINGS

Baseline characteristics of doctors and women enrolled in the weave trial are described in detail elsewhere (see also online supplemental table 1).¹⁵ These characteristics were even across intervention and control groups.¹⁵ Mean age of family doctors was 48.1 years (SD=8.1), which is similar to the mean age overall for family doctors in Australia (49.3 years).¹⁵ Sixty-two per cent (n=32) of family doctors in the trial were female, compared with 39% overall of Australian family doctors.¹⁵ Nonetheless, their communication skill levels were similar to other family doctors and few had prior training in IPV.¹⁵ Seventy-one per cent (n=37) of doctors in the trial were from urban practices. Mean baseline age of patients in the trial was 38.5 (SD=8.1), with 16% (n=44) aged 17–29, 31% (n=83) aged 30–39 and 53% (n=140) aged 40–50. Fifty-three per cent (n=144) lived with a partner at baseline and 59% (n=159) had children under 18 years old at home. Year 12 schooling had not been completed by 42% (n=114) of participants, 30% (n=73) were not currently employed and 23% (n=61) received a government pension as their main source of income. The majority of participants (94%, n=257) spoke English as their first language.

Figure 1 shows the flow of participants through the trial. The 24-month response rate was 59% (81/137) in the intervention group and 63% (85/135) in the control group. The number of participants retained and analysed at this time point exceeded the sample size needed to detect prespecified differences on outcome variables. Baseline characteristics were similar for participants who did and did not return the 24-month survey (online supplemental table 1). There were also no statistically significant differences between those who did and did not return the 24-month survey on previous time point measures of quality of life, SF-12 mental or physical health status, depression, anxiety or IPV caseness (see online supplemental table 2; PTSD and physical symptom caseness was not assessed at previous time points). There were also no statistically significant differences between intervention and control groups on use of health services

or other professional support services at any time point (see online supplemental table 3–8).

We detected no differences between intervention and control groups on quality of life dimensions or SF-12 mental health status at 24 months (**table 1**). Both intervention and control groups improved on quality of life dimensions and SF-12 mental health status from baseline to 24 months (**table 1**), although examination of 12-month data shows that most of this improvement had occurred during the 12 month time frame (12-month data are reported elsewhere; see also means and SDs reported in online supplemental table 2).¹⁵ We also detected no differences between groups at 24 months on caseness for IPV, depression, anxiety, PTSD or physical symptoms, nor on SF-12 physical health status (**table 2**). Both intervention and control groups displayed lower IPV and anxiety caseness at 24 months than at baseline (**table 2**). For IPV caseness, most of this improvement had occurred during the 12-month time frame.¹⁵ There were also no differences between groups on 24-month outcomes when excluding intervention group participants who had not attended the counselling intervention (online supplemental tables 9 and 10). When excluding these non-attenders the same patterns of improvement from baseline to 24 months on IPV, anxiety and primary outcomes were found (online supplemental tables 9 and 10). Supplementary analyses of fear levels (in the last 2 weeks and 6 months ago) also found no significant differences between groups at 24 months, regardless of whether or not analyses excluded intervention non-attenders (online supplemental tables 11 and 12).

As detailed in a previous publication,²⁶ there were no significant harms detected. Most 24-month survey respondents agreed that they were glad they participated in the project (n=145, 87.3%). We detected no differences between groups on the harm–benefit Visual Analogue Scale used as part of harm assessment (intervention mean=77.0 (SD 20.5); control mean=73.7 (SD 18.9); mean difference=4.4, 95% CI -0.8 to 9.6, p=0.092).

DISCUSSION

The current analyses reported on findings from the weave trial at 24-month follow-up. As had been found at 12-month follow-up,¹⁵ there were no significant differences between intervention and control groups on the primary outcomes of quality of life or overall mental health status. For both groups, quality of life and mental health status remained stable from 12 months to 24 months, having improved in both groups between baseline and 12 months.¹⁵ There were no significant differences between groups on depression caseness at 24 months, despite this difference being present at 12 months. There were also no differences between groups on physical health status or symptoms, nor on caseness for anxiety, PTSD or IPV at 24 months. Instead, by 24-month follow-up both groups showed lower rates of anxiety and IPV than they had at baseline, although the proportion of women experiencing

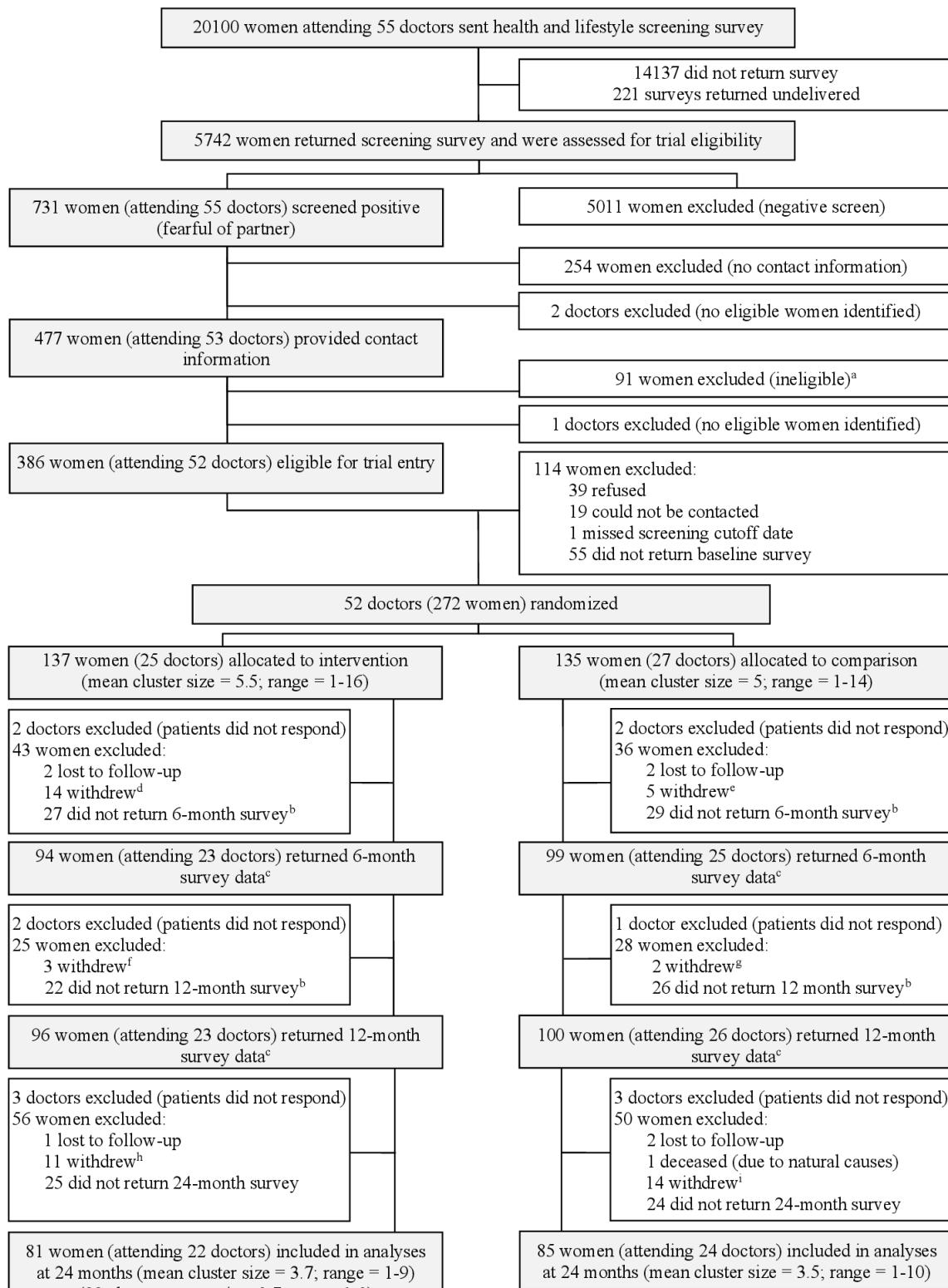


Figure 1 Weave trial Consolidated Standards of Reporting Trials flow diagram. ^aReasons for ineligibility: afraid more than 12 months ago (50); no longer visits the weave doctor (5); misinterpreted the fear item (34); poor English (1); outside age range (1). ^bExcluded from complete case analysis but retained in trial. ^cAnalyses and findings are reported in the weave 6–12 months outcome paper. ^dReasons for withdrawal: does not wish to give reason (4), no longer interested/not relevant (4), too busy/survey too long (3), weave doctor not their usual family doctor (2), wants to move on (1); ^eDoes not wish to give reason (2), no longer interested/not relevant (1), too busy/survey too long (1), wants to move on (1); ^fDoes not wish to give reason (1), no longer interested/not relevant (1), unhappy with weave doctor (1); ^gDoes not wish to give reason (1), no longer interested/not relevant (1); ^hDoes not wish to give reason (1), no longer interested/not relevant (7), too busy/survey too long (1), wants to move on (2); ⁱDoes not wish to give reason (2), no longer interested/not relevant (9), too similar to 12 months survey (1), wants to move on (1), moving overseas (1).

Table 1 Primary outcomes at baseline and 24 months, by study arm*

	Study arm		Intervention		Control		Between groups fixed effect		Within groups random effect	
	n	M (SD)	n	M (SD)	n	M (SD)	Mean difference (95% CI)	P value	Mean change (95% CI)	P value
Physical QOL (WHOQOL-Bref)	Baseline	136	59.5 (20.7)	135	58.3 (17.5)					
	24 months	81	63.5 (21.9)	85	63.9 (19.1)	1.5 (-2.9 to 5.9)	0.513	3.1 (0.7 to 5.4)	0.011	
Psychological QOL (WHOQOL-Bref)	Baseline	136	50.0 (18.4)	135	48.4 (18.1)					
	24 months	81	54.8 (20.6)	85	55.6 (17.5)	-0.2 (-4.8 to 4.4)	0.938	5.5 (3.1 to 7.9)	<0.001	
Social QOL (WHOQOL-Bref)	Baseline	137	47.7 (23.5)	135	47.0 (24.6)					
	24 months	81	52.9 (24.6)	84	54.3 (23.2)	-1.4 (-8.2 to 5.4)	0.679	6.8 (3.2 to 10.5)	<0.001	
Environmental QOL (WHOQOL-Bref)	Baseline	136	59.4 (15.4)	135	58.0 (15.8)					
	24 months	81	64.3 (17.8)	85	65.6 (15.8)	-0.8 (-4.0 to 2.5)	0.631	6.3 (4.4 to 8.3)	<0.001	
Mental health status (SF-12)	Baseline	130	36.6 (11.9)	129	35.9 (11.9)					
	24 months	77	39.4 (13.2)	79	41.4 (11.3)	-1.6 (-5.3 to 2.1)	0.393	5.0 (2.6 to 7.5)	<0.001	

*Results are presented as mean differences, with 95% CIs and p values, calculated using mixed effects linear regression with robust SEs, allowing for clustering effect and rural versus urban practice location; intraclass correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance; estimated ICCs are not shown, as all were <0.0001.

poor mental health, physical health and IPV remained at concerning levels.

Strengths and limitations of the weave trial have been discussed in detail elsewhere.^{15 18 26} To the authors' knowledge, this study remains the only trial to date of an IPV intervention delivered directly by family doctors to their female patients in primary care.¹³ Other strengths included low risk of bias arising from the randomisation process; using doctors (and their practice) as the unit of randomisation, to minimise risk of contamination; low rate of active withdrawals; and no differences between the arms in terms of missing data or drop-outs. The management of safety was also a strength, for example, our systematic monitoring of participant safety. Retention rates met prespecified requirements, and were high for this field of research, with multiple retention strategies in place including follow-up contact, participant newsletters, and allowing participants to nominate multiple safe addresses and preferred contact times. Outcome assessment was by self-report; notwithstanding this, few IPV trials have included 24-month follow-up, and none that involve family doctor interventions.¹³ One constraint of the weave trial, common to the delivery of trials across the field, was that masking of doctors and patients was not possible, due to the nature of the trial.¹⁵ Also, sample characteristics may restrict generalisability of findings to other similar populations and settings. Patients who returned the initial screening survey were more likely to be employed, born in Australia and have completed secondary schooling than the Australian female population; further, women not fluent in English were excluded from the sample.³ Young women (ie, between 16 and 29 years of age) were under-represented in the sample. Also, the rate of female family doctors was higher for the weave trial than for Australian family doctors in general, although their communication skill levels were similar to other family doctors and few had prior training in IPV.¹⁵

One key challenge in the weave trial was the low uptake of the brief counselling intervention, and the limited number of sessions attended by those who did take up this offer.^{15 18} Similar challenges with engaging women in an intervention have also been experienced in previous trials.³⁷ Interview data as part of a weave process evaluation identified several barriers that prevented some women attending services when offered.¹⁸ These included the belief that family doctors only treat physical problems, perceptions around time pressures that family doctors face, and fears about managing emotional aspects of the session (eg, fear of breaking down in tears or not knowing where to start). Poor emotional health or embarrassment about emotional health status also made it difficult for some women to attend appointments. Quantitative analyses showed that those who did not attend the counselling intervention were more likely to be in a current relationship and rated their weave doctor's communication skills at a lower level than those who did attend.¹⁸ Future trials

Table 2 Secondary outcomes at baseline and 24 months, by study arm*

	Study arm		Between groups fixed effect		Within groups random effect	
	Intervention	Control	ICC	OR (95% CI)	P value	OR (95% CI)
IPV caseness (CAS)†	Baseline	135	101 (74.8)	132	93 (70.5)	0.037
	24 months	80	32 (40.0)	81	34 (42.0)	0.5 (0.2 to 1.7)
Depression caseness (HADS)‡	Baseline	136	62 (45.6)	134	69 (51.5)	<0.001
	24 months	78	33 (42.3)	84	35 (41.7)	1.0 (0.4 to 2.9)
Anxiety caseness (HADS)‡	Baseline	136	98 (72.1)	134	94 (70.2)	0.014
	24 months	79	48 (60.8)	84	51 (60.7)	0.6 (0.2 to 2.2)
PTSD caseness (PCL-C)§	Baseline	81	23 (28.4)	84	25 (29.4)	—
	24 months	78	40 (49.4)	84	43 (50.6)	0.9 (0.5 to 1.9)
Physical symptom caseness¶		n	M (SD)	n	M (SD)	Mean difference (95% CI)
Physical health status (SF-12)	Baseline	130	49.4 (11.0)	129	47.6 (10.9)	<0.001
	24 months	77	48.1 (10.8)	79	46.1 (11.6)	2.4 (-0.8 to 5.6)

*Results are presented as mean differences or ORs, with 95% CIs and p values, calculated using mixed effects linear regression or logistic regression with robust SEs, allowing for clustering effect and rural versus urban practice location; ICCs for outcomes at baseline were estimated using one-way analysis of variance.

†CAS total score ≥ 7 .

‡HADS subscale score ≥ 8 .

§PCL-C score ≥ 50 ; not measured at baseline.

¶Experienced at least physical symptoms on checklist, in the past 4 weeks; Not measured at baseline. CAS, Composite Abuse Scale; HADS, Hospital Anxiety Depression Scale; ICC, intraclass cluster correlations; IPV, intimate partner violence; PCL-C, PTSD Checklist-Civilian Version; PTSD, post-traumatic stress disorder; SF-12, Short-Form Health Survey.



may need to focus further on addressing these potential barriers.

With regard to depression, the current findings suggest that family doctor-delivered, brief counselling for IPV is only more effective than usual care within a year of being implemented. In the longer term, after cessation of counselling, differences between groups on depression are not maintained. Further research is needed to test whether the difference between intervention and control groups on depression found at 12 months could persist in the longer term if counselling was better attended or offered at additional time points, for example, in year 2. The current findings also suggest that brief counselling is no more effective than usual care in improving quality of life, general mental or physical health, anxiety, PTSD and abuse levels for IPV survivors at 24 months. Again, the low uptake of counselling may have contributed to these null findings, or, alternatively these complex outcomes may require more multifaceted, long-term interventions. It may be that the study did not take sufficient account of the extent to which survivors need different interventions at different points in their journey, which extend beyond the theoretical approaches adopted in the current model of weave. For example, there will be considerable variation across IPV survivors within a primary care sample in terms of psychological, safety, advocacy and children's needs depending on whether violence is ongoing; the nature, frequency and severity of the violence; the presence of trauma symptoms; past exposure to abuse; and available support networks.

Another important consideration is that by the 24-month time point, both groups had improved on all outcomes except depression and SF-12 physical health status (PTSD and number of physical health symptoms were not measured at baseline). As outlined earlier, it is possible that initial improvements could have been due to study-related influences experienced by both groups, such as survey completion and participant reminders.^{15 20} If so, this could have attenuated the intervention effect. Despite these improvements, the burden of disease remained high at this 2 years time point. Many of the women still experienced IPV by a partner or ex-partner and had significant mental and physical health issues. This points to the need for long-term, multifaceted system responses to the complex issues surrounding IPV.³⁸

Future studies are needed to refine the intervention further and assess whether and what aspects of this refinement enable long-term effects. Key areas to target include uptake, duration and intensity of the intervention, including conceptual development of interventions for survivors with a diverse range of experiences and an assessment of patient's readiness and ability to take up the intervention. With regard to uptake, barriers and facilitators identified as part of the weave process evaluation could be used as a guide for increasing uptake in future studies.¹⁸ Some women's concerns about attending primary care may be alleviated through messaging that

family doctors are open and trained to address emotional and social issues, improving the communication skills of doctors and providing more time through continuity of care. Duration of the intervention could be increased, for example by inviting participants for periodic follow-up or 'booster' counselling sessions after the initial round of counselling sessions. Training of doctors could further emphasise strategies to continue ongoing support and monitoring of patient progress, beyond the initial intervention phase. Further IPV trials with greater diversity including more young women, different cultural backgrounds, Indigenous peoples, and diverse gender and sexual identities are also needed.

In conclusion, this 24-month follow-up analyses of the weave trial found that training family doctors to deliver a brief counselling intervention, and inviting their female IPV survivors to attend this counselling, was no more effective than usual care in improving long-term quality of life, mental and physical health and IPV exposure. This is despite shorter-term effects of the intervention on depression (at 12 months) and doctor enquiry about safety (at 6 months).¹⁵ Further research is needed to test whether refining the uptake, duration and intensity of the intervention could have an effect on long-term outcomes. We urgently need to test additional healthcare interventions for IPV, including system responses³⁸ to enable healing and pathways to safety for women exposed to IPV attending primary care settings.³⁹

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REFERENCES

- 1 World Health Organization. *Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence*. Geneva: WHO, 2013.
- 2 Webster K. *A preventable burden: measuring and addressing the prevalence and health impacts of intimate partner violence in Australian women (ANROWS COMPASS, 07/2016)*. Sydney, Australia: ANROWS, 2016.
- 3 Hegarty KL, O'Doherty LO, Astbury J, et al. Identifying intimate partner violence when screening for health and lifestyle issues among women attending general practice. *Aust J Prim Health* 2012;18:327–31.
- 4 Hegarty KL, Bush R. Prevalence and associations of partner abuse in women attending general practice: a cross-sectional survey. *Aust N Z J Public Health* 2002;26:437–42.
- 5 Richardson J, Coid J, Petrukevitch A, et al. Identifying domestic violence: cross sectional study in primary care. *BMJ* 2002;324:274–6.
- 6 Hegarty K, Gunn J, Chondros P, et al. Association between depression and abuse by partners of women attending general practice: descriptive, cross sectional survey. *BMJ* 2004;328:621–4.
- 7 Ellsberg M, Jansen HAFM, Heise L, et al. Intimate partner violence and women's physical and mental health in the WHO multi-country study on women's health and domestic violence: an observational study. *Lancet* 2008;371:1165–72.
- 8 García-Moreno C, Hegarty K, d'Oliveira AFL, et al. The health-systems response to violence against women. *Lancet* 2015;385:1567–79.
- 9 National Institute for Health and Care Excellence. *Domestic violence and abuse: how health services, social care and the organisations they work with can respond effectively*. London, England: National Institute for Health and Care Excellence, 2014.
- 10 Royal Australian College of General Practitioners. *Abuse and violence: working with our patients in general practice*. 4th ed. Melbourne, Australia: Royal Australian College of General Practitioners, 2014.
- 11 World Health Organization. *Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines*. Geneva, Switzerland: WHO, 2013.
- 12 Rivas C, Ramsay J, Sadowski L, et al. Advocacy interventions to reduce or eliminate violence and promote the physical and psychosocial well-being of women who experience intimate partner abuse. *Cochrane Database Syst Rev* 2015;26:CD005043.
- 13 Bair-Merritt MH, Lewis-O'Connor A, Goel S, et al. Primary care-based interventions for intimate partner violence: a systematic review. *Am J Prev Med* 2014;46:188–94.
- 14 Hegarty K, Leung TP-Y. Interventions to support the identification of domestic violence, response and healing in mental health care settings. *Aust Psychol Soc* 2017;3:6–18.
- 15 Hegarty K, O'Doherty L, Taft A, et al. Screening and counselling in the primary care setting for women who have experienced intimate partner violence (weave): a cluster randomised controlled trial. *Lancet* 2013;382:249–58.
- 16 Hegarty KL, Gunn JM, O'Doherty LJ, et al. Women's evaluation of abuse and violence care in general practice: a cluster randomised controlled trial (weave). *BMC Public Health* 2010;10:2.
- 17 Reisenhofer S, Taft A. Women's journey to safety - the Transtheoretical model in clinical practice when working with women experiencing Intimate Partner Violence: a scientific review and clinical guidance. *Patient Educ Couns* 2013;93:536–48.
- 18 O'Doherty L, Taket A, Valpied J, et al. Receiving care for intimate partner violence in primary care: barriers and enablers for women participating in the weave randomised controlled trial. *Soc Sci Med* 2016;160:35–42.
- 19 Fayers P, Machin D. *Quality of life: the assessment, analysis and reporting of patient-reported outcomes*. New York, NY: John Wiley and Sons, 2016.
- 20 Spangaro J, Zwi AB, Poulos R. The elusive search for definitive evidence on routine screening for intimate partner violence. *Trauma Violence Abuse* 2009;10:55–68.
- 21 Cluss PA, Chang JC, Hawker L, et al. The process of change for victims of intimate partner violence: support for a psychosocial readiness model. *Womens Health Issues* 2006;16:262–74.
- 22 Sullivan CM, Bybee DI. Reducing violence using community-based advocacy for women with abusive partners. *J Consult Clin Psychol* 1999;67:43–53.
- 23 Hegarty KL, O'Doherty LJ, Gunn J, et al. A brief counselling intervention by health professionals utilising the 'readiness to change' concept for women experiencing intimate partner abuse: The weave project. *J Fam Stud* 2008;14:376–88.
- 24 Hegarty KL, O'Doherty LJ, Chondros P, et al. Effect of type and severity of intimate partner violence on women's health and service use: findings from a primary care trial of women afraid of their partners. *J Interpers Violence* 2013;28:273–94.
- 25 Campbell MK, Piaggio G, Elbourne DR, et al. Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012;345:e5661.
- 26 Valpied J, Cini A, O'Doherty L, et al. "Sometimes cathartic. Sometimes quite raw": Benefit and harm in an intimate partner violence trial. *Aggress Violent Behav* 2014;19:673–85.
- 27 MacMillan HL, Wathen CN, Jamieson E, et al. Screening for intimate partner violence in health care settings: a randomized trial. *JAMA* 2009;302:493–501.
- 28 Stata Statistical Software: Release 12 [program]. College Station, TX: StataCorp LLC. 2011.
- 29 Skevington SM, Lotfy M, O'Connell KA, et al. The world Health organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the International field trial. A report from the WHOQOL group. *Qual Life Res* 2004;13:299–310.
- 30 Ware JE, Kosinski M, Bayliss MS, et al. Comparison of methods for the scoring and statistical analysis of SF-36 health profile and summary measures: summary of results from the medical outcomes study. *Med Care* 1995;33:AS264–79.
- 31 Hegarty K, Bush R, Sheehan M, et al. The composite abuse scale: further development and assessment of reliability and validity of a multidimensional partner abuse measure in clinical settings. *Violence Vict* 2005;20:529–47.



- 32 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
- 33 Blanchard EB, Jones-Alexander J, Buckley TC, et al. Psychometric properties of the PTSD checklist (PCL). *Behav Res Ther* 1996;34:669–73.
- 34 Weathers F, Litz B, Huska J, Huska J, et al. PTSD checklist - civilian version. Boston, MA: Nation Center for PTSD. Behavioral Sciences Division, 1994
- 35 Eldridge SM, Ashby D, Kerry S. Sample size for cluster randomized trials: effect of coefficient of variation of cluster size and analysis method. *Int J Epidemiol* 2006;35:1292–300.
- 36 Tabachnick B, Fidell L. *Using multivariate statistics*. 6th ed. Boston: Pearson, 2013.
- 37 Kiely M, El-Mohandes AAE, El-Khorazaty MN, et al. An integrated intervention to reduce intimate partner violence in pregnancy: a randomized controlled trial. *Obstet Gynecol* 2010;115:273–83.
- 38 Young-Wolff KC, Kotz K, McCaw B. Transforming the Health Care Response to Intimate Partner Violence: Addressing "Wicked Problems". *JAMA* 2016;315:2517–8.
- 39 Hegarty K, Tarzia L, Hooker L, et al. Interventions to support recovery after domestic and sexual violence in primary care. *Int Rev Psychiatry* 2016;28:519–32.