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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

Two-year follow-up of primary care-based counselling intervention (*weave*) for women experiencing intimate partner violence (IPV). At 12 months, intervention participants experienced lower depression than control participants, with no differences on primary outcomes. We aimed to assess whether differences in depression would be sustained at 24 months and differences in quality in life, general mental and physical health and IPV would emerge.

Methods

Cluster randomised controlled trial involving 52 family doctors and 272 English-speaking, female patients in Victoria, Australia (intervention: doctors n=25, patients n=137; control: doctors n=27, patients n=135). Participants screened positive for fear of partner in past 12 months. Doctors were unit of randomisation; researchers blinded to allocation. Intervention doctors received training to deliver brief, woman-centred counselling. Intervention patients invited to receive this counselling (uptake rate: 49%). Control doctors received standard IPV information; delivered usual care. Data collected through postal survey. Twenty-four-month primary outcomes: WHO Quality of Life-Bref dimensions, SF-12 mental health. Secondary outcomes: SF-12 physical health and caseness for depression and anxiety (Hospital Anxiety Depression Scale), posttraumatic stress disorder (PTSD Check List - Civilian), IPV (Composite Abuse Scale), physical symptoms (≥ 6 in last month). Analyses used mixed effects regression, adjusting for location (rural/urban) and clustering.

Results

Twenty-four-month response rates: intervention 59% (81/137), control 63% (85/135). No differences detected between groups on quality of life (physical: 1.5 [-2.9 to 5.9]; psychological: -0.2 [-4.8 to 4.4]; social: -1.4 [-8.2 to 5.4]; environmental: -0.8 [-4.0 to 2.5]), mental health status (-1.6 [-5.3 to 2.1]) or secondary outcomes. Both groups improved on primary outcomes, IPV and anxiety.

Conclusion

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

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ROLE OF THE FUNDING SOURCE

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COMPETING INTERESTS

The authors declare that they have no competing interests.

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 two-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.

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.[1 2] 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 United Kingdom 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.[1 6 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, the World Health Organization 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 and colleagues 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-minute sessions using motivational interviewing or non-directive problem-solving techniques depending on the patient's readiness to change.[17 16] 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, and many of these women only attended one session.[15 18]

This paper reports results of the 24-month follow-up of the *weave* trial. Firstly, 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, multi-faceted 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.

Secondly, we were interested in whether rates of depression would remain lower for the intervention group than control group at the 24-month timepoint. 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. Thirdly, we were interested in whether levels of IPV, posttraumatic 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- 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 CONSORT 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 to 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 re-confirm 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 Tool[27] 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] Ethics approval

was granted by University of Melbourne's Human Research Ethics Committee (ethics approval number: 0824166).

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 Version 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 six-hour distance learning package, and a one-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 World Health Organization Quality of Life Brief Version; WHOQOL-Bref)[29] and Short Form Health Survey (SF-12) mental health status.[30] Secondary outcomes were IPV caseness (score ≥ 7 on the Composite Abuse Scale, CAS)[31], depression and anxiety caseness (score ≥ 8 on the Hospital Anxiety Depression Scale, HADS)[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 a half standard deviation difference on primary outcomes, with 80% power (α = 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 Version 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 versus urban) and clustering of data by practice and were conducted according to intention-to-treat principles. All available data was included from all participants who had completed baseline, regardless of whether they had

completed all follow-up timepoints, and, for intervention group participants, regardless of whether they had 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 Supplementary Table 1, Appendix).[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 percent (n = 32) of family doctors in the trial were female, compared to 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 percent (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 to 29, 31% (n = 83) aged 30 to 39 and 53% (n = 140) aged 40 to 50. Fifty-three percent (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. Baseline characteristics were similar for participants who did and did not return the 24-month survey (Supplementary Table 1, Appendix). There were also no statistically significant differences between those who did and did not return the 24-month survey on previous timepoint measures of quality of life, SF-12 mental or physical health status, depression, anxiety, or IPV caseness (see Supplementary Table 2, Appendix; PTSD and physical symptom caseness was not assessed at previous timepoints).

[FIGURE 1 HERE]

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 timeframe (12 month data is reported elsewhere; see also means and SDs reported in Supplementary Table 2, Appendix).[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 timeframe.[15]

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 = .092).

Table 1. Primary outcomes at baseline and 24 months, by study arm[a]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	N	M (SD)	Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
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)	.513	3.1 (0.7 to 5.4)	.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)	.938	5.5 (3.1 to 7.9)	<.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)	.679	6.8 (3.2 to 10.5)	<.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 2.4)	.631	6.3 (4.4 to 8.3)	<.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)	.393	5.0 (2.6 to 7.5)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval; QOL = quality of life; WHOQOL-Bref = World Health Organization Quality of Life Brief Version; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences, with 95% CIs and p-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance; estimated ICCs are not shown, as all were <0.0001.

Table 2. Secondary outcomes at baseline and 24 months, by study arm[a]

		Study arm				ICC	Between groups fixed effect		Within groups random effect	
		Intervention		Control						
		n	n (%)	n	n (%)		OR (95% CI)	*p*	OR (95% CI)	*p*
IPV caseness (CAS)[b]	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)	.275	0.1 (0.1 to 0.4)	<.001
Depression caseness (HADS)[c]	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)	.933	0.6 (0.3 to 1.1)	.105
Anxiety caseness (HADS)[c]	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)	.464	0.5 (0.2 to 1.0)	.036
PTSD caseness (PCL-C)[d]	24 months	81	23 (28.4)	84	25 (29.8)	-	0.9 (0.3 to 2.5)	.778	-	
Physical symptom caseness[e]	24 months	78	40 (51.3)	84	43 (51.2)	-	0.9 (0.5 to 1.5)	.681	-	
		n	M (SD)	n	M (SD)		Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
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)	.145	-2.8 (-4.9 to -0.7)	.009

Notes. ICC = intra-cluster correlation; CI = confidence interval; OR = odds ratio; CAS = Composite Abuse Scale; HADS = Hospital Anxiety and Depression Scale; PTSD = posttraumatic stress disorder; PCL-C = PTSD Checklist – Civilian Version; M = mean; SD = standard deviation; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences or odds ratios, with 95% CIs and p-values, calculated using mixed effects linear regression or logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance. [b]CAS total score ≥ 7. [c]HADS subscale score ≥ 8. [d]PCL-C score ≥ 50; Not measured at baseline. [e]Experienced at least physical symptoms on checklist, in the past four weeks; Not measured at baseline.

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 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. 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] Estimated participant retention rates continued to be met at 24 months. 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 (i.e. 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 (e.g. 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. Future trials may need to focus further on addressing these potential barriers.

With regards 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 timepoints, for example in year two. 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 multi-faceted, 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 timepoint, 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 two-year timepoint. 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. With regards 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, and providing 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 responses[38] to enable healing and pathways to safety for women exposed to IPV attending primary care settings.[39]

AUTHORS' CONTRIBUTIONS

All authors contributed to the design of the *weave* trial, interpretation of results, and writing, and approved the final manuscript. Additionally, KH had major responsibility for the design and conduct of the trial and co-developed and delivered the doctor training. JV oversaw and undertook analyses and contributed to interpretation of results. Both KH and JV made major contributions to drafting and revising of the manuscript. LOD was trial coordinator, and provided substantial input to implementation, analysis and interpretation of results.

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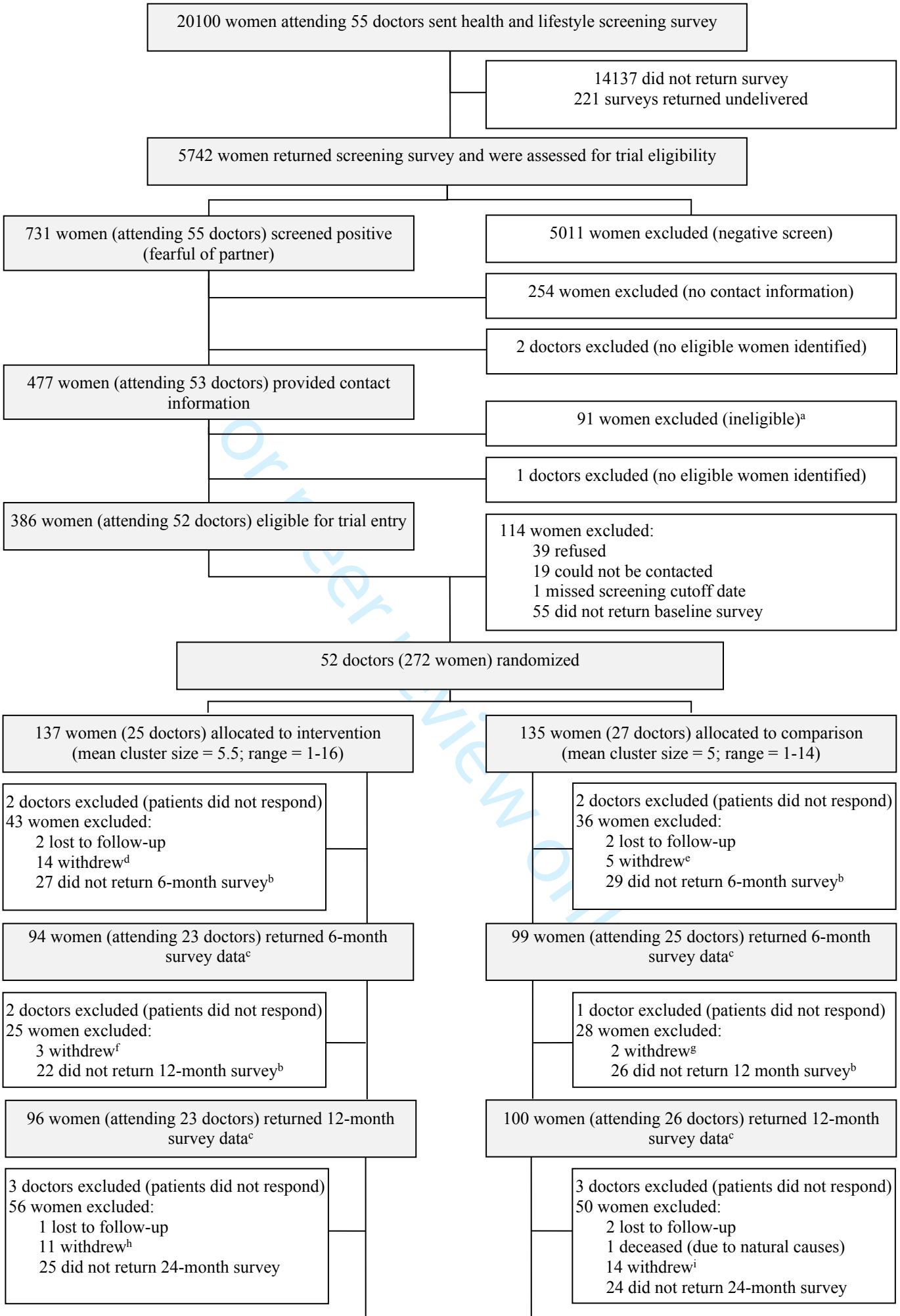
WEAVE Trial CONSORT Flow Diagram



[a]Reasons 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). [b]Excluded from complete case analysis but retained in trial. [c]Analyses and findings are reported in the weave 6- to 12-month outcome paper [*]. [d]Reasons 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); [e]Does not wish to give reason (2), no longer interested/not relevant (1), too busy/survey too long (1), wants to move on (1); [f]Does not wish to give reason (1), no longer interested/not relevant (1), unhappy with weave doctor (1); [g]Does not wish to give reason (1), no longer interested/not relevant (1); [h]does not wish to give reason (1), no longer interested/not relevant (7), too busy/survey too long (1), wants to move on (2); [i]does not wish to give reason (2), no longer interested/not relevant (9), too similar to 12-month survey (1), wants to move on (1), moving overseas (1).

Supplementary Appendix

Supplementary Table 1. Baseline characteristics of women who did and did not return 24-month survey, by study arm

	Women who returned 24-month survey (n = 166)				Women who did not return 24-month survey (n = 106)			
	Intervention (n = 81)		Comparison (n = 85)		Intervention (n = 81)		Comparison (n = 85)	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age	39.4	7.3	38.0	8.6	38.6	7.4	37.7	9.0
	n	(%)	n	(%)	n	(%)	n	(%)
Marital status								
Married	31	(36.9)	20	(25.3)	19	(38.0)	13	(23.6)
Separated / divorced	34	(40.5)	28	(35.4)	14	(28.0)	23	(41.8)
Never married	19	(22.6)	31	(39.2)	17	(34.0)	19	(34.6)
Lives with partner	46	(54.1)	39	(48.2)	32	(64.0)	27	(48.2)
Children < 18yrs at home	57	(67.1)	39	(48.2)	29	(59.2)	34	(60.7)
Year 12 not completed	33	(39.3)	29	(36.3)	30	(60.0)	22	(39.3)
Healthcare Card	50	(58.8)	38	(47.5)	24	(48.0)	32	(57.1)
Unemployed	26	(32.5)	20	(29.9)	15	(34.1)	12	(24.0)
Pension as main source of income	18	(22.2)	23	(29.9)	14	(29.2)	6	(10.9)
Born outside Australia	11	(12.9)	15	(18.5)	8	(16.0)	14	(25.0)
Type of abuse (CAS)								
Severe Combined Abuse	21	(25.3)	24	(30.0)	25	(51.0)	18	(32.7)
Physical and Emotional Abuse	20	(24.1)	22	(27.5)	10	(20.4)	18	(32.7)
Emotional Abuse only	24	(28.9)	24	(30.0)	10	(20.4)	13	(23.6)
Physical Abuse only	3	(3.6)	0	(0.0)	0	(0.0)	2	(3.6)

Supplementary Table 2. Relevant outcomes at previous timepoints for women who did and did not return 24-month survey, by study arm

	Women who returned 24-month survey (n = 166)				Women who did not return 24-month survey (n = 106)				Comparison estimates for those who did versus those who did not return 24-month survey		
	Intervention (n = 81)		Comparison (n = 85)		Intervention (n = 56)		Comparison (n = 50)				
	Mean	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**OR**	**(95% CI)**	***p***
Physical QoL											
Baseline	61.4	(15.9)	58.5	(20.9)	53.1	(18.9)	61.0	(20.6)	1.01	(0.99 to 1.02)	.257
6 months	61.8	(16.3)	63.6	(21.7)	55.6	(22.0)	66.2	(24.8)	1.01	(0.99 to 1.02)	.559
12 months	63.0	(18.4)	63.3	(21.3)	59.2	(20.7)	64.0	(25.0)	1.00	(0.99 to 1.02)	.721
Psychological QoL											
Baseline	50.8	(15.7)	48.8	(18.4)	44.4	(21.1)	51.8	(18.4)	1.00	(0.99 to 1.02)	.514
6 months	52.6	(16.9)	53.5	(20.3)	50.6	(19.6)	56.9	(18.9)	1.00	(0.98 to 1.02)	.866
12 months	53.2	(17.1)	55.2	(20.8)	52.0	(18.3)	56.0	(19.8)	1.00	(0.98 to 1.02)	>.999
Social QoL											
Baseline	48.6	(22.7)	47.0	(23.3)	44.3	(27.5)	48.7	(24.0)	1.00	(0.99 to 1.01)	.691
6 months	49.0	(22.4)	54.0	(24.2)	53.5	(26.1)	56.2	(27.6)	0.99	(0.98 to 1.01)	.436
12 months	50.8	(24.1)	55.2	(23.0)	58.3	(22.2)	54.0	(26.7)	0.99	(0.98 to 1.01)	.451
Environmental QoL											
Baseline	60.0	(14.7)	58.6	(15.9)	54.4	(17.0)	60.5	(14.8)	1.01	(0.99 to 1.02)	.360
6 months	61.6	(14.9)	62.0	(16.5)	62.5	(19.1)	64.3	(16.6)	0.99	(0.97 to 1.02)	.599
12 months	63.0	(16.5)	63.9	(17.5)	65.2	(11.2)	64.5	(16.0)	0.99	(0.98 to 1.01)	.577
Mental Health Status											
Baseline	37.3	(11.6)	35.3	(11.9)	33.3	(12.1)	38.7	(11.7)	1.00	(0.98 to 1.02)	.919
6 months	37.1	(11.5)	37.7	(11.9)	38.4	(12.2)	41.5	(12.6)	0.98	(0.95 to 1.01)	.222
12 months	39.1	(11.8)	40.2	(13.4)	36.1	(13.5)	43.1	(12.0)	1.00	(0.97 to 1.03)	.884
Physical Health Status											
Baseline	49.0	(10.5)	49.0	(10.9)	45.0	(11.4)	50.0	(11.4)	1.01	(0.99 to 1.04)	.334
6 months	48.4	(10.6)	47.4	(12.6)	43.4	(12.8)	49.8	(12.1)	1.01	(0.98 to 1.04)	.491
12 months	47.5	(10.4)	47.1	(11.7)	46.0	(13.0)	48.3	(11.5)	1.00	(0.97 to 1.03)	.996
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**OR**	**(95% CI)**	***p***
Depression caseness											
Baseline	37	(44.1)	42	(51.9)	32	(64.0)	20	(36.4)	0.94	(0.57 to 1.53)	.792
6 months	35	(48.0)	26	(36.6)	10	(40.0)	8	(34.8)	1.22	(0.62 to 2.40)	.555
12 months	45	(57.7)	31	(43.7)	12	(57.1)	8	(32.0)	1.35	(0.69 to 2.64)	.374
Anxiety caseness											
Baseline	58	(69.1)	61	(75.3)	36	(72.0)	37	(67.3)	1.13	(0.66 to 1.94)	.647
6 months	50	(68.5)	49	(69.0)	18	(72.0)	12	(52.2)	1.32	(0.67 to 2.62)	.426
12 months	52	(66.7)	47	(66.2)	14	(66.7)	14	(56.0)	1.27	(0.64 to 2.52)	.490
Abuse caseness											
Baseline	53	(63.9)	62	(77.5)	40	(81.6)	39	(70.9)	0.76	(0.43 to 1.33)	.335
6 months	33	(47.8)	34	(47.9)	10	(40.0)	9	(40.9)	1.35	(0.69 to 2.65)	.379
12 months	32	(42.7)	33	(47.8)	8	(38.1)	11	(45.8)	1.13	(0.57 to 2.22)	.732

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BMC Public Health

STUDY PROTOCOL Open Access

Women's evaluation of abuse and violence care in general practice: a cluster randomised controlled trial (weave)

Kelsey L Hegarty*, Jane M Gunn, Lorna J O'Doherty, Angela Taft, Patty Chondros, Gene Feder, Jill Astbury, Stephanie Brown

Abstract

Background: Intimate partner abuse (IPA) is a major public health problem with serious implications for the physical and psychosocial wellbeing of women, particularly women of child-bearing age. It is a common, hidden problem in general practice and has been under-researched in this setting. Opportunities for early intervention and support in primary care need to be investigated given the frequency of contact women have with general practice. Despite the high prevalence and health consequences of abuse, there is insufficient evidence for screening in primary care settings. Furthermore, there is little rigorous evidence to guide general practitioners (GPs) in responding to women identified as experiencing partner abuse. This paper describes the design of a trial of a general practice-based intervention consisting of screening for fear of partner with feedback to GPs, training for GPs, brief counselling for women and minimal practice organisational change. It examines the effect on women's quality of life, mental health and safety behaviours.

Methods/Design: weave is a cluster randomised controlled trial involving 40 general practices in Victoria, Australia. Approximately 500 women (16-50 years) seen by the GP in the previous year are mailed a short lifestyle survey containing an item to screen for IPA. Women who indicate that they were afraid of a partner/ex-partner in the last year and provide contact details are invited to participate. Once baseline data are collected, GPs are randomly assigned to either a group involving healthy relationship and responding to IPA training plus inviting women for up to 6 sessions of counselling or to a group involving basic education and usual care for women. Outcomes will be evaluated by postal survey at 6 and 12 months following delivery of the intervention. There will be an economic evaluation, and process evaluation involving interviews with women and GPs, to inform understanding about implementation and outcomes.

Discussion: The **weave** trial responds to an urgent need for more evidence on what can be achieved in primary care with regard to responding to women who experience IPA. It will provide important knowledge about the effectiveness of a brief method of screening, professional IPA training program and brief counselling for women.

Trail Registration: [ACTRN12608000032358]

Background

Intimate partner abuse (IPA) or violence is defined as any behaviour within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship [1]. Behaviours include acts of physical aggression such as slapping and kicking; psychological abuse such as intimidation and humiliation; forced intercourse and other forms of sexual coercion; and various controlling behaviours such as isolating a person from their family and friends, monitoring their movements, and restricting access to information or assistance. IPA sits within the broader context of gendered violence and the majority of assaults by partners are directed at females [1,2]. Moreover, sexual abuse and partner violence resulting in

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significant injury are much more commonly perpetrated against women by their partners than against men [3]. Partner abuse is a major public health problem globally. It diminishes women's capacity to participate in occupational, social and familial life and contributes to significant morbidity and mortality among women of child-bearing age [4]. IPA is a complex problem arising from an interplay of personal, situational and socio-cultural factors [2]. Thus, in addition to the need for multifaceted social and educational interventions, early intervention in healthcare settings is required. Primary care offers such an opportunity.

Prevalence of IPA

Partner abuse is a common but hidden problem for women of child-bearing age. Across ten culturally and economically diverse countries, the World Health Organisation reported the lifetime prevalence of physical and/or sexual partner violence as ranging from 15% to 71% [5]. An Australian general practice study found that almost 30% of women had at some point in their lives been afraid of a partner [6]. A further GP study using the Composite Abuse Scale (CAS) [7] to measure abuse in the previous 12 months reported that 6% of women of child-bearing age had experienced severe combined physical, emotional and/or sexual abuse; a further 7% experienced physical and emotional abuse; 6% experienced physical abuse alone and 6% reported emotional abuse alone [8]. Similarly, a United Kingdom study reported that 17% of women attending general practice had experienced physical violence from a partner/ex-partner in the previous year [9].

Health consequences of IPA

Partner abuse has been estimated as the leading cause of death and disability among women of child-bearing age [10]. Research consistently highlights a range of severe physical and mental health problems that are associated with partner abuse [4]. Abused women are at increased risk of anxiety, depression, post-traumatic stress disorder, suicide, and drug and alcohol abuse [8,11,12]. Women indicate that the psychological abuse is even more difficult to endure than the physical abuse itself [13]. The most common physical health problems include injuries, chronic pain and gynaecological, cardiovascular, neurological and gastrointestinal problems [14]. Partner abuse may commence, or increase during pregnancy affecting up to 1 in 4 pregnant women [13,15]. In a UK cross-sectional study of women attending general practice, 15% of respondents who had ever been pregnant reported partner violence during pregnancy, with a quarter reporting that this violence was worse than when they were not pregnant and almost one third saying that it had caused a miscarriage [9]. Partner abuse is associated with adverse maternal and infant outcomes e.g. low birth weight [16], foetal injury and pre-term birth [17], and even death of the mother or the foetus [18]. Partner abuse also has associations with common maternal physical health issues - back pain, headache, urinary incontinence and some less common health issues such as bleeding in first trimester, faecal incontinence [19,20]. Partner abuse also has serious consequences for the physical and emotional well-being of children who witness it [21].

IPA and health care

Abused women are overrepresented in outpatient settings and in primary care [22,23]. Approximately a third of abused women disclose abuse to their GP [24]. Women describe barriers to disclosure that are both internal (e.g. feeling ashamed and embarrassed) and external (e.g. perceiving that doctor is only there for physical problems). GP inquiry is associated with increased disclosure [24], however only 1 in 10 abused women are asked about abuse by the GP [24,25]. Yet there is evidence that women consider it appropriate to be asked about partner abuse [26]. This is moderated by the context of the consultation, the relationship with the health care provider and the woman's readiness to address the problem [27]. Reluctance on the part of health professionals, including GPs, to inquire about abuse owes to factors such as lack of time and training, lack of effective interventions and the complexities of providing whole family care [28,29]. Low levels of inquiry and disclosure have triggered a shift in research focus from studies about prevalence, consequences and patient-health provider interactions to finding improved approaches to screening and intervention.

Screening

A recent systematic review shows that there is insufficient evidence to justify implementing screening programs [30]. Further support came from a recent Canadian study [31], the first IPA screening trial to examine health outcomes for women. It included 12 primary care sites. The authors concluded that there was not enough evidence to support IPA screening in health care settings as routinely asking all patients in the intervention group about abuse, though not found to be harmful, was no more beneficial in terms of health outcomes than usual care. There was no specific intervention offered to women who were detected by the screening program. Despite women's doctors being informed that they screened positive, half reported that IPA was not raised in subsequent consultations. A major criterion for screening that is not being met relates to the availability of an effective treatment once abuse is identified/disclosed. This means that IPA fails to fulfil public health policy criteria for a screening program in health care settings [30]. There is therefore an urgent need for rigorous testing of specific interventions and services for women following identification of IPA

[31,32]. IPA screening instruments are increasingly evaluated against criterion standards such as the Conflict Tactics Scale [33] or Composite Abuse Scale [7]. In a review of 18 brief screening tools in 15 validation studies, Feder et al. found several to be valid for use in health care settings [30]. Inquiring about fear of a partner or ex-partner is receiving increased attention [6,34] and has significant potential as a stand alone screening item. Abused women attending primary care are much more likely (OR = 64.1, 95% CI 44.4-94.1) to have been afraid of a partner or ex-partner at some point in their lives than non-abused women [6]. The fear question has been shown to have good sensitivity and specificity for identifying women who have experienced physical abuse (75.5% sensitivity, 82.4% specificity) or severe combined physical, emotional and sexual abuse (85% sensitivity, 77.7% specificity) in a large sample of women attending GPs for primary care. It does not perform as well in identifying women who have experienced emotional abuse alone (60.6% sensitivity, 80.4% specificity) [7]. It may be concluded that the implementation of screening for IPA is hampered by the absence of evidence for intervention following screening, particularly intervention for women in the early stages of recognising and disclosing abuse. Therefore expanding the evidence base on the optimal method of screening and effective responding is a priority.

Interventions for women in health care settings

Ramsay et al. reviewed 19 studies to evaluate the effectiveness of health care interventions for women on physical and psychosocial wellbeing and their experiences of abuse [35]. This was recently updated with the addition of 14 studies, 5 of which focused on children for the first time [30]. Studies came from diverse settings (e.g. antenatal clinics, refuges, community settings, primary care) and variously tested the impact of advocacy, support group and psychological (individual or group) interventions on outcomes such as post-traumatic stress disorder, depression, self-esteem and abuse. Overall, the evidence was sufficient to recommend access to advocacy services but this only applied to women who had actively sought help (as opposed to women identified through screening). Evidence for the effectiveness of psychological group therapy, support groups, and child interventions was insufficient on account of too few studies, poor quality design and lack of data for calculating effect sizes. There was sufficient evidence to recommend individual psychological treatments. However, treatments were diverse (e.g. cognitive behavioural therapy, problem-solving, expressive writing, psycho-education, feminist-oriented and grief counselling and forgiveness therapy) and since they largely involved survivors and those actively seeking assistance, they can be extrapolated neither to women identified through screening nor those attending primary care settings. There was a clear absence of qualitative studies examining what women themselves think should be contained in an intervention for IPA [30].

Similar to the absence of women's voices, primary care was under-represented across these studies and settings. The review demonstrates the lack of focus on early intervention and the need for more evidence about woman-centred interventions. While health practitioners are widely encouraged to assume a role in supporting abused women, there are limited guidelines available on how to do this [36]. Most tend to focus on identification and referral rather than on appropriate ways of responding to and counselling women following disclosure. It is imperative to expand the evidence base with respect to the types of counselling that might be effective for abused women who screen positive for abuse. This paper describes the development and design of a trial of screening and intervention in primary care for women who have been afraid of a partner or ex-partner in the last year.

Evidence informing the development and design of weave

We have outlined in detail [37] the development of the counselling intervention based on the Transtheoretical Model of Behaviour Change [38] adapted to partner abuse [39,40]. We particularly focused on the 'Psychosocial Readiness Model' [41] to conceptualise women's experiences. We used evidence of best practice from systematic reviews of health care-based interventions [30,35] and of qualitative studies with women [27], international primary care guidelines on partner violence [36] and evaluation of general practice-based partner abuse pilots in Australia and overseas. The **weave** brief counselling intervention [37] incorporates motivational interviewing [42] and problem-solving techniques [43], which have been increasingly applied in the primary care setting for depression issues [44]. Finally, partner abuse interventions frequently aim to improve the safety of women [45-47], and this forms a core aspect of our 'Healthy Relationships' training for GPs.

Outcomes

A key issue in trial design is to identify a set of outcomes that are important to women experiencing abuse and selecting an appropriate means of operationalising these outcomes. Programs focused on women should not be expected to necessarily produce decreased violence in women's lives [48] suggesting that the use of violent events as a primary outcome in trials may be problematic. Change that is internal to the woman is potentially more informative when evaluating the impact of an intervention for partner abuse, especially one that involves direct counselling. Indeed it may be that significant changes in experience of abuse may not be

observable for some time after the seeds of change have been sown. Instead it may be more effective to focus on health outcomes for women, such as quality of life and mental health, which have received limited attention in trials to date [31,49]. Emergent areas of measurement include harm - that which potentially emanates from screening, intervention and from participating in IPA research [30].

Aims of weave

The primary aim of the **weave** study is to determine if a multifaceted intervention consisting of screening for intimate partner abuse and feedback for GPs, training for GPs, a brief counselling intervention for women and minimal practice organisational change results in:

- increased quality of life;
- increased mental health, and;
- increased safety behaviours and planning for women who experience partner abuse.

The secondary aims are to determine if the intervention results in:

- increased readiness for change with regard to the abuse;
- increased comfort on the part of women to discuss partner abuse with GPs;
- increased inquiry by GPs about the safety of women and children;
- reduced anxiety and depression;

and is cost effective.

We hypothesise that the brief counselling intervention will increase women's perceived support and comfort to discuss abuse and lead to positive changes in women's self-efficacy and readiness to change, and that these 'internal' changes will collectively lead to increases in safety planning and behaviours and improvement in mental health and quality of life.

Methods/Design

The study conforms to the guidelines contained in the CONSORT statement for cluster randomised controlled trials [50]. Individual GPs (cluster) will be the unit of randomisation. The study includes one GP only per practice to circumvent the threat of contamination due to cross-over effects. Interventions and analyses will target two levels - the cluster (GP) level and individual (woman) level. The trial will include 40 GPs and consist of two arms - intervention and comparison. Figure 1 presents the anticipated flow of clusters and individual patients over the course of the trial. The study has received ethics approval from the Human Research Ethics Committee of The University of Melbourne.

Inclusion and exclusion criteria

General practitioners

GPs will be eligible if they work three or more sessions per week and are based at a computerised practice. GPs will be excluded if 30% or more of their patients are non-English speaking or if the GP has not been actively practising in the last 12 months.

Women

Women will be eligible for the initial screening component of the study if they have consulted the participating GP within the last 12 months and are aged between 16 and 50 years. Women will be excluded if, in exercising clinical judgement, the GP anticipates they may encounter difficulties in providing informed consent, understanding the content of surveys and/or participating in other aspects of the study due to mental or physical health issues, cognitive impairment, intellectual disability or poor English language skills. Additional criteria are required for inclusion in the trial - women will be invited to participate (over the telephone) if they indicate in the screening survey that they have been afraid of their partner or ex-partner in the last 12 months and are interested in hearing more about the **weave** project. Women will be excluded at this stage if it is established during the recruitment phone call that they no longer attend the GP or they are a false-positive. False positives are women who misinterpreted the fear item in that they have never felt afraid of a partner or they have not felt afraid in the previous 12 months.

Number of participants required

The final sample size of 89 women in each of the two groups will have at least 80% power (alpha 5%, 2-sided test) allowing for a clustering effect (intra-cluster correlation of 0.02 [8]) to detect clinically important differences on the primary outcomes at 12 months between the intervention and comparison groups (See Table 1). To have sufficient power to test our hypotheses, 40 practitioners (20 in each arm) are required in order to allow screening of approximately 500 women per practice (20000 women in total). Based on women's response rates from the **weave** pilot study and *diamond* study [51] 40% of women will return the screening survey (8000). Of these, it is estimated that 10% (800) will have experienced abuse that includes combined physical, sexual and/or emotional abuse in the last 12 months and will therefore screen positive to having been afraid of a partner or ex-partner during this period. Of these, 60% (480) will indicate an interest in hearing more about the project and being contacted by the research team. It is estimated that 70% (336) of these women will agree over the phone to being involved in the trial (a proportion will decline and a proportion will prove ineligible at this stage), 80% (268) of whom will return their baseline surveys and enter the trial. Following randomisation,

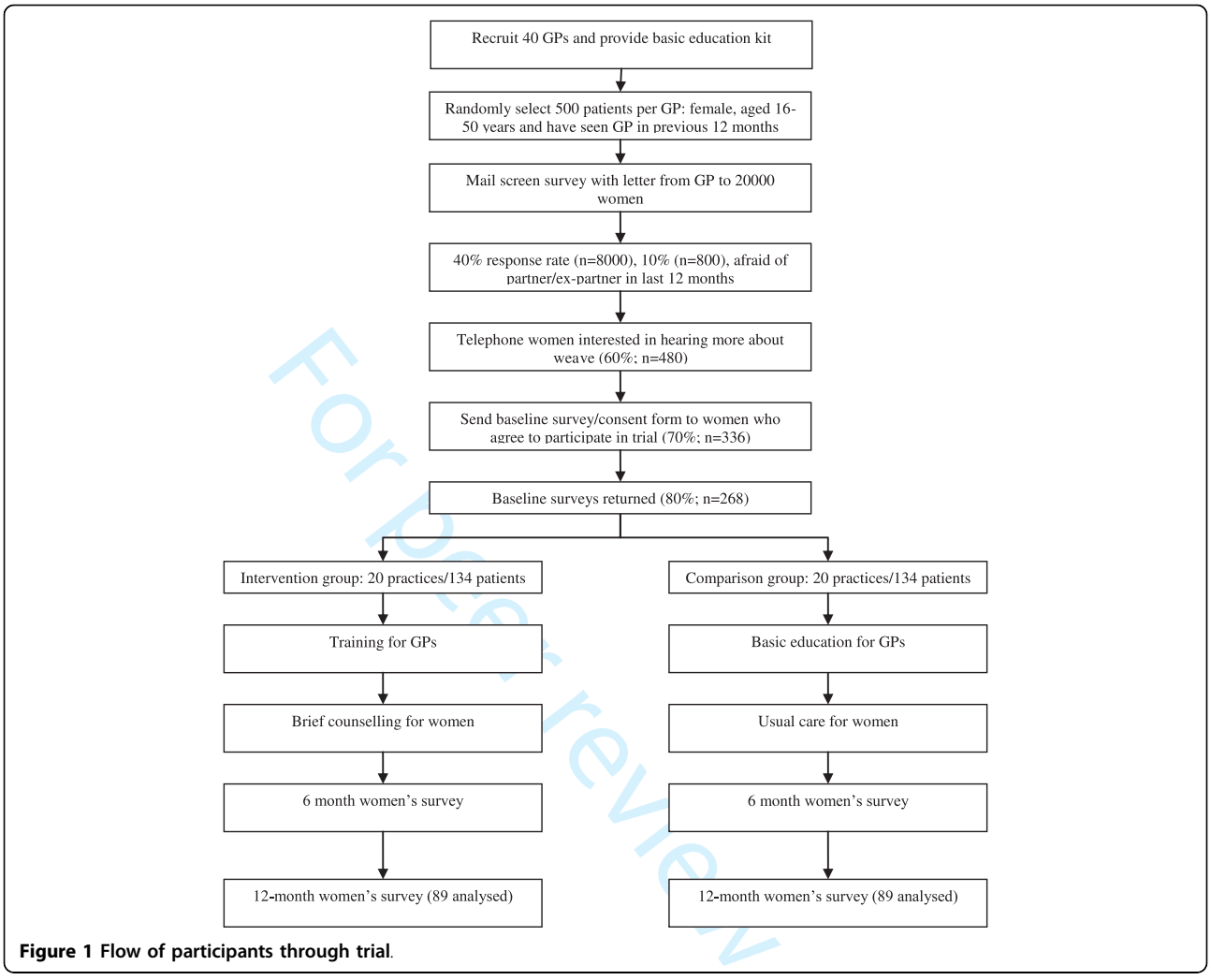

Figure 1 Flow of participants through trial.

approximately a third (88) will be lost to follow-up at 12 months based on data from the *diamond* cohort [51] and MOSAIC [52] leaving 89 women per group at 12 months.

Recruitment

Multiple strategies will be used to recruit GPs. These include mailing to randomly selected GPs (750 urban, 250 rural; within 150 km radius of Melbourne) registered with the Australasian Medical Publishing Company. GPs will be sent a letter of invitation, information about the project and a faxback form in the mail. If we still require more GPs, we will re-contact eligible practices from this original list, and request that the practice manager advertise the project among GPs with interest in women's health, domestic violence, mental health or research. Additionally, we will mail out to 600 GPs involved in shared maternity care in Melbourne using the same protocol.

Although we will utilise the lists described above as much as possible to minimise selection bias, we will

Table 1 Primary outcomes, measures and hypothesised differences between study groups

Outcome	Measure/tool	Hypothesis
Quality of life	World Health Organisation Quality of Life-Bref [58]	There will be a difference of half of a standard deviation between the two groups (assuming a SD of 20) [66]
Mental health status	SF-12 Mental Component Summary [59]	There will be a difference of half of a standard deviation (SD = 11) between the two groups [67]
Safety planning	Safety plan in the last 12 months	Have a safety plan at 12 months: 10% vs 40%
Safety behaviours	Safety-Promoting Behaviour Checklist [60]	There will be a difference of half of a standard deviation (SD= 2.5) between the two groups [68]

enlist the services of VicReN if required. This is a Victorian-based general practice research network service based at the Primary Care Research Unit at The University of Melbourne. Staff from VicReN will assist by advertising the project in newsletters of the Royal Australian College of General Practitioners (RACGP) and Divisions of General Practice and by engaging GPs using various strategies. All eligible GPs will be asked to read and sign a Memorandum of Understanding and consent form, complete a baseline survey (allowing comparison with the Australian GP population) and to complete the basic education kit. Practices are reimbursed at a rate of $500 for time involved in generating patient lists and GPs will be eligible for RACGP Quality Assurance and Continuing Professional Development points.

Patient recruitment

Patient recruitment will be done through methods validated in a recent primary care cohort study that screened for probable depression via postal survey, and included a screen for abuse [51]. In **weave**, for each participating GP, a list of female patients, aged 16 to 50 years who consulted the GP at least once in the previous 12 months will be randomly generated (maximum 600 patients per list). The GP will review the list and exclude those women who meet exclusion criteria. The remaining women will be mailed the screening questionnaire together with a letter from their GP endorsing the project, an information sheet, a resource card listing contact numbers for various support agencies and a reply paid envelope. In the survey the respondents are told that the **weave** team is trying to work out ways to improve the care women receive in general practice, and particularly in relation to emotional well-being. At the end of the screening survey, respondents are asked if they would like to hear more about **weave**, the next stage of which involves "completing a survey about relationship and emotional issues (e.g. depression, domestic violence, stress or worry)." A reminder is mailed out from the practice to all women 14 days following mail-out of the screening survey.

Eligible women will be phoned by a research assistant who will explain the nature of the study (a project looking at ways of improving the care women receive from their GP when they are experiencing relationship and emotional issues, such as being afraid of your partner or ex-partner). It will be explained that the project will involve three surveys over approximately 18 months and that they may or may not be invited to see the GP to discuss relationship and emotional issues depending on the group in which they are placed by chance. Those eligible and agreeing to be involved are sent a baseline survey, information sheet, resource card and a reply paid envelope. Once the baseline survey and consent form have been returned, women are officially enrolled in the trial. A reminder is sent to patients 10 days post baseline survey and a phone call reminder at 20 days. All GPs (and their female patients) in a given wave (there will be four waves) are randomised to intervention or comparison once the cut-off for the return of the baseline survey (30 days following mail-out) for the final GP in the wave has been reached.

Sequence generation and allocation concealment

Allocation to intervention or comparison will be based on clusters rather than individuals. The trial will be run in four consecutive overlapping waves. Approximately 10 GPs will be randomised in each wave. Characteristics of GPs, including age, sex, years of general practice experience and knowledge about management of partner abuse, will be measured at baseline to check the extent to which randomisation creates equivalence across the two groups. To promote comparability of the intervention and comparison clusters with respect to cluster characteristics, practitioners will be stratified according to whether they are urban or rural and block randomisation with random block sizes will be used within each stratum. The randomisation will be performed by a statistician not directly involved in the study and who is blinded to the identity of the practitioners. Allocation of clusters to intervention or comparison will done following collection of baseline data. In other words, at the time of screening and recruitment of women, the allocation of GPs (and therefore, of women) will be unknown.

Blinding

weave is a pragmatic intervention study. Due to the nature of the intervention (professional training plus patient counselling) it is not possible to blind the GPs to their status as intervention or control. Similarly, the immediate project team is not blind to GP participant status as much interaction between the team and the GPs must occur as part of the training and organising for women to attend their counselling appointments. In the same vein, women are not blinded in that they need to be aware that they may (intervention group) or may not (comparison group) be invited by the GP to discuss relationship issues as part of **weave**. Women will be made aware that they will receive surveys regardless of the group they have been assigned to. There is no blinding as regards data collection based on the CONSORT guidelines [50], as the women and GPs themselves complete the surveys (i.e. data were not collected by a research assistant blinded to the allocation). However the wider investigator team (and the statistician) remain blinded to the identity and allocation of GP participants and women.

Intervention

The **weave** intervention [37] is a multifaceted, practice-based program refined by the multidisciplinary team and project reference group. It consists of professional,

patient and organisational elements. The aim of the professional intervention (**weave** Healthy Relationships Training) is to train GPs in how to respond to IPA when women are identified, and to facilitate GPs to deliver a brief counselling intervention to patients who have been afraid of their partner or ex-partner. It will equip practitioners with an innovative, time-efficient and structured approach to use with patients. The intervention was developed with particular attention to overcome the challenges of changing physician behaviour [53] by being practice-based and including group discussion via teleconference, clinical audits, distance learning, evidence-based guidelines [36] and two interactive practice visits [37]. Key elements of the visits are active listening exercises [54], attitudinal exercises [55], involvement of simulated patients and role play of different readiness for change scenarios [40], use of survivors' voices [56], and modelling of non-abusive behaviours in teaching interactions with health providers [55]. As required, additional practice visits, email and telephone support will be provided.

The patient component of the **weave** intervention involves a brief counselling intervention for delivery by the intervention (trained) group GPs within the primary care setting. Female patients who have been 'afraid' of a partner or ex-partner in the last 12 months (participants in the study) will receive a letter from their GP inviting them to make an appointment to discuss relationship and emotional issues. Women will be offered several 30-minute counselling sessions by their GP for relationship issues and their emotional wellbeing. Where women have not made an appointment within a fortnight of receiving the invitation the research assistant will contact them and offer to connect them immediately with the practice to book an appointment. The main aim of the **weave** brief intervention is to assist women to:

- feel listened to, validated and supported by their GP;
- experience increased awareness about the abuse;
- increase their readiness for change and self-efficacy, and;
- increase their safety planning and behaviours.

At the first visit, the GP establishes with the woman the number of sessions that might be required (up to 6). The woman's readiness for change is established and the GP then selects motivational interviewing and/or problem-solving techniques as part of an appropriate response to the woman's position. GPs complete encounter forms during the women's visits to allow gathering of process data on the content of the counselling.

The minimal organisational change component of the intervention involves circulating information about **weave** to the administrative and clinical staff, placing posters on the wall and working with the practice staff to identify suitable and consistent methods of reminder and recall for the women. Each aspect of the organisational change will prioritise the confidentiality of women and will be practice-centred (i.e. guided by advice of the participating GP and practice manager). At the conclusion of the trial, comparison group GPs will be invited to participate in a day long workshop based on the **weave** Healthy Relationships Training Program.

Data collection

Outcome evaluation

Data will be collected from women by postal questionnaire at the screening stage and at three further points over the duration of the project. Similar to other studies in this area [30,31], we will collect data from women in both groups at baseline, and at 6 and 12 months following the invitation to the intervention group women to attend counselling. Development of study materials has been informed by a primary care cohort study on depression which also gathered data on abuse [51].

Screening phase

The primary purpose of the screening questionnaire is to identify women who have been afraid of a partner or ex-partner in the last 12 months and of those, the women willing to be contacted by the project team. The additional items in the survey ask about depression, smoking, alcohol, anxiety, dietary issues and exercise. These help to conceal the purpose of the survey and protect participants. Responses are on a five point likert scale ranging from 'None of the time' to 'All of the time'. If a woman selects an option other than 'None of the time' for the afraid question, and indicates an interest in hearing more about the project, then she is contacted and invited to participate in the trial. Other items include a sub-dimension of the General Practice Assessment Questionnaire [57] and sociodemographic items. We also included items to establish whether women have disclosed being afraid to a GP previously, if they would use help from the GP or general practice nurse if it were available and how comfortable they would be discussing feeling afraid with the GP. It is explained in the screen survey that not every woman who provides her contact details can be contacted by the project team.

Trial phase

The primary outcomes (Table 1) include quality of life, measured across four dimensions (physical, psychological, environmental, social) using the WHOQoL-Bref [58], and mental health status, using the mental component of the SF-12 [59]. The third primary outcome is safety and is measured based on the existence of a safety plan (yes/no) and the number of safety behaviours

enacted (Safety-Promoting Behaviour Checklist [60]). The secondary outcomes include open ended questions about readiness for change, based on the Domestic Violence Survivor Assessment [61], comfort to discuss abuse with GP (5-point likert scale), GPs' inquiry about the safety of women and their children (yes/no) and anxiety and depression, based on the Hospital Anxiety and Depression Scale [62]. Health care utilisation is measured based on visits to health professionals, days out-of-role and hospital admissions. Other variables measured at different stages of the trial were included to investigate mediating variables (see Table 2) and to provide process data to help understand why the intervention may or may not have been effective. Harm associated with participation in the research (e.g. acceptability of screening, distress caused by being invited into the project, partner's awareness of the research, adverse effects arising from participating in counselling, response burden) was measured using an adapted version of the COST questionnaire [31].

The readiness of GPs to manage intimate partner abuse is assessed before and after the training using PREMIS, a validated questionnaire assessing knowledge, attitude and behaviours of doctors with regard to IPA [63].

Economic evaluation

The primary economic evaluation will use a cost-consequences analysis, with any incremental costs compared to all incremental outcomes as detailed above. If this does not reveal a dominant result for the cost-effectiveness of the intervention, secondary economic analysis will involve incremental cost-effectiveness analysis using individual outcome measures and cost-utility analysis using SF-12 data. The economic evaluation will be conducted from both a health care and societal perspective, with costs including resources used in intervention delivery and practice-based system change and women's use of health care and other societal resources.

Table 2 Other variables and measures included in 6 and 12 month surveys

Variable	Measure/tool
Sense of safety	How safe have you felt at home in the last two weeks/6/12 months ago? (visual analogue scale)
Safety behaviours	What things do you do (or have you done in the last 6 months) to keep you safe from your partner or ex-partner? (open-ended question)
Nature/frequency of abuse	Composite Abuse Scale [7]
Health status	Short Form-12 (PCS) [59] Smoking Alcohol (AUDIT) [69] Medications (analgesics, antidepressants and sedatives)
Post-traumatic stress disorder	Short Screening Scale for DSM-IV PTSD [70]
Self-esteem and self-efficacy	Rosenberg Self-Esteem Scale [71] Generalized Self-Efficacy Scale [72]
Social support	Oslo 3 Social Support [73]

Process evaluation

The Realistic Evaluation model was used in the trial to develop a causal model (Figure 2) to allow understanding of 'what works for whom in what circumstances?' [64]. This evaluative framework examines context, mechanism and outcomes. Process data will include completion of encounter forms describing what GPs did during the sessions e.g. counselling methods used, billing, follow-up and written plans. In addition we will ask GPs to audio-record consultations. We anticipate that only a small proportion of GPs and women will agree to have the sessions recorded. We will conduct semi-structured interviews with a sample of up to 20 women from each arm of the trial after the 12 month assessment. We will purposively sample the women such that a range of women's level of fear, severity of abuse and their readiness to change at baseline are represented. The purpose will be to assess their experiences of receiving the intervention or usual care and perceived outcomes. We will gather data on satisfaction with counselling sessions/usual care, extent to which expectations of sessions/usual care were met, changes to usual GP care, quality of relationship with GP, experiences of being in the project, relationship with research team, and any changes women made in their relationships as a result of being involved in **weave**. Individual semi-structured telephone interviews with all GPs from both comparison and intervention at the end of the trial will assess their perceptions of the research and intervention process and the impact on their practice, both positive and negative. We will ask about satisfaction with training and counselling process/usual care, perceived impact of counselling/usual care on women, whether expectations of being involved in **weave** were met and perceived impact on their practice and sustainability of skills and practice. Data from all sources including the 6 month patient surveys will be combined to understand what works for whom in what circumstances.

Data analysis and reporting

Characteristics of GPs and women will be summarised using frequencies and percentages for categorical data, and means and standard deviations or percentiles for continuous data, for the two study arms. GP and women's characteristics will be compared between the two arms at recruitment to ensure that randomisation was effective. Intra-cluster correlations will be calculated for key outcome variables and patient variables at baseline. Appropriate modelling techniques will be used to account for the complexity of the study design, its hierarchical structure (women clustered within practices), stratification of

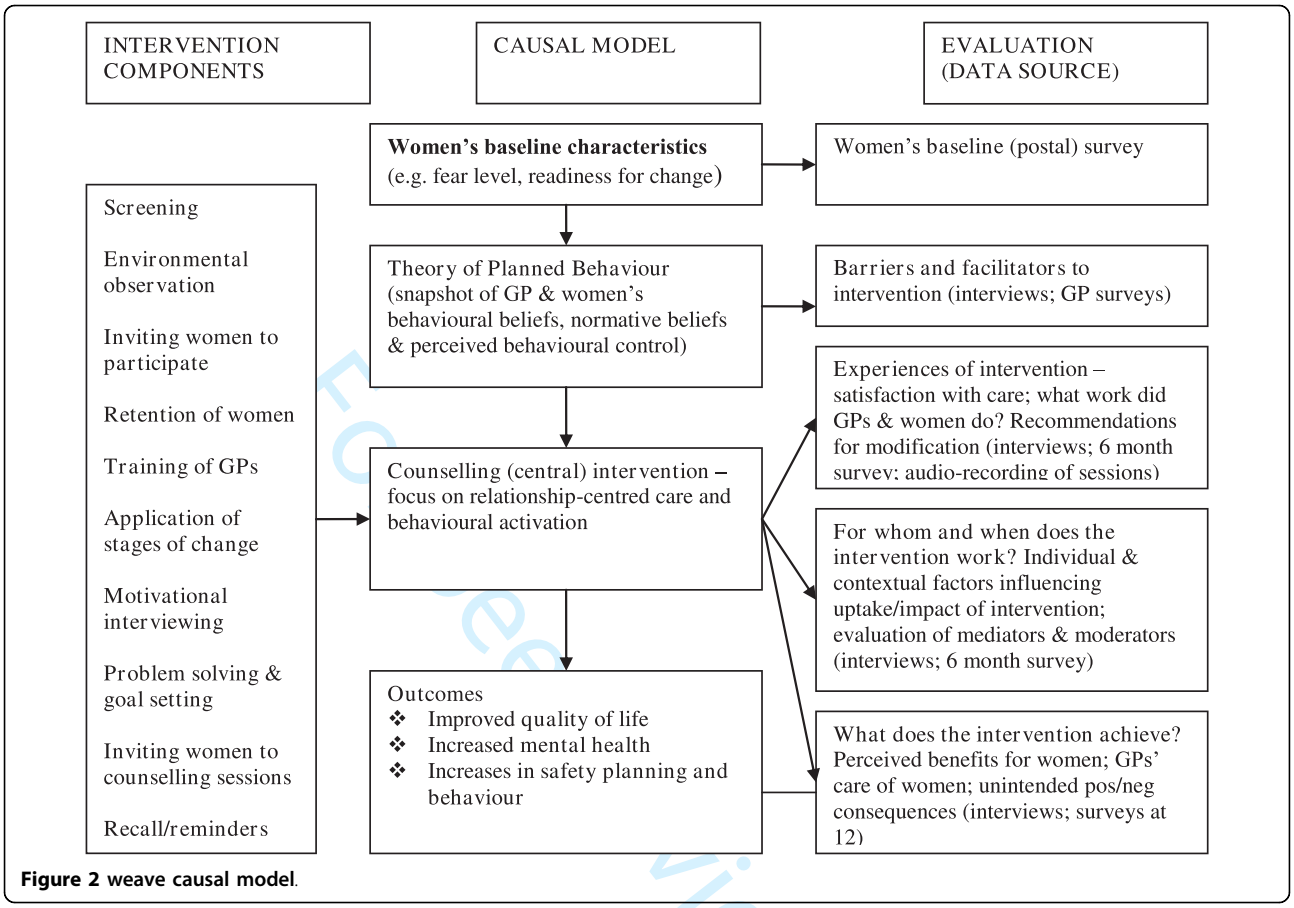

Figure 2 weave causal model.

practices at randomisation and repeated measures over time. GP practice will be set as the primary sampling unit and analysis will be intention-to-treat. Marginal logistic regression using Generalised Estimating Equations (GEE) with information sandwich estimates of standard error will be used for the binary outcomes. Mixed-effects linear regression will be used to compare the scores between the two study groups for mental health status and quality of life measures. Baseline outcome measures and any imbalanced factors strongly associated with the outcomes will be adjusted for in the regression model. An independent data monitoring committee (DMC) consisting of 5 members (GP/researcher, IPA researcher, community service worker, GP, and a statistician) will be convened on approximately four occasions over the course of the trial. The aim of the **weave** DMC is to monitor the safety of the participants and ensure the integrity of the trial data. This will be achieved by checking interim data and monitoring progress against the trial protocol including recruitment rates, uptake of the intervention and loss to follow-up.

Discussion

In summary, there is a strong rationale for developing and testing interventions of screening and counselling for women who experience partner abuse, for embedding this research in primary care and for measuring the effect in terms of health outcomes for women. Primary care allows considerable scope in terms of the women who are reached, and is unique in that it has the potential to facilitate early intervention as well as support for women who are in recovery but remain at risk. Notwithstanding the challenges [65], well-designed randomised controlled trials are essential for testing hypotheses with strong theoretical underpinnings to produce high quality evidence [30]. Evaluation needs to incorporate adequate follow-up and a focus on safety and health outcomes for women. Finally, process measurement is essential to explain the 'why and how' of the intervention, focusing on areas such as uptake of intervention, harm, readiness for change, inquiry by health professionals, abuse, support, self-efficacy and expectations. With intimate partner abuse the leading contributor to death, disability and illness among Victorian women aged 15 to 44 years [10], there is an urgent need to build evidence about effective response to this complex social problem in primary care. An 'effective' response not only requires an assessment of the safety of women and children, it must also respect

and promote the dignity of women, validate and understand the diversity of women's experiences, withhold judgement about what a woman should do and when, and place ongoing support at the centre of the interaction between the woman and practitioner.

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Authors' contributions
KH has major responsibility for the design and conduct of the **weave** trial, co-developed and delivers the GP training and drafted and revised this manuscript. JG contributed to the design of **weave** and the development of the training. LOD provides substantial input to the implementation of **weave** and drafting and revising of the manuscript. AT, GF, JA and SB contributed to the design of **weave** and the drafting and revising of the manuscript. PC advises on design and analysis and contributed to the draft manuscript. All authors approved the final manuscript.

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

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Screening and counselling in the primary care setting for women who have experienced intimate partner violence (WEAVE): a cluster randomised controlled trial

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Summary

Background Evidence for a benefit of interventions to help women who screen positive for intimate partner violence (IPV) in health-care settings is limited. We assessed whether brief counselling from family doctors trained to respond to women identified through IPV screening would increase women's quality of life, safety planning and behaviour, and mental health.

Methods In this cluster randomised controlled trial, we enrolled family doctors from clinics in Victoria, Australia, and their female patients (aged 16–50 years) who screened positive for fear of a partner in past 12 months in a health and lifestyle survey. The study intervention consisted of the following: training of doctors, notification to doctors of women screening positive for fear of a partner, and invitation to women for one-to-six sessions of counselling for relationship and emotional issues. We used a computer-generated randomisation sequence to allocate doctors to control (standard care) or intervention, stratified by location of each doctor's practice (urban *vs* rural), with random permuted block sizes of two and four within each stratum. Data were collected by postal survey at baseline and at 6 months and 12 months post-invitation (2008–11). Researchers were masked to treatment allocation, but women and doctors enrolled into the trial were not. Primary outcomes were quality of life (WHO Quality of Life-BREF), safety planning and behaviour, mental health (SF-12) at 12 months. Secondary outcomes included depression and anxiety (Hospital Anxiety and Depression Scale; cut-off ≥8); women's report of an inquiry from their doctor about the safety of them and their children; and comfort to discuss fear with their doctor (five-point Likert scale). Analyses were by intention to treat, accounting for missing data, and estimates reported were adjusted for doctor location and outcome scores at baseline. This trial is registered with the Australian New Zealand Clinical Trial Registry, number ACTRN12608000032358.

Findings We randomly allocated 52 doctors (and 272 women who were eligible for inclusion and returned their baseline survey) to either intervention (25 doctors, 137 women) or control (27 doctors, 135 women). 96 (70%) of 137 women in the intervention group (seeing 23 doctors) and 100 (74%) of 135 women in the control group (seeing 26 doctors) completed 12 month follow-up. We detected no difference in quality of life, safety planning and behaviour, or mental health SF-12 at 12 months. For secondary outcomes, we detected no between-group difference in anxiety at 12 months or comfort to discuss fear at 6 months, but depressiveness caseness at 12 months was improved in the intervention group compared with the control group (odds ratio 0·3, 0·1–0·7; p=0·005), as was doctor enquiry at 6 months about women's safety (5·1, 1·9–14·0; p=0·002) and children's safety (5·5, 1·6–19·0; p=0·008). We recorded no adverse events.

Interpretation Our findings can inform further research on brief counselling for women disclosing intimate partner violence in primary care settings, but do not lend support to the use of postal screening in the identification of those patients. However, we suggest that family doctors should be trained to ask about the safety of women and children, and to provide supportive counselling for women experiencing abuse, because our findings suggest that, although we detected no improvement in quality of life, counselling can reduce depressive symptoms.

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Introduction

WHO endorses primary care as a setting for early intervention in intimate partner violence (IPV), which is a major public health issue.[1] Family doctors are often the first professional group that women speak with about such problems,[2] but restricted evidence exists to guide doctors' responses to women who screen positive for IPV.[2,3] Despite policy recommendations for health-care screening,[4] evidence suggests that such screening without offering structured intervention to those identified has little effect.[2,5] A systematic review[3] identified five trials in which an intervention was offered after screening in health-care settings. The one primary care screening trial included in this review showed no effect of a nurse-led management protocol compared with the use of a wallet-sized referral card on reducing IPV.[6] Thus, evidence informing response in primary care is based on very few trials, with little focus on clinically important outcomes for women.[2,3]

In this trial, we addressed this evidence gap by assessing the effect of a brief counselling intervention offered by family doctors to women identified through IPV screening in Australia. Counselling interventions should not be expected to decrease violence in women's lives in the short-term,[7] which suggests that measuring abuse as a primary outcome in trials or referral to IPV-related services might be problematic. We hypothesised that the intervention will increase women's perceived support and comfort to discuss abuse and thus lead to positive changes in women's self-efficacy and to improvements in women's safety planning and behaviours, mental health, and quality of life. In this Article, we report the main findings of this trial at 6-months and 12-months follow-up.

See Online for appendix

Methods

Study design and participants

For the **protocol** see www.biomedcentral.com/1471-2458/10/2

Our protocol is described elsewhere.[8] Briefly, we did a cluster randomised controlled trial enrolling family doctors and their female patients who screened positive for IPV; the trial conforms to the CONSORT guidelines.[9] Doctors were recruited between Jan 31, 2008, and Jan 18, 2010; doctors and their female patients were randomised between Sept 22, 2008, and June 18, 2010. 6 month data collection occurred from Aug 26, 2009, to June 24, 2011, and 12 month data collection from March 18, 2010, to Nov 24, 2011. Family doctors were the unit of randomisation, to minimise contamination that could otherwise occur if trained doctors were seeing both intervention and control patients. Outcomes were measured at the individual level; those considered to be clinically meaningful and selected as our primary measures were quality of life, safety planning and behaviour, and mental health.[2,10]

For details of **the Healthy Relationships Training programme** see http://www.gp.unimelb.edu.au/pcru/abuse/resources.html

We sent doctors (one per practice) from urban (710 [71%] of 1004 doctors) and rural (294 [29%] of 1004 doctors) Victoria, as listed by the Australian Medical Publishing Company, written invitation to participate in the trial. Doctors were eligible for inclusion if they worked three or more sessions per week, used electronic records, and if 70% or more of their patients spoke English. For every doctor recruited, women (aged 16–50 years) who had visited the doctor in past 12 months were mailed a brief survey from the practice (done by researchers).[8] The survey assessed the frequency of eight health and lifestyle issues, including how often in the past 12 months they were afraid of their partner or ex-partner (five-point Likert scale: "none of the time", "a little", "some", "most", "all of the time").[11] This item has been shown to have good sensitivity and specificity for the identification of women who have experienced physical, emotional, or sexual abuse.[12] We did not send a health and lifestyle survey to women for whom we had no address or if their doctor anticipated difficulties in responding because of cognitive impairment or poor English-language skills. Women who screened positive for fear of their partner and provided contact details were eligible for the trial and were invited to participate by telephone by researchers. Further exclusions were undertaken at this point: if patients had misinterpreted the fear item, had experienced fear but not in the past 12 months, had insufficient English-language skills, or were no longer seeing the trial doctor (figure). Eligible women who agreed to participate were mailed an information leaflet, resources card, and baseline survey to a nominated safe address. We excluded otherwise eligible doctors if no women were enrolled from the practice. We randomly allocated doctors (and their patients) once all baseline data were collected.

The study intervention[13] consisted of the following: training of doctors, notification to doctors of women screening positive for fear of a partner, and invitation to women for brief counselling for relationship and emotional issues (appendix). The counselling intervention was based on the Psychosocial Readiness Model,[14] which acknowledges that abused women might not be ready or able to take advantage of referrals offered by providers.[15] There is an opportunity for health practitioners to facilitate a woman's shift towards changing her IPV situation.[16] When designing the intervention, we consulted the following sources: systematic reviews of health-care-based interventions,[2] meta-analysis of qualitative studies,[17] and international IPV primary care guidelines.[18]

Doctors in the intervention group received the Healthy Relationships Training programme, designed to train them to respond to women and deliver a brief counselling intervention (appendix). Training consisted of a 6-h distance learning package and two 1-h interactive practice visits delivered by an academic clinician using simulated patient role plays.[13] Training emphasised the importance of patient-centred care and promoted active listening, motivational interviewing, and problem-solving techniques for validating women's experiences and feelings, assessing readiness for change, and supporting decisions.[13] Women attending the practices of doctors in the intervention group who were fearful of a partner were sent a letter from the doctor to invite them to attend between one and six counselling sessions (depending on women's needs) over a 6 month period at no cost to the patient. Doctors in both groups (intervention and control) received a basic IPV education pack and Continuing Professional Development points. All women received a list of resources (with the surveys) and women in the control group received usual care if they presented to their doctor with concerns during the trial period.

Data were collected via postal survey 6 months and 12 months after sending the initial counselling invitation. Primary outcome measures were: WHO Quality of Life-BREF (four dimensions);[19] mental health score SF-12;[20] patients' response to whether or not they had ever made a safety plan (appendix); and responses to a Safety-Promoting Behaviour Checklist.[21] Secondary outcomes included depression and anxiety (Hospital Anxiety and Depression Scale; cut-off ≥8);[22] women's report of an inquiry from their doctor about the safety of

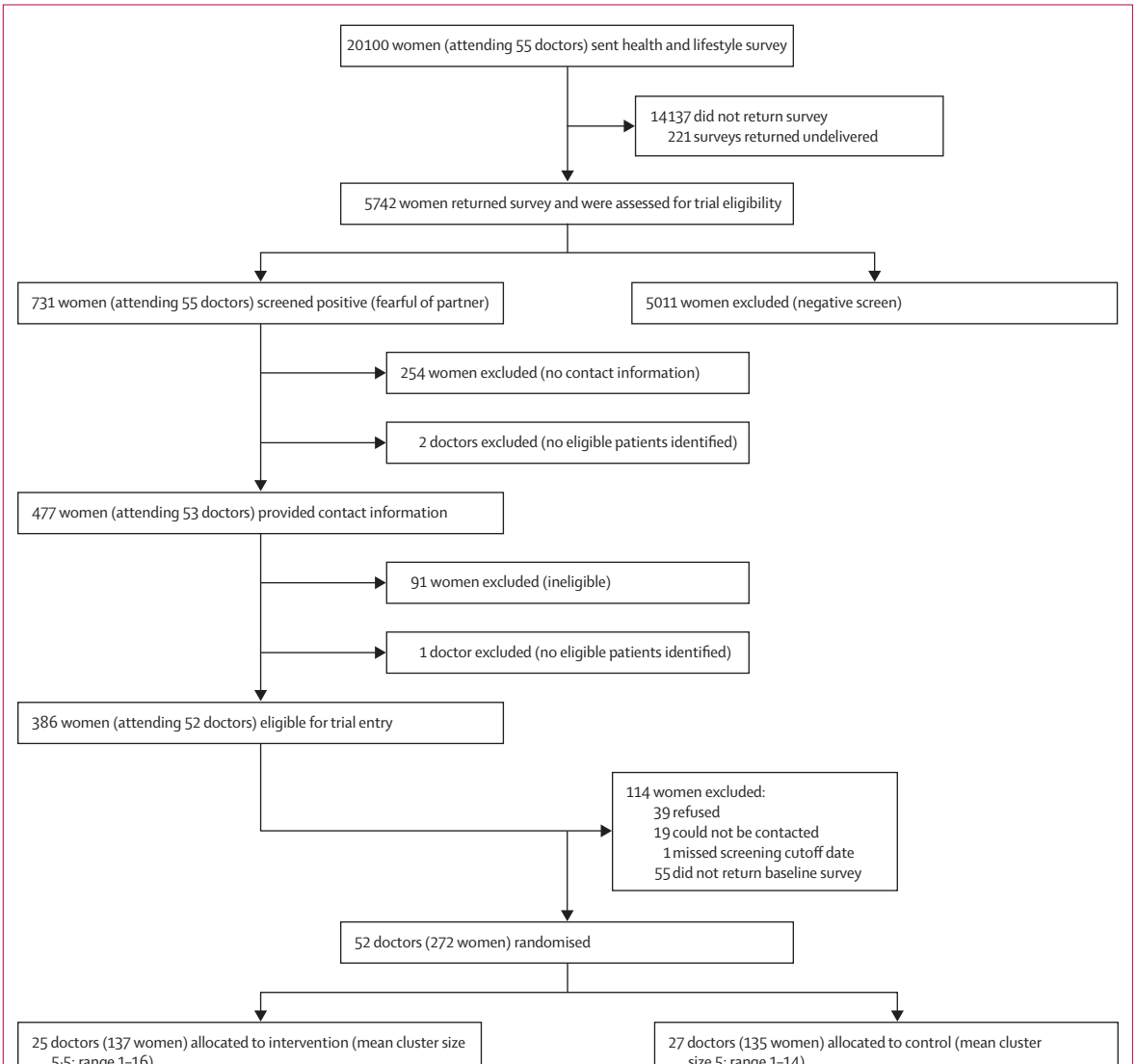

Figure: **Trial profile**
ITT=intention to treat. *Primary analysis imputed missing cases. †Analysis includes women who returned surveys only.

them and their children; and comfort to discuss fear with their doctor (five-point Likert scale). We have not yet analysed the open-ended questions (at 6 months and 12 months) about readiness for change. Other variables included IPV (Composite Abuse Scale; cut-off ≥7),[12] harm (items from Consequences of Screening Tool),[23] a harm or benefit visual analogue scale (VAS), perceived doctor support VAS, and health and community service use (appendix).

	Intervention	Comparison	Total	Australian average
Family doctors				
Number	25	27	52	25 707
Urban*	18 (72%)	19 (70%)	37 (71%)	89%
Women	14 (56%)	18 (67%)	32 (62%)	39%
Age in years	49·3 (8·4)	46·9 (7·7)	48·1 (8·1)	49·3
Works in group practice	23 (92%)	27 (100%)	50 (96%)	88%
Hours per week in clinical practice	36·6 (11·6)	30·0 (12·1)	33·6 (12·1)	38·3
Graduated in Australia	19 (83%)	18 (78%)	37 (80%)	74%
GPAQ communication score†	81·4 (19·3)	81·7 (19·0)	81·6 (19·1)	84·0‡
Time in years since graduation	24·6 (8·6)	22·3 (8·3)	23·5 (8·4)	..
Years as a family doctor	18·4 (8·5)	16·8 (7·3)	17·6 (7·9)	..
Mental health skills training				
Level 1 (2 h)	7 (28%)	6 (22%)	13 (25%)	..
Level 2 (≥6 h)	5 (20%)	4 (15%)	9 (17%)	..
Total training about intimate partner violence§				
0–2 h	12 (48%)	12 (44%)	24 (46%)	..
3–5 h	8 (32%)	6 (22%)	14 (27%)	..
6–10 h	2 (8%)	5 (19%)	7 (14%)	..
Women§				
Number	137	135	272	..
Mean age in years	37·9 (8·8)	39·1 (7·3)	38·5 (8·1)	..
Marital status				
Married	33 (25%)	50 (37%)	83 (31%)	..
Separated or divorced	51 (38%)	48 (36%)	99 (37%)	..
Never married	50 (37%)	36 (27%)	86 (31%)	..
Lives with a partner	66 (48%)	78 (58%)	144 (53%)	..
Children (younger than 18 years) at home	73 (53%)	86 (64%)	159 (59%)	..
Year 12 schooling not completed	51 (38%)	63 (47%)	114 (42%)	..
Unemployed	32 (27%)	41 (33%)	73 (30%)	..
Pension as main income source	29 (22%)	32 (25%)	61 (23%)	..
English not first language	8 (6%)	7 (5%)	15 (6%)	..
Fearful most or all the time	21 (15%)	17 (13%)	38 (14%)	..
Positive for abuse on CAS (total score ≥7)	101 (75%)	93 (71%)	194 (73%)	..
Severe combined abuse on CAS	42 (31%)	46 (35%)	88 (33%)	..
Physical and emotional abuse¶ on CAS	40 (30%)	30 (23%)	70 (26%)	..
Emotional abuse¶ only on CAS	37 (27%)	34 (26%)	71 (27%)	..
Physical abuse only on CAS	2 (2%)	3 (2%)	5 (2%)	..

Data are n, n (%), or mean (SD). Data for Australian averages are mean or percent. CAS=Composite Abuse Scale. GPAQ=General Practice Assessment Questionnaire. *Rural, Remote, and Metropolitan Areas classification 1–2. †As rated by trial participants before randomisation—scores are expressed as a percentage of the maximum possible score (100) for communication, with higher scores indicating greater satisfaction. ‡Data from reference 33. §Denominators vary due to missing data. ¶Emotional abuse, harassment, or both.

Table 1: **Baseline characteristics of family doctors and women**

Ethics approval was granted by The University of Melbourne's Human Research Ethics Committee. Safety of women was a foremost concern (appendix): women were contacted at times nominated by them, using safe addresses and phone numbers to minimise the likelihood of their partners becoming aware of the intervention. All women received resource cards, and a distress protocol was followed for women and researchers. The data monitoring committee monitored the trial's integrity and assessed women's wellbeing through annual meetings in which they reviewed outcome and harm data.

Randomisation and masking

A statistician who was otherwise not involved in the study follow-up generated a random allocation sequence in Stata,[24] stratified by location of each doctor's practice (urban *vs* rural), with random permuted block sizes of two and four within each stratum (appendix). Doctors were assigned unique identifier codes so that the statistician was masked to group allocation. The statistician randomly allocated doctors to a study group, with the trial coordinator (LOD) notifying doctors to their allocation. The allocation sequence was fully protected until doctors and women had consented, provided baseline data, and enrolled. Because of the nature of the intervention, neither doctors nor patients could be masked to intervention, but study investigators and researchers following-up patients and entering and analysing data were masked to allocation.

Statistical analysis

Our calculated sample size was 136 women from 34 practices (four women per practitioner; appendix). This calculation was based on a two-sample *t* test, allowing for a design effect of 1·08 due to clustering (intra-cluster correlation of 0·02) and variable cluster size. We increased the number of doctors to 40 (160 women) to allow for loss of clusters. As estimated in the protocol,[8] this was sufficient for at least 80% power (α 5%, two-sided test), to detect clinically important differences on the primary outcomes. We hypothesised a difference between the two arms at 12 months of 0·5 SDs on the WHO Quality of Life-BREF (SD=20), mental health SF-12 (SD=11) and safety behaviours (SD=2·5), and a 30% difference in proportion with safety plans (40% *vs* 10%). We used descriptive statistics to summarise doctors' and women's characteristics and outcomes at baseline, 6 months, and 12 months by study group. We report intracluster correlations for key baseline variables estimated by one-way analysis of variance. Doctors were the main sampling unit, and doctors and women were analysed in the groups to which they were originally assigned. All continuous outcomes followed a broadly normal distribution, except for the number of safety behaviours (0–15; appendix) which had a strong right-skewed distribution, and were therefore dichotomised

(0–5 and 6–15). For continuous outcomes, we used a linear mixed effects model in which study group was fitted as a fixed effect, and data for doctors and women were treated as random effects to account for the correlation of responses of women attending the same practice and correlation of repeated outcome measures (at 6 months and 12 months) for women, respectively. We used marginal logistic regression with generalised estimating equations with information sandwich estimates of SEs, adjusting for correlated responses at the doctor-level for binary outcomes. Multivariable regression analysis adjusted for stratification (urban *vs* rural) and the baseline outcome.[25] We used multiple imputation to account for missing data (appendix). We did analyses of complete cases and multiply imputed data in Stata (version 12).[24] Analyses reported were prespecified,[8] apart from the multiple imputation.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

	Study group				Unadjusted		Adjusted†		Adjusted† with missing imputation	
	Intervention		Comparison		Estimated effect size‡ (95% CI)	p value	Estimated effect size‡ (95% CI)	p value	Estimated effect size‡ (95% CI)	p value
	N	Mean (SD) or n (%)	N	Mean (SD) or n (%)						
WHO Quality of Life-BREF										
Physical										
Baseline	136	59·5 (20·7)	135	58·3 (17·5)						
6 months	94	64·2 (22·4)	99	60·2 (18·0)	5·1 (–0·5 to 10·7)	0·08	5·2 (1·3 to 9·0)	0·008	4·9 (1·1 to 8·6)	0·01
12 months	96	63·5 (22·2)	100	62·2 (18·8)	1·9 (–3·6 to 7·5)	0·50	2·1 (–1·7 to 5·9)	0·28	2·7 (–1·4 to 6·8)	0·20
Psychological										
Baseline	136	50·0 (18·4)	135	48·4 (18·1)						
6 months	94	54·3 (19·9)	99	52·1 (17·6)	3·2 (–2·0 to 8·3)	0·23	2·4 (–1·1 to 6·0)	0·18	2·5 (–1·2 to 6·2)	0·19
12 months	96	55·4 (20·4)	100	53·0 (17·3)	2·2 (–2·9 to 7·4)	0·39	2·2 (–1·3 to 5·7)	0·23	2·3 (–1·5 to 6·1)	0·23
Social										
Baseline	137	47·7 (23·5)	135	47·0 (24·6)						
6 months	94	54·5 (24·9)	99	50·2 (23·4)	4·6 (–2·0 to 11·3)	0·17	4·6 (–1·1 to 10·3)	0·12	4·8 (–1·0 to 10·7)	0·11
12 months	96	54·9 (23·9)	100	52·4 (23·8)	2·0 (–4·6 to 8·6)	0·56	2·2 (–3·5 to 7·8)	0·46	2·1 (–4·3 to 8·5)	0·52
Environmental										
Baseline	136	59·4 (15·4)	135	58·0 (15·8)						
6 months	94	62·5 (16·4)	99	61·9 (16·0)	0·3 (–4·9 to 5·4)	0·93	1·2 (–2·8 to 5·1)	0·57	1·0 (–2·6 to 4·7)	0·57
12 months	96	64·1 (17·0)	100	63·5 (15·5)	0·5 (–4·7 to 5·7)	0·85	1·9 (–2·0 to 5·8)	0·35	1·9 (–1·7 to 5·5)	0·29
SF-12										
Mental Health Status										
Baseline	130	36·6 (11·9)	129	35·9 (11·9)						
6 months	93	38·6 (12·1)	92	37·4 (11·6)	1·3 (–2·2 to 4·7)	0·46	0·9 (–2·3 to 4·1)	0·60	0·8 (–2·3 to 3·9)	0·61
12 months	94	41·0 (13·0)	94	38·4 (12·2)	2·6 (–0·9 to 6·0)	0·15	2·3 (–0·8 to 5·5)	0·15	2·4 (–1·0 to 5·7)	0·17
Other										
More than five safety behaviours§										
Baseline	136	31 (23%)	131	38 (29%)						
6 months	92	6 (7%)	97	10 (10%)	0·6 (0·2 to 1·8)	0·37	0·8 (0·3 to 2·3)	0·63	0·9 (0·3 to 3·0)	0·89
12 months	95	45 (47%)	96	50 (52%)	0·8 (0·5 to 1·5)	0·52	0·8 (0·5 to 1·5)	0·49	1·0 (0·5 to 2·1)	0·92
Ever had a safety plan										
Baseline	137	34 (25%)	133	32 (24%)						
6 months	93	34 (37%)	98	31 (32%)	1·2 (0·7 to 2·2)	0·57	1·1 (0·6 to 2·2)	0·71	1·0 (0·4 to 2·5)	0·91
12 months	95	43 (45%)	97	27 (28%)	2·0 (1·1 to 3·5)	0·03	2·4 (1·2 to 4·9)	0·01	1·7 (0·8 to 4·0)	0·20

Some denominators vary because of missing data. Estimated intra-cluster correlation for all the baseline outcomes were truncated to zero. *Primary outcomes were measured at 12 months. †Adjusted for outcome measures at baseline and practice location. ‡Mean difference for WHO quality of life-Bref and SF-12 and odds ratios for other. §Proportion of women who reported implementing more than five safety behaviours in the past 6 months, on the Safety Promoting Behaviour Checklist.

Table 2: **Primary outcomes***

Results

We randomly allocated 52 doctors (and 272 women) to either intervention or control (figure).[26] Compared with the average for Australian family doctors,[27,28] doctors in this trial were more likely to be women and from rural practices (table 1).[26,29] Baseline characteristics of doctors and women were much the same between the intervention and control groups (table 1), as were the response rates to the 6-month and 12-month follow-up surveys (figure). Scores for both primary and secondary outcomes were also much the same between women in the two groups (tables 1 and 2). Baseline characteristics of women retained and those lost to follow-up at 12 months were similar between study groups (appendix). Of the 137 women invited for counselling, 67 women (49%) attended 160 appointments (median of one visit, range one to six). 29 women (21%) had not attended an appointment at 6 months despite three reminder calls. 41 women refused to attend—nine of these women felt they did not need counselling, nine were busy or not interested, eight had moved locality, seven had counselling elsewhere, five were dissatisfied with their study doctor, and three were unprepared to discuss the reasons for their refusal.

We detected no between-group difference in quality of life, safety plans or behaviours, or mental health SF-12 at 12 months (table 2). Most estimated intervention effects for the complete case and multiple imputation analyses were much the same, except for ever having a safety plan, suggesting that multiple imputation corrects for an upward bias in the odds ratio estimated using complete cases only. In terms of the secondary outcomes (table 3), fewer women in the intervention arm had depressive symptoms at 12 months; more women reported an inquiry from their doctor about safety of women and safety of children at 6 months. We recorded no between-group difference in anxiety symptoms or comfort to discuss fear of partner with the doctor (table 3).

The number of women who had a Composite Abuse Scale of 7 or more decreased in both groups from baseline (101 [75%] of 135 women in the intervention group and 93 [71%] of 132 women in the control group) to month 12 (44 [47%] of 93 women in the intervention group and 40 [42%] of 96 women in the control group). Table 4 shows the assessment of harms and benefits related to women's participation in the trial. Most women agreed that they were glad they participated, and for half of them the quality of their life was somewhat better or better. Several women described negative and positive partner behaviours when their partner became aware they were in the trial, but we detected no between-group difference. More

	Study group					Unadjusted		Adjusted†		Adjusted† with missing imputation	
	Intervention		Comparison		ICC	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value
	n	n (%)*	n	n (%)*							
HADS depression score ≥8‡					0§						
Baseline	136	62 (46%)	134	69 (52%)							
6 months	94	34 (36%)	98	45 (46%)		0·6 (0·3–1·1)	0·09	0·6 (0·3–1·1)	0·08	0·4 (0·1–1·0)	0·05
12 months	96	39 (41%)	99	57 (58%)		0·5 (0·3–0·9)	0·01	0·4 (0·2–0·8)	0·006	0·3 (0·1–0·7)	0·005
HADS anxiety score ≥8‡					0·014						
Baseline	136	98 (72%)	134	94 (70%)							
6 months	94	61 (65%)	98	68 (69%)		0·7 (0·4–1·3)	0·29	0·6 (0·3–1·2)	0·14	0·5 (0·2–1·3)	0·14
12 months	96	61 (64%)	99	66 (67%)		0·9 (0·5–1·6)	0·67	0·8 (0·4–1·6)	0·55	0·4 (0·2–1·2)	0·11
Enquiry from doctor about woman's safety¶					0·02						
Baseline	136	17 (13%)	133	19 (14%)							
6 months	93	30 (32%)	96	12 (13%)		3·3 (1·5–6·9)	0·002	3·5 (1·7–7·5)	0·001	5·1 (1·9–14·0)	0·002
12 months	94	19 (20%)	99	11 (11%)		2·1 (0·9–4·7)	0·09	2·1 (0·9–4·7)	0·08	2·7 (0·9–7·5)	0·07
Enquiry from doctor about child's safety‖					0·05						
Baseline	73	6 (8%)	84	15 (18%)							
6 months	43	16 (37%)	61	11 (18%)		2·8 (1·1–6·9)	0·03	6·0 (1·7–20·5)	0·005	5·5 (1·6–19·0)	0·008
12 months	51	11 (22%)	69	6 (9%)		2·2 (0·8–6·2)	0·14	3·8 (1·1–13·3)	0·04	4·4 (1·0–20·7)	0·06
Comfort to discuss fear**					0·03						
Baseline	136	82 (60%)	133	85 (64%)							
12 months	96	60 (63%)	98	65 (66%)		0·8 (0·4–1·6)	0·59	0·9 (0·5–1·8)	0·79	0·9 (0·5–1·7)	0·75

HADS=hospital anxiety and depression scale. ICC=intra-cluster correlation for baseline outcome. *Some denominators vary because of missing data. †Adjusted for outcome measures at baseline and practice location. ‡HADS score ≥8—outcome timepoint was 12 months. §ICC was truncated at zero. ¶As reported by woman (denominator includes all women who returned the survey, even if they had not visited the trial doctor in the past 6 months; outcome timepoint was 6 months). ‖As reported by woman (denominator includes women with children younger than 18 years, who returned the survey, even if they had not visited the trial doctor in the past 6 months (outcome timepoint was 6 months). **Measured only at baseline and 12 months.

Table 3: **Secondary outcomes**

	Intervention n (%)		Comparison n (%)	
	6 months (n=94)	12 months (n=96)	6 months (n=99)	12 months (n=100)
I am glad to be a participant in the WEAVE project				
Strongly agree	47 (51%)	54 (57%)	37 (38%)	47 (48%)
Agree	30 (33%)	30 (32%)	45 (46%)	37 (37%)
Neither agree nor disagree	12 (13%)	10 (11%)	16 (16%)	13 (13%)
Disagree	1 (1%)	1 (1%)	0 (0%)	1 (1%)
Strongly disagree	2 (2%)	0 (0%)	0 (0%)	1 (1%)
I felt judged negatively by practice staff (eg, nurses, receptionists) for being a participant in this trial				
Strongly agree	0 (0%)	0 (0%)	1 (1%)	1 (1%)
Agree	2 (2%)	0 (0%)	1 (1%)	1 (1%)
Neither agree nor disagree	25 (28%)	23 (25%)	35 (36%)	26 (27%)
Disagree	20 (22%)	29 (31%)	20 (21%)	18 (19%)
Strongly disagree	44 (48%)	42 (45%)	40 (41%)	50 (52%)
As a result of participating in the trial, I see the quality of my own life as...				
Better	21 (23%)	26 (27%)	15 (16%)	22 (23%)
Somewhat better	33 (36%)	31 (33%)	27 (28%)	25 (26%)
About the same as before	37 (40%)	34 (36%)	50 (53%)	47 (50%)
Somewhat worse	1 (1%)	4 (4%)	3 (3%)	1 (1%)
Worse	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Abusive partner's awareness*				
Aware she talked to the trial doctor about relationship issues at 6 months† or was involved in a project about relationship issues at 12 months	16/57 (28%)	23/95 (24%)	5/49 (10%)	12/96 (13%)
Consequences of abusive partner's awareness‡				
Positive partner behaviours per woman/number of women§	0·5/16	0·7/23	0·8/5	0·3/12
Negative partner behaviours per woman/number of women¶	1·6/16	0·3/23	3·0/5	0·2/12

Data are n (%) or n/N (%) unless otherwise stated. Some denominators vary because of missing data. *Items adapted from consequences of screening tool (appendix). †Denominator includes only women who had visited the trial doctor in the past 6 months. ‡Rate of positive and negative partner behavioural consequences per woman; only women who reported partner awareness of trial doctor discussion or trial involvement were asked to complete this item. §For example, improved his behaviour towards her, tried to do something about partner violence. ¶For example, got angry, made her more afraid for herself or her children, restricted her freedom.

Table 4: **Women's assessment of participating in the trial**

detailed analysis of the specific effect of surveys (appendix), shows that even at baseline 40% of women felt the survey had "made them more open to dealing with possible relationship problems" in both groups. Furthermore, 4586 (80%) of 5742 women who returned the screening survey and 229 (84%) of 272 women enrolled into the trial stated that it was acceptable or very acceptable to be asked about fear of their partner in a survey. We detected no between-group difference in terms of the harm-benefit VAS (intervention mean score=79·5 [SD 17·4]; comparison mean 74·6 [19·2]; adjusted difference 5·0 (85% CI –0·2 to 10·2), p=0·06). Perceived support from doctors at 6 months was higher in the intervention group than it was in the control group (intervention mean VAS 50·3 [SD 38·5]; comparison mean 35·4 [34·9]; adjusted difference 16·0 (3·4 to 28·7), p=0·01). We detected no difference in the proportion of women using the trial doctor or other counselling or IPV services between groups (appendix).

Discussion

In our trial, brief counselling from family doctors trained to respond to women identified through IPV screening did not improve women's quality of life, safety planning and behaviour, or global mental health, but it did decrease symptoms of depression compared with women who were not invited for counselling. Trained doctors more often inquired about safety of women and children in the intervention group compared to those in the control group. We detected no differences between the intervention and control groups in women's anxiety symptoms or comfort to discuss fear.

By contrast with a primary care case-finding trial,[30] our intervention did not focus only on referral (panel). Instead, doctors were trained to respond to women's needs in view of the fact that many women are not ready to use counselling or IPV services at the point of identification.[15] Despite women having a range of IPV severities with poor mental health and quality of life at enrolment,[29] use of IPV-related services was low and much the same between groups at baseline and 6 month and 12 month follow-up, and not all women accepted the counselling invitation. Women in our trial who chose not to go to the intervention counselling sessions were not ready or perceived no need for them, were already seeing counsellors, or the trial doctor was not their usual doctor. In line with our findings,

in an antenatal care trial of counselling from social workers for women receiving antenatal care,[31] a quarter of women attended no sessions and half of women received less than the full quota offered.

Strengths of our trial included the randomisation of doctors to minimise the risk of contamination, and the recruitment of doctors and women before allocation to study group to minimise selection bias. We accurately estimated loss of participants to follow-up in this trial (30%),[8] which was similar to or lower than in other trials done in the past decade.[3,23,31] Women lost to follow-up were not more likely to report IPV or depression at baseline, and those who actively withdrew gave similar reasons across study groups. No doctor withdrew from the trial and only 24 women (9%) actively withdrew. We promoted safety using international guidelines[1] and systematically assessed harm. Limitations of previous studies in this subject area have included lack of randomisation or baseline assessment before randomisation, greater loss to follow-up than 30%, lack of assessment of differences between those lost to follow-up, and minimal assessment of harm.[2]

Our trial had several limitations. Recruitment of doctors to this trial was low but similar to levels seen in other similar trials done in Australia, and resulted from using a strategy of extensive mail-out of invitations with little follow-up.[32] Most doctors were women, and although the doctors might have been interested in the problem under investigation, very few had undertaken previous IPV training, and communication skills were similar to other populations of doctors.[33] Most women who responded to screening invitations had more years of education than those that did not respond, were employed, and spoke English,[26] which restricts the generalisabilty of our findings because our study population would not be applicable to, for example, refuge or shelter populations.[7] However, the prevalence of IPV in our screening sample (13%) was similar to that seen in larger surveys done in waiting rooms of primary-care clinics, in which a higher proportion of women responded to the survey (78%).[34] Masking of doctors and women during implementation was not feasible,[3] and, because women's outcomes were self-reported, there could have been some bias in response to survey questions. Another limitation is the potential for a so-called Hawthorne Effect from the baseline surveys, which could have attenuated the intervention effect.[3,35]

Our findings do not lend support to the protocol hypothesis that increased support from doctors for women screening positive for IPV and discussion about safety with doctors would lead to improvement in women's mental health, safety planning and behaviour, and quality of life. For women who are ready to accept help,[15] trained doctors seemed to provide more support and inquired more often about their safety, and they were less likely to report depressive symptoms. We interpreted the 17% between-group difference in reports of depressive symptoms as clinically relevant, and in line with findings from other studies testing interventions for depression.[36] No adverse events were reported and we detected no evidence of a difference in harm or abuse between groups. The harm reported was at a similar level (4%) to the WHO multicountry study,[1] with few women's partners being aware that they were involved in the trial (table 4).

Future research could refine and test interventions that improve the pathway from screening to counselling. We selected to post surveys to participants because evidence suggests that women prefer such distal methods of screening to face-to-face approaches.[2] The WEAVE intervention's reach could be broadened by, for example, doing screening in waiting rooms, using computerised methods of screening, offering counselling to only women who would like help with the issue on that day, and follow-up of women not attending counselling, all of which have been shown to increase uptake of counselling or other interventions.[3,11] Other recommendations for future primary care interventions include the provision of opportunities for multiple points of entry to counselling that do not rely only on universal screening—for example, use of nurses and bicultural health workers to deliver the intervention, increase in the amount of training and inclusion of all primary care staff, and the further tailoring of counselling to women's diverse experiences. Removal of baseline surveys could eliminate the independent effects of research participation (the Hawthorne effect).

***Panel:* Research in context**

Systematic review

We updated previous systematic reviews[2] and compared our results with a 2004 systematic review.[3] We searched Medline, Scopus, Cinahl, PsycINFO, and the Cochrane Library using the search terms "domestic violence", "spouse abuse", "battered women", "screen*" "identif*" "interven*", "counsel*" "advocacy" "health service" "primary care", "general practice", and "family doctor" for randomised clinical trials published in English from Jan 1, 2007, to March 1, 2012. We identified one primary care screening and intervention trial that showed no effect of a nurse-led management protocol compared with the use of a wallet-sized referral card on reducing violence.[6] In antenatal care, a safety-planning and empowerment intervention by nurses in Hong Kong and a psychosocial behavioural intervention for black women by social workers showed a reduction in minor physical violence.[29,39] Screening trials by MacMillan and colleagues[23] and Klevens and colleagues[5] did not provide interventions post-screening and therefore cannot inform research into a response intervention for women identified through screening.[23] We were unable to find a primary care population intervention effectiveness trial with quality of life and health outcomes for women identified through screening.

Interpretation

We know of no other randomised trial to test counselling delivered by family doctors for women identified through primary care-based screening for intimate partner violence. Our findings can help inform research into future steps for intervention research, but do not lend support to the use of a postal screening process. Training of doctors can successfully lead to more safety discussions with women, and greater identification and referral to services.[30] However, greater attention needs to be paid to the pathway from identification of women through to attendance at supportive counselling. Future interventions need refinement to be tailored to the diverse needs of women at different points in the trajectory of abuse and help-seeking.

Recent recommendations from the US Preventive Task Force[4] for post-screening intervention are mainly based on the findings of one good quality antenatal care trial.[31] Rates of screening female patients for IPV in health-care settings are often low, with many barriers to increasing screening.[2] Findings from a review of international studies reported a median screening rate of 19% of patients, based on the 11 studies that examined data on the basis of patients' self-reports.[37] Our findings add to this evidence base in primary care by suggesting that postal screening might not reach a large proportion of women. Furthermore, although doctors can be trained to discuss safety of women and children and to invite women for brief counselling with consequent reductions in depressive symptoms, there is no effect on women's quality of life, safety planning and behaviour, and global mental health at 12 months. In keeping with other trials that assessed only screening,[5,23] this trial does not lend support to screening for IPV in health-care settings. More research is urgently needed into how to increase identification of women who experience IPV and into what interventions would help women achieve safer, healthier lives.[38]

Contributors

All authors contributed to the design of the trial, interpretation of results, and writing and approval of the final paper. Additionally, KH led the design and conduct of the trial, codeveloped and delivered the training of family doctors, and drafted and revised this paper. LOD was trial coordinator, and provided substantial input into implementation and analysis and interpretation of results. PC advised on design of the study, did the randomisation, oversaw and undertook analyses, and contributed to interpretation of results. JV contributed to the implementation of the study and analyses and interpretation of results. JG contributed to the development of the training and surveys.

Conflicts of interest

We declare that we have no conflicts of interest.

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CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	2-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6-8
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	8
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	9-10 (& Supplement)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N/A
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	9
	4b	Settings and locations where the data were collected		9, 11
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	10-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	11-12

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	12, 16-17 (see also six to twelve months outcomes paper, reference 15)
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		10 (see also six to twelve months outcomes paper, reference 15
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	10

	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	9
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		10
	11b	If relevant, description of the similarity of interventions		N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	12-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		N/A
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1 & p.11
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		9, 11

	14b	Why the trial ended or was stopped		N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Supplement (see also (see also six to twelve months outcomes paper, reference 15)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Table 1 (p.16), Table 2 (p.17), Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Table 1 (p.16), Table 2 (p.17)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		N/A See also pp. 9, 15 & Supplement
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		18-20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	19
Interpretation	22	Interpretation consistent		18-21

		with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3

** Note: page numbers optional depending on journal requirements*

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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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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

Two-year follow-up of primary care-based counselling intervention (*weave*) for women experiencing intimate partner violence (IPV). At 12 months, intervention participants experienced lower depression than control participants, with no differences on primary outcomes. We aimed to assess whether differences in depression would be sustained at 24 months and differences in quality in life, general mental and physical health and IPV would emerge.

Methods

Cluster randomised controlled trial involving 52 family doctors and 272 English-speaking, female patients in Victoria, Australia (intervention: doctors n=25, patients n=137; control: doctors n=27, patients n=135). Participants screened positive for fear of partner in past 12 months. Doctors were unit of randomisation; researchers blinded to allocation. Intervention doctors received training to deliver brief, woman-centred counselling. Intervention patients invited to receive this counselling (uptake rate: 49%). Control doctors received standard IPV information; delivered usual care. Data collected through postal survey. Twenty-four-month primary outcomes: WHO Quality of Life-Bref dimensions, SF-12 mental health. Secondary outcomes: SF-12 physical health and caseness for depression and anxiety (Hospital Anxiety Depression Scale), posttraumatic stress disorder (PTSD Check List - Civilian), IPV (Composite Abuse Scale), physical symptoms (≥ 6 in last month). Analyses used mixed effects regression, adjusting for location (rural/urban) and clustering.

Results

Twenty-four-month response rates: intervention 59% (81/137), control 63% (85/135). No differences detected between groups on quality of life (physical: 1.5 [-2.9 to 5.9]; psychological: -0.2 [-4.8 to 4.4]; social: -1.4 [-8.2 to 5.4]; environmental: -0.8 [-4.0 to 2.5]), mental health status (-1.6 [-5.3 to 2.1]) or secondary outcomes. Both groups improved on primary outcomes, IPV and anxiety.

Conclusion

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

Australian New Zealand Clinical Trial Registry ACTRN12608000032358.

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ROLE OF THE FUNDING SOURCE

The National Health and Medical Research Council of Australia had no role in design or conduct of the study; collection, management, analysis, or interpretation of the data; or in the preparation, review, or approval of the manuscript.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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 two-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.

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.[1 2] 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 United Kingdom 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.[1 6 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, the World Health Organization 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 and colleagues 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-minute sessions using motivational interviewing or non-directive problem-solving techniques depending on the patient's readiness to change.[17 16] 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, and many of these women only attended one session.[15 18]

This paper reports results of the 24-month follow-up of the *weave* trial. Firstly, 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, multi-faceted 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.

Secondly, we were interested in whether rates of depression would remain lower for the intervention group than control group at the 24-month timepoint. 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. Thirdly, we were interested in whether levels of IPV, posttraumatic 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- 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 CONSORT 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 to 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 re-confirm 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 Tool[27] 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] Ethics approval

was granted by University of Melbourne's Human Research Ethics Committee (ethics approval number: 0824166).

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 Version 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 six-hour distance learning package, and a one-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 World Health Organization Quality of Life Brief Version; WHOQOL-Bref)[29] and Short Form Health Survey (SF-12) mental health status.[30] Secondary outcomes were IPV caseness (score ≥ 7 on the Composite Abuse Scale, CAS)[31], depression and anxiety caseness (score ≥ 8 on the Hospital Anxiety Depression Scale, HADS)[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 pre-specified effect size of half a standard deviation difference on primary outcomes, with 80% power (α = 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 Version 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 versus urban) and clustering of data by practice and were conducted according to intention-to-treat principles. All available data was included from all participants who had completed baseline, regardless of whether they had

completed all follow-up timepoints, 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 Supplementary Table 1, Appendix).[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 percent (n = 32) of family doctors in the trial were female, compared to 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 percent (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 to 29, 31% (n = 83) aged 30 to 39 and 53% (n = 140) aged 40 to 50. Fifty-three percent (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 timepoint exceeded the sample size needed to detect pre-specified differences on outcome variables. Baseline characteristics were similar for participants who did and did not return the 24-month survey (Supplementary Table 1, Appendix). There were also no statistically significant differences between those who did and did not return the 24-month survey on previous timepoint measures of quality of life, SF-12 mental or physical health status, depression, anxiety, or IPV caseness (see Supplementary Table 2, Appendix; PTSD and physical symptom caseness was not assessed at previous timepoints). 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 Supplementary Tables 3 to 8, Appendix).

[FIGURE 1 HERE]

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 timeframe (12 month data is reported elsewhere; see also means and SDs reported in Supplementary Table 2, Appendix).[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 timeframe.[15] There were also no differences between groups on 24-month outcomes when excluding intervention group participants who had not attended the counselling intervention (Supplementary Tables 9 and 10, Appendix). When excluding these non-attenders the same patterns of improvement from baseline to 24 months on IPV, anxiety and primary outcomes were found (Supplementary Tables 9 and 10, Appendix). Supplementary analyses of fear levels (in the last two weeks and six months ago) also found no significant differences between groups at 24 months, regardless of whether or not analyses excluded intervention non-attenders (Supplementary Tables 11 and 12, Appendix).

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 = .092).

Table 1. Primary outcomes at baseline and 24 months, by study arm[a]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	N	M (SD)	Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
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)	.513	3.1 (0.7 to 5.4)	.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)	.938	5.5 (3.1 to 7.9)	<.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)	.679	6.8 (3.2 to 10.5)	<.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 2.4)	.631	6.3 (4.4 to 8.3)	<.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)	.393	5.0 (2.6 to 7.5)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval; QOL = quality of life; WHOQOL-Bref = World Health Organization Quality of Life Brief Version; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance; estimated ICCs are not shown, as all were <0.0001.

Table 2. Secondary outcomes at baseline and 24 months, by study arm[a]

		Study arm				ICC	Between groups fixed effect		Within groups random effect	
		Intervention		Control						
		n	n (%)	n	n (%)		OR (95% CI)	*p*	OR (95% CI)	*p*
IPV caseness (CAS)[b]	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)	.275	0.1 (0.1 to 0.4)	<.001
Depression caseness (HADS)[c]	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)	.933	0.6 (0.3 to 1.1)	.105
Anxiety caseness (HADS)[c]	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)	.464	0.5 (0.2 to 1.0)	.036
PTSD caseness (PCL-C)[d]	24 months	81	23 (28.4)	84	25 (29.4)	-	0.9 (0.3 to 2.5)	.778	-	
Physical symptom caseness[e]	24 months	78	40 (49.4)	84	43 (50.6)	-	0.9 (0.5 to 1.9)	.877	-	
		n	M (SD)	n	M (SD)		Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
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)	.145	-2.8 (-4.9 to -0.7)	.009

Notes. ICC = intra-cluster correlation; CI = confidence interval; OR = odds ratio; CAS = Composite Abuse Scale; HADS = Hospital Anxiety and Depression Scale; PTSD = posttraumatic stress disorder; PCL-C = PTSD Checklist – Civilian Version; M = mean; SD = standard deviation; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences or odds ratios, with 95% CIs and *p*-values, calculated using mixed effects linear regression or logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance. [b]CAS total score ≥ 7. [c]HADS subscale score ≥ 8. [d]PCL-C score ≥ 50; Not measured at baseline. [e]Experienced at least physical symptoms on checklist, in the past four weeks; Not measured at baseline.

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 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 pre-specified 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 (i.e. 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 (e.g. 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 may need to focus further on addressing these potential barriers.

With regards 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 timepoints, for example in year two. 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 multi-faceted, 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 timepoint, 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 two-year timepoint. 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 regards 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 responses[38] to enable healing and pathways to safety for women exposed to IPV attending primary care settings.[39]

AUTHORS' CONTRIBUTIONS

KH had major responsibility for the design and conduct of the *weave* trial and co-developed and delivered the doctor training. JV was responsible for analyses and contributed to implementation of the study and interpretation of results. Both KH and JV made major contributions to drafting and revising of the manuscript. KH, AT, SB, LG and JG were chief investigators on the trial, which included contributing to design of the trial, interpretation of results and drafting of the manuscript. JG also contributed to co-development of the training and surveys. LOD was trial coordinator, and provided substantial input to implementation, analysis and interpretation of results, and contributed to drafting of the manuscript. KH, JV, AT, SB, LG, JG and LOD all approved the final manuscript.

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DATA AVAILABILITY

De-identified participant data that underlie the results reported in this article may be available to investigators whose proposed use of the data has been approved by chief investigators of this study, in accordance with The University of Melbourne's data policies.

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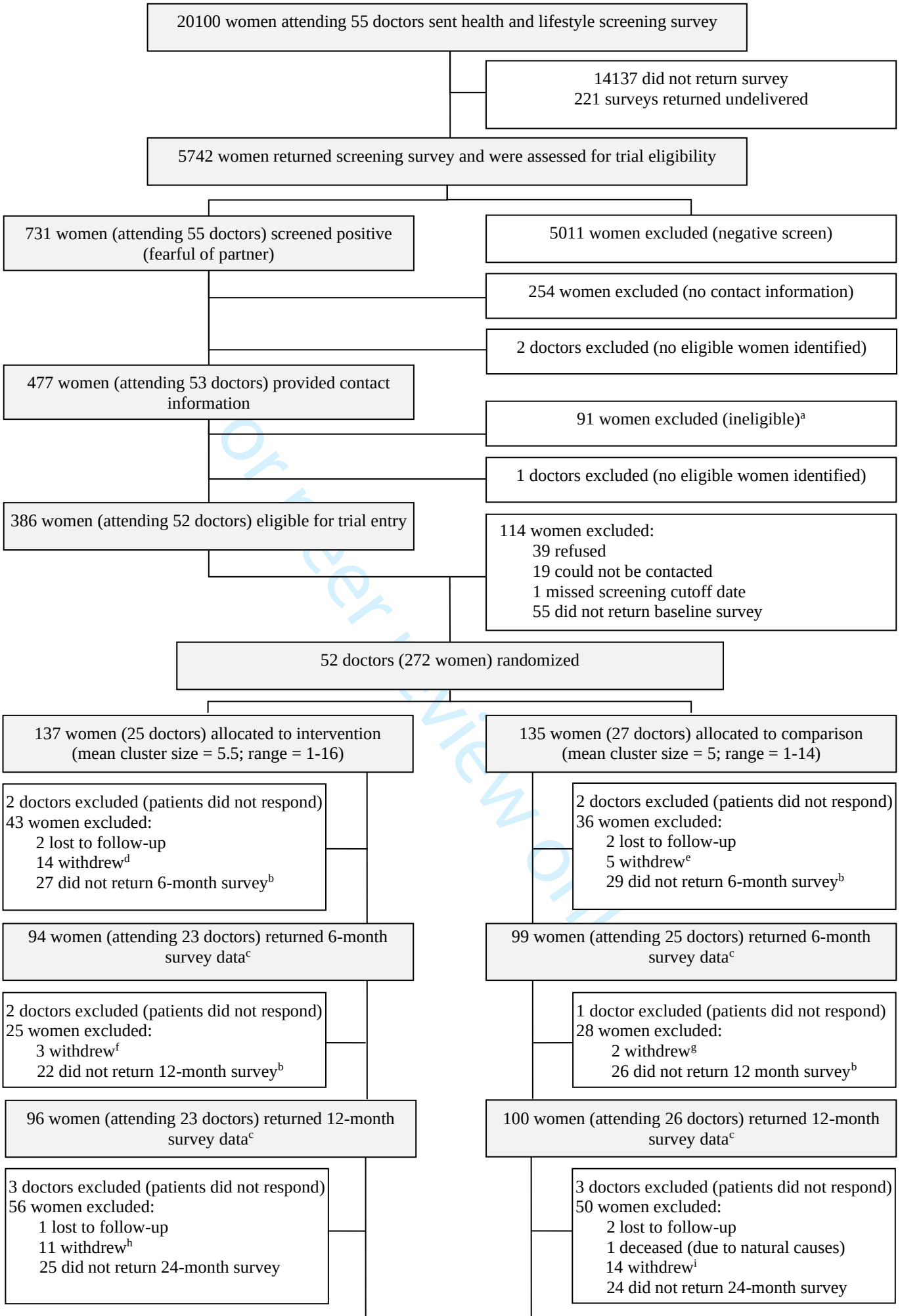
Figure 1. WEAVE Trial CONSORT Flow Diagram

[a]Reasons 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). [b]Excluded from complete case analysis but retained in trial. [c]Analyses and findings are reported in the weave 6- to 12-month outcome paper [*]. [d]Reasons 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); [e]Does not wish to give reason (2), no longer interested/not relevant (1), too busy/survey too long (1), wants to move on (1); [f]Does not wish to give reason (1), no longer interested/not relevant (1), unhappy with weave doctor (1); [g]Does not wish to give reason (1), no longer interested/not relevant (1); [h]Does not wish to give reason (1), no longer interested/not relevant (7), too busy/survey too long (1), wants to move on (2); [i]Does not wish to give reason (2), no longer interested/not relevant (9), too similar to 12-month survey (1), wants to move on (1), moving overseas (1).

WEAVE Trial CONSORT Flow Diagram



[a]Reasons 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). [b]Excluded from complete case analysis but retained in trial. [c]Analyses and findings are reported in the weave 6- to 12-month outcome paper [*]. [d]Reasons 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); [e]Does not wish to give reason (2), no longer interested/not relevant (1), too busy/survey too long (1), wants to move on (1); [f]Does not wish to give reason (1), no longer interested/not relevant (1), unhappy with weave doctor (1); [g]Does not wish to give reason (1), no longer interested/not relevant (1); [h]does not wish to give reason (1), no longer interested/not relevant (7), too busy/survey too long (1), wants to move on (2); [i]does not wish to give reason (2), no longer interested/not relevant (9), too similar to 12-month survey (1), wants to move on (1), moving overseas (1).

Supplementary Appendix

Supplementary Table 1. Baseline characteristics of women who did and did not return 24-month survey, by study arm

	Women who returned 24-month survey (n = 166)				Women who did not return 24-month survey (n = 106)			
	Intervention (n = 81)		Control (n = 85)		Intervention (n = 81)		Control (n = 85)	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age	39.4	(7.3)	38.0	(8.6)	38.6	(7.4)	37.6	(9.0)
	n	(%)	N	(%)	n	(%)	n	(%)
Marital status								
Married	31	(36.9)	20	(25.3)	19	(38.0)	13	(23.6)
Separated / divorced	34	(40.5)	28	(35.4)	14	(28.0)	23	(41.8)
Never married	19	(22.6)	31	(39.2)	17	(34.0)	19	(34.6)
Lives with partner	46	(54.1)	39	(48.2)	32	(64.0)	27	(48.2)
Children < 18yrs at home	57	(67.1)	39	(48.2)	29	(59.2)	34	(60.7)
Year 12 not completed	33	(39.3)	29	(36.3)	30	(60.0)	22	(39.3)
Healthcare Card	50	(58.8)	38	(47.5)	24	(48.0)	32	(57.1)
Unemployed	26	(32.5)	20	(29.9)	15	(34.1)	13	(24.0)
Pension as main source of income	18	(22.2)	23	(29.9)	14	(29.2)	6	(10.9)
Born outside Australia	11	(12.9)	15	(18.5)	8	(16.0)	14	(25.0)
Type of abuse (CAS)								
Severe Combined Abuse	21	(25.3)	24	(30.0)	25	(51.0)	18	(32.7)
Physical and Emotional Abuse	20	(24.1)	22	(27.5)	10	(20.4)	18	(32.7)
Emotional Abuse only	24	(28.9)	24	(30.0)	10	(20.4)	13	(23.6)
Physical Abuse only	3	(3.6)	0	(0.0)	0	(0.0)	2	(3.6)

Supplementary Table 2. Relevant outcomes at previous timepoints for women who did and did not return 24-month survey, by study arm

	Women who returned 24-month survey (n = 166)				Women who did not return 24-month survey (n = 106)				Comparison estimates for those who did versus those who did not return 24-month survey		
	Intervention (n = 81)		Control (n = 85)		Intervention (n = 56)		Control (n = 50)				
	Mean	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**OR**	**(95% CI)**	***p***
Physical QoL											
Baseline	61.4	(15.9)	58.5	(20.9)	53.1	(18.9)	61.0	(20.6)	1.01	(0.99 to 1.02)	.257
6 months	61.8	(16.3)	63.6	(21.7)	55.6	(22.0)	66.2	(24.8)	1.01	(0.99 to 1.02)	.559
12 months	63.0	(18.4)	63.3	(21.3)	59.2	(20.7)	64.0	(25.0)	1.00	(0.99 to 1.02)	.721
Psychological QoL											
Baseline	50.8	(15.7)	48.8	(18.4)	44.4	(21.1)	51.8	(18.4)	1.00	(0.99 to 1.02)	.514
6 months	52.6	(16.9)	53.5	(20.3)	50.6	(19.6)	56.9	(18.9)	1.00	(0.98 to 1.02)	.866
12 months	53.2	(17.1)	55.2	(20.8)	52.0	(18.3)	56.0	(19.8)	1.00	(0.98 to 1.02)	>.999
Social QoL											
Baseline	48.6	(22.7)	47.0	(23.3)	44.3	(27.5)	48.7	(24.0)	1.00	(0.99 to 1.01)	.691
6 months	49.0	(22.4)	54.0	(24.2)	53.5	(26.1)	56.2	(27.6)	0.99	(0.98 to 1.01)	.436
12 months	50.8	(24.1)	55.2	(23.0)	58.3	(22.2)	54.0	(26.7)	0.99	(0.98 to 1.01)	.451
Environmental QoL											
Baseline	60.0	(14.7)	58.6	(15.9)	54.4	(17.0)	60.5	(14.8)	1.01	(0.99 to 1.02)	.360
6 months	61.6	(14.9)	62.0	(16.5)	62.5	(19.1)	64.3	(16.6)	0.99	(0.97 to 1.02)	.599
12 months	63.0	(16.5)	63.9	(17.5)	65.2	(11.2)	64.5	(16.0)	0.99	(0.98 to 1.01)	.577
Mental Health Status											
Baseline	37.3	(11.6)	35.3	(11.9)	33.3	(12.1)	38.7	(11.7)	1.00	(0.98 to 1.02)	.919
6 months	37.1	(11.5)	37.7	(11.9)	38.4	(12.2)	41.5	(12.6)	0.98	(0.95 to 1.01)	.222
12 months	39.1	(11.8)	40.2	(13.4)	36.1	(13.5)	43.1	(12.0)	1.00	(0.97 to 1.03)	.884
Physical Health Status											
Baseline	49.0	(10.5)	49.0	(10.9)	45.0	(11.4)	50.0	(11.4)	1.01	(0.99 to 1.04)	.334
6 months	48.4	(10.6)	47.4	(12.6)	43.4	(12.8)	49.8	(12.1)	1.01	(0.98 to 1.04)	.491
12 months	47.5	(10.4)	47.1	(11.7)	46.0	(13.0)	48.3	(11.5)	1.00	(0.97 to 1.03)	.996
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**OR**	**(95% CI)**	***p***
Depression caseness											
Baseline	37	(44.1)	42	(51.9)	32	(64.0)	20	(36.4)	0.94	(0.57 to 1.53)	.792
6 months	35	(48.0)	26	(36.6)	10	(40.0)	8	(34.8)	1.22	(0.62 to 2.40)	.555
12 months	45	(57.7)	31	(43.7)	12	(57.1)	8	(32.0)	1.35	(0.69 to 2.64)	.374
Anxiety caseness											
Baseline	58	(69.1)	61	(75.3)	36	(72.0)	37	(67.3)	1.13	(0.66 to 1.94)	.647
6 months	50	(68.5)	49	(69.0)	18	(72.0)	12	(52.2)	1.32	(0.67 to 2.62)	.426
12 months	52	(66.7)	47	(66.2)	14	(66.7)	14	(56.0)	1.27	(0.64 to 2.52)	.490
Abuse caseness											
Baseline	53	(63.9)	62	(77.5)	40	(81.6)	39	(70.9)	0.76	(0.43 to 1.33)	.335
6 months	33	(47.8)	34	(47.9)	10	(40.0)	9	(40.9)	1.35	(0.69 to 2.65)	.379
12 months	32	(42.7)	33	(47.8)	8	(38.1)	11	(45.8)	1.13	(0.57 to 2.22)	.732

Supplementary Table 3. Number of participants who sought help or advice or discussed fear of a partner/ex-partner with a professional, by timepoint and treatment arm[a]

Service	Timepoint	Intervention		Control		Total		Between groups fixed effect			Within groups random effect		
		n	(%)	n	(%)	n	(%)	OR	(95% CI)	*p*	OR	(95% CI)	*p*
Sought help or advice for IPV or relationship issues from an IPV, counselling, religious or legal service[b,c]	Baseline	62	(46.3)	58	(43.6)	120	(44.9)						
	6 months	42	(46.7)	44	(45.8)	86	(46.2)	0.9	(0.3 to 2.3)	.836	1.1	(0.6 to 2.0)	.731
	12 months	41	(42.7)	40	(40.8)	81	(41.8)	0.8	(0.3 to 2.3)	.701	0.9	(0.5 to 1.7)	.713
	24 months	26	(32.1)	33	(39.3)	59	(35.8)	0.4	(0.2 to 1.1)	.081	0.8	(0.5 to 1.4)	.489
Discussed feeling afraid with a health professional other than *weave* doctor[d]	Baseline	93	(69.4)	94	(72.9)	187	(71.1)						
	6 months	52	(55.9)	46	(47.9)	98	(51.9)	1.9	(0.8 to 4.7)	.144	0.2	(0.1 to 0.4)	<.001
	12 months	41	(45.1)	45	(45.5)	86	(45.3)	1.1	(0.4 to 3.0)	.831	0.2	(0.1 to 0.3)	<.001
	24 months	36	(45.6)	33	(40.2)	69	(42.9)	2.1	(0.7 to 6.7)	.199	0.1	(0.0 to 0.3)	<.001

Notes. OR = odds ratio; CI = confidence interval; IPV = intimate partner violence. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location. [b]See Supplementary Tables 4 to 6 for further breakdown of types of services used. [c]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and past 6 months for 6-month timepoint. [d]Timeframe is past 12 months for 12-month and 24-month timepoints, past 6 months for 6-month timepoint, and ever (for current fear of partner/ex-partner) for Baseline.

Supplementary Table 4. Number of times sought help or advice regarding intimate partner violence or relationship issues from intimate partner violence services or women's services, by timepoint and treatment arm[a,b]

Service	Timepoint	Number of times	Intervention n	Intervention (%)	Control n	Control (%)	Total n	Total (%)	Between groups fixed effect OR	Between groups fixed effect (95% CI)	*p*	Within groups random effect OR	Within groups random effect (95% CI)	*p*
IPV or women's face-to-face service	Baseline	1 to 4	5	(3.7)	5	(3.8)	10	(3.8)						
		5 or more	2	(1.5)	5	(3.8)	7	(2.6)						
	6 months	1 to 4	4	(4.4)	1	(1.1)	5	(2.7)	3.6	(0.4 to 32.3)	.258	0.3	(0.1 to 1.5)	.148
		5 or more	1	(1.1)	2	(2.1)	3	(1.6)						
	12 months	1 to 4	2	(2.1)	1	(1.0)	3	(1.6)	1.5	(0.1 to 19.4)	.759	0.2	(0.0 to 1.1)	.058
		5 or more	0	(0.0)	1	(1.0)	1	(0.5)						
	24 months	1 to 4	4	(4.9)	2	(2.4)	6	(3.6)	2.1	(0.3 to 15.7)	.466	0.6	(0.1 to 3.5)	.578
		5 or more	1	(1.2)	2	(2.4)	3	(1.8)						
IPV or women's information telephone helpline	Baseline	1 to 4	11	(8.2)	11	(8.3)	22	(8.3)						
		5 or more	2	(1.5)	1	(0.8)	3	(1.1)						
	6 months	1 to 4	4	(4.4)	1	(1.1)	5	(2.7)	6.4	(0.5 to 85.5)	.162	0.1	(0.0 to 0.5)	.013
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	12 months	1 to 4	5	(5.3)	2	(2.0)	7	(3.7)	3.5	(0.4 to 27.4)	.241	0.1	(0.0 to 0.7)	.019
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
	24 months	1 to 4	5	(6.3)	5	(6.0)	10	(6.1)	0.9	(0.1 to 10.7)	.942	0.5	(0.1 to 4.4)	.571
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
IPV or women's emergency helpline	Baseline	1 to 4	9	(6.8)	10	(7.6)	19	(7.2)						
		5 or more	1	(0.8)	1	(0.8)	2	(0.8)						
	6 months	1 to 4	0	(0.0)	3	(3.2)	3	(1.6)	*Too few cells for analysis*			0.3	(0.1 to 1.3)	.119
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
	12 months	1 to 4	4	(4.2)	2	(2.0)	6	(3.1)	2.0	(0.2 to 17.6)	.521	0.2	(0.0 to 1.2)	.081
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
	24 months	1 to 4	0	(0.0)	2	(2.4)	2	(1.2)	0.3	(0.0 to 6.2)	.473	0.2	(0.0 to 3.0)	.269
		5 or more	1	(1.2)	0	(0.0)	1	(0.6)						

Notes. OR = odds ratio; CI = confidence interval; IPV = intimate partner violence. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell. [b]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and past 6 months for 6-month timepoint.

Supplementary Table 5. Number of times sought help or advice regarding intimate partner violence or relationship issues from health, counselling or religious services, by timepoint and treatment arm[a,b]

Service	Timepoint	Number of times	Intervention n	Intervention (%)	Control n	Control (%)	Total n	Total (%)	Between groups fixed effect OR	Between groups fixed effect (95% CI)	*p*	Within groups random effect OR	Within groups random effect (95% CI)	*p*
General counselling face-to-face service	6 months	1 to 4	16	(17.8)	16	(16.8)	32	(17.3)						
		5 or more	9	(10.0)	16	(16.8)	25	(13.5)						
	12 months	1 to 4	9	(9.5)	13	(13.3)	22	(11.4)	1.3	(0.5 to 3.3)	.633	0.5	(0.2 to 1.1)	.091
		5 or more	12	(12.6)	11	(11.2)	23	(11.9)						
	24 months	1 to 4	9	(11.1)	11	(13.3)	20	(12.2)	0.7	(0.2 to 2.6)	.598	0.6	(0.2 to 1.6)	.302
		5 or more	5	(6.2)	11	(13.3)	16	(9.8)						
General counselling telephone helpline	Baseline	1 to 4	17	(12.8)	22	(16.7)	39	(14.7)						
		5 or more	2	(1.5)	4	(3.0)	6	(2.3)						
	6 months	1 to 4	8	(8.9)	9	(9.6)	17	(9.2)	1.5	(0.4 to 6.6)	.570	0.3	(0.1 to 0.7)	.004
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	12 months	1 to 4	7	(7.4)	8	(8.2)	15	(7.8)	1.4	(0.2 to 8.9)	.693	0.2	(0.1 to 0.8)	.027
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	24 months	1 to 4	0	(0.0)	6	(7.1)	6	(3.6)	0.2	(0.0 to 1.0)	.053	0.3	(0.1 to 0.8)	.023
		5 or more	2	(2.5)	1	(1.2)	3	(1.8)						
Religious professional	Baseline	1 to 4	8	(6.0)	10	(7.6)	18	(6.8)						
		5 or more	3	(2.2)	2	(1.5)	5	(1.9)						
	6 months	1 to 4	4	(4.4)	5	(5.4)	9	(4.9)	0.9	(0.1 to 10.1)	.910	0.3	(0.0 to 2.5)	.289
		5 or more	0	(0.0)	1	(1.1)	1	(0.6)						
	12 months	1 to 4	6	(6.3)	8	(8.2)	14	(7.3)	0.5	(0.1 to 4.0)	.492	1.8	(0.4 to 7.8)	.457
		5 or more	1	(1.1)	3	(3.1)	4	(2.1)						
	24 months	1 to 4	5	(6.2)	5	(6.1)	10	(6.1)	0.3	(0.0 to 3.1)	.295	1.7	(0.5 to 6.0)	.426
		5 or more	0	(0.0)	2	(2.4)	2	(1.2)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell. [b]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and in past 6 months for 6-month timepoint.

Supplementary Table 6. Number of times sought help or advice regarding intimate partner violence or relationship issues from police or services, by timepoint and treatment arm[a,b]

Service	Timepoint	Number of times	Intervention		Control		Total		Between groups fixed effect			Within groups random effect		
			n	(%)	n	(%)	n	(%)	OR	(95% CI)	*p*	OR	(95% CI)	*p*
Police	Baseline	1 to 4	30	(22.7)	18	(14.1)	48	(18.5)						
		5 or more	0	(0.0)	5	(3.9)	5	(1.9)						
	6 months	1 to 4	10	(11.1)	10	(10.9)	20	(11.0)	0.8	(0.2 to 3.9)	.775	0.4	(0.1 to 1.4)	.159
		5 or more	1	(1.1)	1	(1.1)	2	(1.1)						
	12 months	1 to 4	9	(9.6)	8	(8.2)	17	(8.9)	0.7	(0.1 to 3.5)	.651	0.3	(0.1 to 1.0)	.043
		5 or more	1	(1.1)	1	(1.0)	2	(1.0)						
	24 months	1 to 4	9	(11.3)	9	(10.7)	18	(11.0)	0.5	(0.1 to 2.6)	.405	0.5	(0.2 to 1.4)	.186
		5 or more	0	(0.0)	1	(1.2)	1	(0.6)						
Other legal services (e.g. lawyer)	Baseline	1 to 4	27	(20.3)	24	(18.3)	51	(19.3)						
		5 or more	7	(5.3)	9	(6.9)	16	(6.1)						
	6 months	1 to 4	11	(12.2)	10	(10.6)	21	(11.4)	1.0	(0.3 to 3.7)	.995	0.4	(0.2 to 0.9)	.031
		5 or more	3	(3.3)	5	(5.3)	8	(4.4)						
	12 months	1 to 4	14	(14.9)	10	(10.2)	24	(12.5)	1.5	(0.3 to 6.7)	.631	0.4	(0.1 to 1.2)	.110
		5 or more	4	(4.3)	4	(4.1)	8	(4.2)						
	24 months	1 to 4	8	(10.0)	12	(14.5)	20	(12.3)	0.5	(0.2 to 1.3)	.144	0.7	(0.3 to 1.6)	.457
		5 or more	4	(5.0)	6	(7.2)	10	(6.1)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell. [b]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and in past 6 months for 6-month timepoint.

Supplementary Table 7. Number of overall visits to non-*weave* doctors and nurses, by timepoint and treatment arm (includes general visits not related to intimate partner violence or relationship issues, as well as visits that were related to partner violence or relationship issues)[a]

Practitioner	Timepoint	Number of visits	Intervention		Control		Total		Between groups fixed effect			Within groups random effect		
			n	(%)	n	(%)	n	(%)	OR	(95% CI)	*p*	OR	(95% CI)	*p*
Family doctor not enrolled in *weave* trial	Baseline	1 to 4	67	(50.8)	63	(49.2)	130	(50.0)						
		5 or more	26	(19.7)	34	(26.6)	60	(23.1)						
	12 months	1 to 4	52	(55.9)	49	(50.5)	101	(53.2)	0.9	(0.4 to 2.3)	.844	1.3	(0.6 to 2.9)	.442
		5 or more	19	(20.4)	28	(28.9)	47	(24.7)						
	24 months	1 to 4	43	(53.8)	42	(52.5)	85	(53.1)	1.5	(0.8 to 2.9)	.217	1.0	(0.6 to 1.6)	.967
		5 or more	19	(23.8)	19	(23.8)	38	(23.8)						
Primary care nurse	Baseline	1 to 4	29	(21.5)	16	(12.3)	45	(17.0)						
		5 or more	4	(3.0)	3	(2.3)	7	(2.6)						
	12 months	1 to 4	13	(14.0)	18	(18.4)	31	(16.2)	0.4	(0.1 to 1.3)	.112	1.7	(0.6 to 4.6)	.278
		5 or more	4	(4.3)	2	(2.0)	6	(3.1)						
	24 months	1 to 4	10	(12.4)	12	(15.4)	22	(13.8)	0.6	(0.2 to 2.0)	.377	1.2	(0.4 to 3.2)	.769
		5 or more	5	(6.2)	1	(1.3)	6	(3.8)						
Hospital doctor	Baseline	1 to 4	44	(32.4)	41	(31.8)	85	(32.1)						
		5 or more	6	(4.4)	6	(4.7)	12	(4.5)						
	12 months	1 to 4	22	(23.2)	20	(20.4)	42	(21.8)	0.9	(0.3 to 2.6)	.903	0.6	(0.3 to 1.1)	.108
		5 or more	4	(4.2)	6	(6.1)	10	(5.2)						
	24 months	1 to 4	18	(22.8)	21	(26.9)	39	(24.8)	0.8	(0.4 to 1.7)	.601	0.8	(0.5 to 1.3)	.407
		5 or more	4	(5.1)	3	(3.9)	7	(4.5)						
Hospital nurse	Baseline	1 to 4	22	(16.2)	20	(15.3)	42	(15.7)						
		5 or more	5	(3.7)	7	(5.3)	12	(4.5)						
	12 months	1 to 4	14	(14.9)	13	(13.3)	27	(14.1)	1.0	(0.4 to 2.6)	.975	0.8	(0.4 to 1.8)	.651
		5 or more	3	(3.2)	5	(5.1)	8	(4.2)						
	24 months	1 to 4	13	(16.1)	14	(17.3)	27	(16.7)	0.8	(0.3 to 2.4)	.734	1.2	(0.5 to 2.6)	.705
		5 or more	3	(3.7)	5	(6.2)	8	(4.9)						
Specialist doctor	Baseline	1 to 4	45	(33.1)	47	(36.4)	92	(34.7)						
		5 or more	14	(10.3)	14	(10.9)	28	(10.6)						
	12 months	1 to 4	31	(32.6)	36	(36.7)	67	(34.7)	0.9	(0.4 to 2.1)	.769	0.9	(0.6 to 1.5)	.798
		5 or more	9	(9.5)	10	(10.2)	19	(9.8)						
	24 months	1 to 4	28	(35.0)	35	(43.2)	63	(39.1)	1.2	(0.5 to 3.1)	.644	0.8	(0.5 to 1.5)	.492
		5 or more	8	(10.0)	3	(3.7)	11	(6.8)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects ordinal logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location.

Supplementary Table 8. Number of visits to domestic violence, mental health, social work, and drug and alcohol practitioners, by timepoint and treatment arm (includes general visits not related to intimate partner violence or relationship issues, as well as visits that were related to partner violence or relationship issues)[a]

Practitioner	Timepoint	Number of visits	Intervention n	(%)	Control n	(%)	Total n	(%)	Between groups fixed effect OR	(95% CI)	p	Within groups random effect OR	(95% CI)	p
Domestic violence worker[b]	Baseline	1 to 4	6	(4.5)	9	(6.9)	15	(5.7)						
		5 or more	3	(2.3)	2	(1.5)	5	(1.9)						
	12 months	1 to 4	5	(5.4)	1	(1.0)	6	(3.2)	2.8	(0.2 to 41.0)	.450	0.2	(0.0 to 2.7)	.250
		5 or more	0	(0.0)	2	(2.0)	2	(1.1)						
	24 months	1 to 4	2	(2.5)	2	(2.5)	4	(2.5)	0.9	(0.1 to 11.0)	.906	0.5	(0.1 to 4.1)	.535
		5 or more	2	(2.5)	2	(2.5)	4	(2.5)						
Social worker	Baseline	1 to 4	9	(6.6)	12	(9.2)	21	(7.9)						
		5 or more	4	(2.9)	5	(3.8)	9	(3.4)						
	12 months	1 to 4	4	(4.3)	3	(3.1)	7	(3.7)	2.6	(0.4 to 18.3)	.325	0.3	(0.1 to 1.4)	.126
		5 or more	3	(3.2)	3	(3.1)	6	(3.1)						
	24 months	1 to 4	7	(8.6)	3	(3.8)	10	(6.2)	4.0	(0.6 to 28.2)	.158	0.4	(0.1 to 1.6)	.182
		5 or more	3	(3.7)	2	(2.5)	5	(3.1)						
Psychologist	Baseline	1 to 4	16	(11.9)	14	(11.0)	30	(11.5)						
		5 or more	29	(21.5)	37	(29.1)	66	(25.2)						
	12 months	1 to 4	14	(14.9)	19	(19.6)	33	(17.3)	1.1	(0.4 to 2.9)	.871	0.6	(0.3 to 1.4)	.278
		5 or more	14	(14.9)	20	(20.6)	34	(17.8)						
	24 months	1 to 4	13	(16.1)	12	(15.2)	25	(15.6)	0.7	(0.2 to 2.3)	.609	0.9	(0.4 to 1.8)	.755
		5 or more	13	(16.1)	21	(26.6)	34	(21.3)						
Psychiatrist	Baseline	1 to 4	9	(6.6)	8	(6.2)	17	(6.4)						
		5 or more	9	(6.6)	13	(10.1)	22	(8.3)						
	12 months	1 to 4	2	(2.2)	3	(3.1)	5	(2.6)	3.4	(0.3 to 36.2)	.305	0.2	(0.0 to 1.1)	.073
		5 or more	8	(8.6)	5	(5.1)	13	(6.8)						
	24 months	1 to 4	4	(4.9)	2	(2.5)	6	(3.7)	1.5	(0.1 to 22.3)	.772	0.2	(0.0 to 1.7)	.156
		5 or more	4	(4.9)	4	(5.0)	8	(5.0)						
Counsellor / family therapist	Baseline	1 to 4	21	(15.8)	19	(14.7)	40	(15.3)						
		5 or more	23	(17.3)	29	(22.5)	52	(19.9)						
	12 months	1 to 4	13	(14.0)	18	(18.2)	31	(16.2)	1.1	(0.4 to 2.8)	.893	0.4	(0.3 to 0.8)	.003
		5 or more	10	(10.8)	8	(8.1)	18	(9.4)						
	24 months	1 to 4	12	(14.8)	14	(17.3)	26	(16.1)	0.3	(0.1 to 1.1)	.074	0.8	(0.5 to 1.5)	.528
		5 or more	4	(4.9)	14	(17.3)	18	(11.1)						
Alcohol or drug worker	Baseline	1 to 4	3	(2.2)	4	(3.1)	7	(2.6)						
		5 or more	1	(0.7)	3	(2.3)	4	(1.5)						
	12 months	1 to 4	3	(3.2)	1	(1.0)	4	(2.1)	*Too few participant per cell for analyses*			*Too few participant per cell for analyses*		
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	24 months	1 to 4	2	(2.5)	0	(0.0)	2	(1.3)						
		5 or more	1	(1.3)	1	(1.3)	2	(1.3)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values; Except where otherwise specified, comparisons were calculated using mixed effects ordinal logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location. [b]Comparisons calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell.

Supplementary Table 9. Primary outcomes at baseline and 24 months, by study arm, when excluding intervention participants who did not attend counselling[a]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	N	M (SD)	Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
Physical QOL (WHOQOL-Bref)	Baseline	66	57.5 (20.6)	135	58.3 (17.5)				
	24 months	43	60.2 (23.3)	85	63.9 (19.1)	-0.1 (-5.4 to 5.2)	.972	3.1 (0.7 to 5.5)	.010
Psychological QOL (WHOQOL-Bref)	Baseline	66	48.7 (18.5)	135	48.4 (18.1)				
	24 months	43	54.0 (20.9)	85	55.6 (17.5)	0.2 (-4.8 to 5.3)	.930	5.5 (3.1 to 7.9)	<.001
Social QOL (WHOQOL-Bref)	Baseline	67	44.2 (22.6)	135	47.0 (24.6)				
	24 months	43	51.9 (23.4)	84	54.3 (23.2)	0.8 (-6.9 to 8.5)	.846	6.8 (3.1 to 10.4)	<.001
Environmental QOL (WHOQOL-Bref)	Baseline	66	57.4 (14.7)	135	58.0 (15.8)				
	24 months	43	62.1 (18.9)	85	65.6 (15.8)	-0.5 (-4.4 to 3.3)	.792	6.3 (4.3 to 8.3)	<.001
Mental health status (SF-12)	Baseline	66	36.4 (11.8)	129	35.9 (11.9)				
	24 months	41	37.9 (13.6)	79	41.4 (11.3)	-3.0 (-6.6 to 0.7)	.113	5.0 (2.6 to 7.4)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval; QOL = quality of life; WHOQOL-Bref = World Health Organization Quality of Life Brief Version; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance; estimated ICCs are not shown, as all were <0.0001.

Supplementary Table 10. Secondary outcomes at baseline and 24 months, by study arm, when excluding intervention participants who did not attend counselling[a]

		Study arm				ICC	Between groups fixed effect		Within groups random effect	
		Intervention		Control						
		n	n (%)	n	n (%)		OR (95% CI)	*p*	OR (95% CI)	*p*
IPV caseness (CAS)[b]	Baseline	66	49 (74.2)	132	93 (70.5)	0.037				
	24 months	43	19 (44.2)	81	34 (42.0)		0.7 (0.2 to 2.5)	.54	0.1 (0.1 to 0.4)	<.001
Depression caseness (HADS)[c]	Baseline	66	36 (54.6)	134	69 (51.5)	<0.001				
	24 months	42	21 (50)	84	35 (41.7)		0.9 (0.3 to 2.6)	.81	0.6 (0.3 to 1.1)	.111
Anxiety caseness (HADS)[c]	Baseline	66	52 (78.8)	134	94 (70.2)	0.014				
	24 months	43	27 (62.8)	84	51 (60.7)		0.4 (0.1 to 1.3)	.12	0.5 (0.2 to 1.0)	.038
PTSD caseness (PCL-C)[d]	24 months	43	13 (30.2)	85	25 (29.4)	-	1.1 (0.5 to 2.7)	.80	-	
Physical symptom caseness[e]	24 months	43	24 (55.8)	85	43 (50.6)	-	1.2 (0.6 to 2.3)	.56	-	
		n	M (SD)	n	M (SD)		Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
Physical health status (SF-12)	Baseline	66	47.7 (10.9)	129	47.6 (10.9)	<0.001				
	24 months	41	46.2 to 11.3	79	46.1 (11.6)		1.8 (-1.7 to 5.3)	.31	-2.8 (-4.9 to -0.7)	.009

Notes. ICC = intra-cluster correlation; CI = confidence interval; OR = odds ratio; CAS = Composite Abuse Scale; HADS = Hospital Anxiety and Depression Scale; PTSD = posttraumatic stress disorder; PCL-C = PTSD Checklist – Civilian Version; M = mean; SD = standard deviation; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences or odds ratios, with 95% CIs and *p*-values, calculated using mixed effects linear regression or logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance. [b]CAS total score ≥ 7. [c]HADS subscale score ≥ 8. [d]PCL-C score ≥ 50; Not measured at baseline. [e]Experienced at least physical symptoms on checklist, in the past four weeks; Not measured at baseline.

Supplementary Table 11. Level of fear of partner/ex-partner at baseline and 24 months, by treatment arm, including all available data from all participants[a,b]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	n	M (SD)	Coeff (95% CI)	*p*	Coeff (95% CI)	*p*
Fear level in the last two weeks	Baseline	135	32.7 (27.0)	131	30.0 (28.0)				
	24 months	81	25.3 (32.5)	84	23.1 (28.2)	-3.0 (-11.0 to 5.1)	.467	-5.5 (-10.9 to -0.2)	.042
Fear level 6 months ago	Baseline	136	47.5 (30.9)	133	49.1 (30.7)				
	24 months	81	33.8 (31.6)	84	28.3 (30.5)	5.8 (-3.2 to 14.8)	.209	-19.4 (-26.1 to -12.6)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval. [a]Fear level was measured on a 100-point visual analogue scale ranging from 0 (not at all afraid) to 100 (very afraid). [b]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location.

Supplementary Table 12. Level of fear of partner/ex-partner at baseline and 24 months, by treatment arm, when excluding intervention participants who did not attend counselling intervention[a,b]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	n	M (SD)	Coeff (95% CI)	*p*	Coeff (95% CI)	*p*
Fear level in the last two weeks	Baseline	65	32.6 (27.7)	131	30.0 (28.0)				
	24 months	43	30.4 (34.5)	84	23.1 (28.2)	1.7 -(7.9 to 11.2)	.733	-5.5 -(10.9 to -0.1)	.045
Fear level 6 months ago	Baseline	66	51.1 (30.0)	133	49.1 (30.7)				
	24 months	43	37.0 (30.9)	84	28.3 (30.5)	5.2 (-5.6 to 16.0)	.345	-19.4 (-26.1 to -12.6)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval. [a]Fear level was measured on a 100-point visual analogue scale ranging from 0 (not at all afraid) to 100 (very afraid). [b]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location.

CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	2-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6-8
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	8
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	9-10 (& Supplement)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N/A
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	9
	4b	Settings and locations where the data were collected		9, 11
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	10-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	11-12

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	12, 16-17 (see also six to twelve months outcomes paper, reference 15)
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		10 (see also six to twelve months outcomes paper, reference 15
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	10

	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	9
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		10
	11b	If relevant, description of the similarity of interventions		N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	12-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		N/A
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1 & p.11
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		9, 11
	14b	Why the trial ended or was stopped		N/A

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Supplement (see also (see also six to twelve months outcomes paper, reference 15)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Table 1 (p.16), Table 2 (p.17), Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Table 1 (p.16), Table 2 (p.17)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		N/A See also pp. 9, 15 & Supplement
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		18-20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant		18-21

		evidence	
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3

** Note: page numbers optional depending on journal requirements*

BMJ Open

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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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 two-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-month primary outcomes: WHO Quality of Life-Bref dimensions, SF-12 mental health. Secondary outcomes: SF-12 physical health and caseness for depression and anxiety

(Hospital Anxiety Depression Scale), posttraumatic stress disorder (PTSD 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 [-2.9 to 5.9]; psychological: -0.2 [-4.8 to 4.4]; social: -1.4 [-8.2 to 5.4]; environmental: -0.8 [-4.0 to 2.5]), mental health status (-1.6 [-5.3 to 2.1]) or secondary outcomes. Both groups improved on primary outcomes, IPV, anxiety.

Conclusions:

Intervention was no more effective than usual care in improving two-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:

Australian New Zealand Clinical Trial Registry ACTRN12608000032358.

FUNDING

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ROLE OF THE FUNDING SOURCE

The National Health and Medical Research Council of Australia had no role in design or conduct of the study; collection, management, analysis, or interpretation of the data; or in the preparation, review, or approval of the manuscript.

COMPETING INTERESTS

The authors declare that they have no competing interests.

DATA AVAILABILITY STATEMENT

De-identified participant data that underlie the results reported in this article may be available to investigators whose proposed use of the data has been approved by chief investigators of this study, in accordance with The University of Melbourne's data policies.

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 two-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.

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.[1 2] 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 United Kingdom 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.[1 6 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, the World Health Organization 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 and colleagues 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-minute sessions using motivational interviewing or non-directive problem-solving techniques depending on the patient's readiness to change.[17 16] 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, and many of these women only attended one session.[15 18]

This paper reports results of the 24-month follow-up of the *weave* trial. Firstly, 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, multi-faceted 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.

Secondly, we were interested in whether rates of depression would remain lower for the intervention group than control group at the 24-month timepoint. 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. Thirdly, we were interested in whether levels of IPV, posttraumatic 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- 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 CONSORT 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 to 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 re-confirm 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 Tool[27] 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] Ethics approval

was granted by University of Melbourne's Human Research Ethics Committee (ethics approval number: 0824166).

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 Version 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 six-hour distance learning package, and a one-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 World Health Organization Quality of Life Brief Version; WHOQOL-Bref)[29] and Short Form Health Survey (SF-12) mental health status.[30] Secondary outcomes were IPV caseness (score ≥ 7 on the Composite Abuse Scale, CAS)[31], depression and anxiety caseness (score ≥ 8 on the Hospital Anxiety Depression Scale, HADS)[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 pre-specified effect size of half a standard deviation difference on primary outcomes, with 80% power (α = 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 Version 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 versus urban) and clustering of data by practice and were conducted according to intention-to-treat principles. All available data was included from all participants who had completed baseline, regardless of whether they had

completed all follow-up timepoints, 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 Supplementary Table 1, Appendix).[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 percent (n = 32) of family doctors in the trial were female, compared to 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 percent (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 to 29, 31% (n = 83) aged 30 to 39 and 53% (n = 140) aged 40 to 50. Fifty-three percent (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 timepoint exceeded the sample size needed to detect pre-specified differences on outcome variables. Baseline characteristics were similar for participants who did and did not return the 24-month survey (Supplementary Table 1, Appendix). There were also no statistically significant differences between those who did and did not return the 24-month survey on previous timepoint measures of quality of life, SF-12 mental or physical health status, depression, anxiety, or IPV caseness (see Supplementary Table 2, Appendix; PTSD and physical symptom caseness was not assessed at previous timepoints). 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 Supplementary Tables 3 to 8, Appendix).

[FIGURE 1 HERE]

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 timeframe (12 month data is reported elsewhere; see also means and SDs reported in Supplementary Table 2, Appendix).[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 timeframe.[15] There were also no differences between groups on 24-month outcomes when excluding intervention group participants who had not attended the counselling intervention (Supplementary Tables 9 and 10, Appendix). When excluding these non-attenders the same patterns of improvement from baseline to 24 months on IPV, anxiety and primary outcomes were found (Supplementary Tables 9 and 10, Appendix). Supplementary analyses of fear levels (in the last two weeks and six months ago) also found no significant differences between groups at 24 months, regardless of whether or not analyses excluded intervention non-attenders (Supplementary Tables 11 and 12, Appendix).

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 = .092).

Table 1. Primary outcomes at baseline and 24 months, by study arm[a]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	N	M (SD)	Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
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 5.5)	.513	3.1 (0.7 to 5.4)	.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)	.938	5.5 (3.1 to 7.9)	<.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)	.679	6.8 (3.2 to 10.5)	<.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)	.631	6.3 (4.4 to 8.3)	<.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)	.393	5.0 (2.6 to 7.5)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval; QOL = quality of life; WHOQOL-Bref = World Health Organization Quality of Life Brief Version; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance; estimated ICCs are not shown, as all were <0.0001.

Table 2. Secondary outcomes at baseline and 24 months, by study arm[a]

		Study arm				ICC	Between groups fixed effect		Within groups random effect	
		Intervention		Control						
		n	n (%)	n	n (%)		OR (95% CI)	*p*	OR (95% CI)	*p*
IPV caseness (CAS)[b]	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)	.275	0.1 (0.1 to 0.4)	<.001
Depression caseness (HADS)[c]	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)	.933	0.6 (0.3 to 1.1)	.105
Anxiety caseness (HADS)[c]	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)	.464	0.5 (0.2 to 1.0)	.036
PTSD caseness (PCL-C)[d]	24 months	81	23 (28.4)	84	25 (29.4)	-	0.9 (0.3 to 2.5)	.778	-	
Physical symptom caseness[e]	24 months	78	40 (49.4)	84	43 (50.6)	-	0.9 (0.5 to 1.9)	.877	-	
		n	M (SD)	n	M (SD)		Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
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)	.145	-2.8 (-4.9 to -0.7)	.009

Notes. ICC = intra-cluster correlation; CI = confidence interval; OR = odds ratio; CAS = Composite Abuse Scale; HADS = Hospital Anxiety and Depression Scale; PTSD = posttraumatic stress disorder; PCL-C = PTSD Checklist – Civilian Version; M = mean; SD = standard deviation; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences or odds ratios, with 95% CIs and *p*-values, calculated using mixed effects linear regression or logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance. [b]CAS total score ≥ 7. [c]HADS subscale score ≥ 8. [d]PCL-C score ≥ 50; Not measured at baseline. [e]Experienced at least physical symptoms on checklist, in the past four weeks; Not measured at baseline.

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 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 pre-specified 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 (i.e. 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 (e.g. 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 may need to focus further on addressing these potential barriers.

With regards 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 timepoints, for example in year two. 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 multi-faceted, 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 timepoint, 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 two-year timepoint. 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 regards 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 responses[38] to enable healing and pathways to safety for women exposed to IPV attending primary care settings.[39]

AUTHORS' CONTRIBUTIONS

KH had major responsibility for the design and conduct of the *weave* trial and co-developed and delivered the doctor training. JV was responsible for analyses and contributed to implementation of the study and interpretation of results. Both KH and JV made major contributions to drafting and revising of the manuscript. KH, AT, SB, LG and JG were chief investigators on the trial, which included contributing to design of the trial, interpretation of results and drafting of the manuscript. JG also contributed to co-development of the training and surveys. LOD was trial coordinator, and provided substantial input to implementation, analysis and interpretation of results, and contributed to drafting of the manuscript. KH, JV, AT, SB, LG, JG and LOD all approved the final manuscript.

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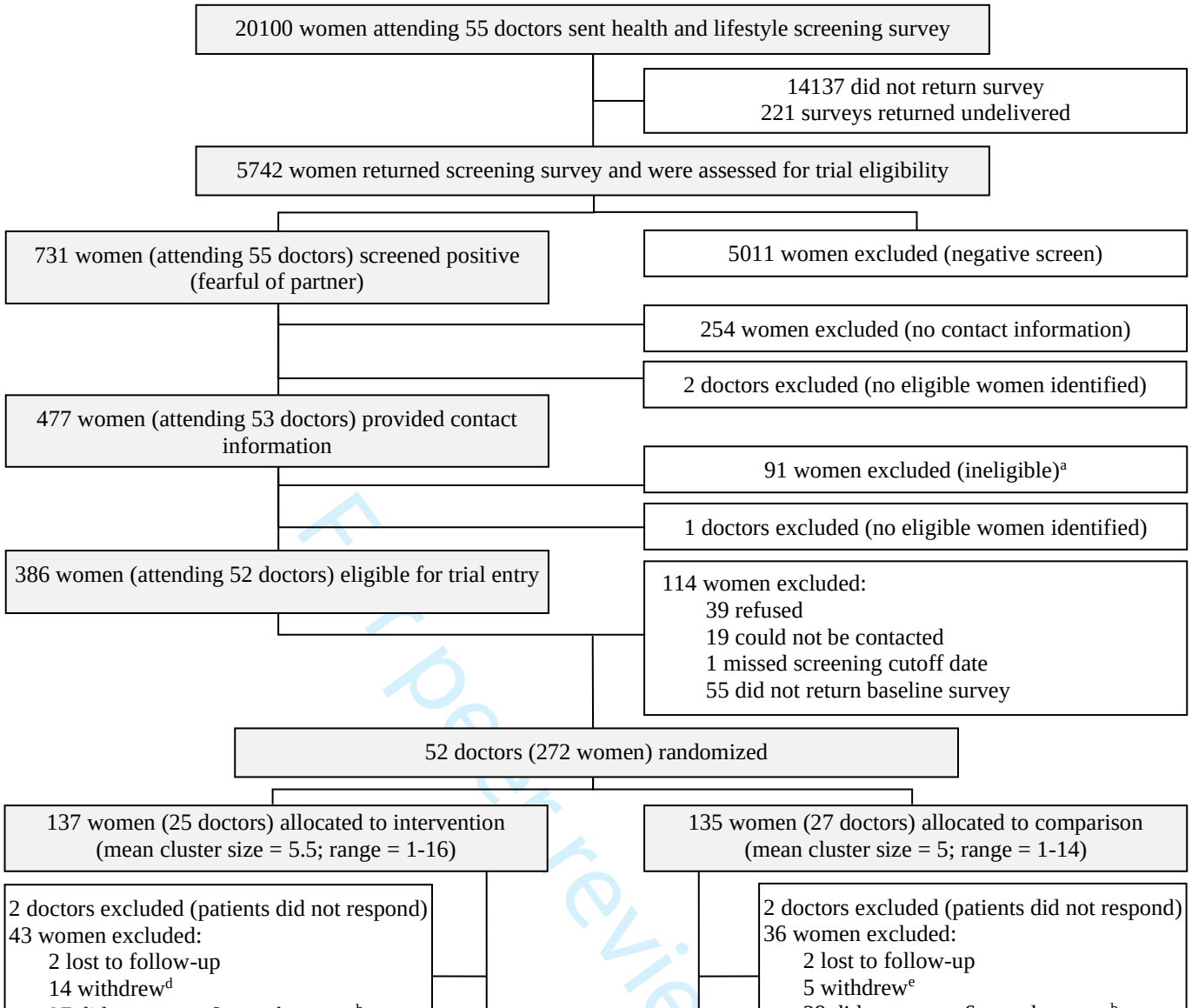
Figure 1. WEAVE Trial CONSORT Flow Diagram

[a]Reasons 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). [b]Excluded from complete case analysis but retained in trial. [c]Analyses and findings are reported in the weave 6- to 12-month outcome paper [*]. [d]Reasons 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); [e]Does not wish to give reason (2), no longer interested/not relevant (1), too busy/survey too long (1), wants to move on (1); [f]Does not wish to give reason (1), no longer interested/not relevant (1), unhappy with weave doctor (1); [g]Does not wish to give reason (1), no longer interested/not relevant (1); [h]Does not wish to give reason (1), no longer interested/not relevant (7), too busy/survey too long (1), wants to move on (2); [i]Does not wish to give reason (2), no longer interested/not relevant (9), too similar to 12-month survey (1), wants to move on (1), moving overseas (1).

WEAVE Trial CONSORT Flow Diagram



[a]Reasons 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). [b]Excluded from complete case analysis but retained in trial. [c]Analyses and findings are reported in the weave 6- to 12-month outcome paper [*]. [d]Reasons 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); [e]Does not wish to give reason (2), no longer interested/not relevant (1), too busy/survey too long (1), wants to move on (1); [f]Does not wish to give reason (1), no longer interested/not relevant (1), unhappy with weave doctor (1); [g]Does not wish to give reason (1), no longer interested/not relevant (1); [h]does not wish to give reason (1), no longer interested/not relevant (7), too busy/survey too long (1), wants to move on (2); [i]does not wish to give reason (2), no longer interested/not relevant (9), too similar to 12-month survey (1), wants to move on (1), moving overseas (1).

Supplementary Appendix

Supplementary Table 1. Baseline characteristics of women who did and did not return 24-month survey, by study arm

	Women who returned 24-month survey (n = 166)				Women who did not return 24-month survey (n = 106)			
	Intervention (n = 81)		Control (n = 85)		Intervention (n = 81)		Control (n = 85)	
	Mean	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**
Age	39.4	(7.3)	38.0	(8.6)	38.6	(7.4)	37.6	(9.0)
	n	**(%)**	**N**	**(%)**	**n**	**(%)**	**n**	**(%)**
Marital status								
Married	31	(36.9)	20	(25.3)	19	(38.0)	13	(23.6)
Separated / divorced	34	(40.5)	28	(35.4)	14	(28.0)	23	(41.8)
Never married	19	(22.6)	31	(39.2)	17	(34.0)	19	(34.6)
Lives with partner	46	(54.1)	39	(48.2)	32	(64.0)	27	(48.2)
Children < 18yrs at home	57	(67.1)	39	(48.2)	29	(59.2)	34	(60.7)
Year 12 not completed	33	(39.3)	29	(36.3)	30	(60.0)	22	(39.3)
Healthcare Card	50	(58.8)	38	(47.5)	24	(48.0)	32	(57.1)
Unemployed	26	(32.5)	20	(29.9)	15	(34.1)	13	(24.0)
Pension as main source of income	18	(22.2)	23	(29.9)	14	(29.2)	6	(10.9)
Born outside Australia	11	(12.9)	15	(18.5)	8	(16.0)	14	(25.0)
Type of abuse (CAS)								
Severe Combined Abuse	21	(25.3)	24	(30.0)	25	(51.0)	18	(32.7)
Physical and Emotional Abuse	20	(24.1)	22	(27.5)	10	(20.4)	18	(32.7)
Emotional Abuse only	24	(28.9)	24	(30.0)	10	(20.4)	13	(23.6)
Physical Abuse only	3	(3.6)	0	(0.0)	0	(0.0)	2	(3.6)

Supplementary Table 2. Relevant outcomes at previous timepoints for women who did and did not return 24-month survey, by study arm

	Women who returned 24-month survey (n = 166)				Women who did not return 24-month survey (n = 106)				Comparison estimates for those who did versus those who did not return 24-month survey		
	Intervention (n = 81)		Control (n = 85)		Intervention (n = 56)		Control (n = 50)				
	Mean	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**Mean**	**(SD)**	**OR**	**(95% CI)**	***p***
Physical QoL											
Baseline	61.4	(15.9)	58.5	(20.9)	53.1	(18.9)	61.0	(20.6)	1.01	(0.99 to 1.02)	.257
6 months	61.8	(16.3)	63.6	(21.7)	55.6	(22.0)	66.2	(24.8)	1.01	(0.99 to 1.02)	.559
12 months	63.0	(18.4)	63.3	(21.3)	59.2	(20.7)	64.0	(25.0)	1.00	(0.99 to 1.02)	.721
Psychological QoL											
Baseline	50.8	(15.7)	48.8	(18.4)	44.4	(21.1)	51.8	(18.4)	1.00	(0.99 to 1.02)	.514
6 months	52.6	(16.9)	53.5	(20.3)	50.6	(19.6)	56.9	(18.9)	1.00	(0.98 to 1.02)	.866
12 months	53.2	(17.1)	55.2	(20.8)	52.0	(18.3)	56.0	(19.8)	1.00	(0.98 to 1.02)	>.999
Social QoL											
Baseline	48.6	(22.7)	47.0	(23.3)	44.3	(27.5)	48.7	(24.0)	1.00	(0.99 to 1.01)	.691
6 months	49.0	(22.4)	54.0	(24.2)	53.5	(26.1)	56.2	(27.6)	0.99	(0.98 to 1.01)	.436
12 months	50.8	(24.1)	55.2	(23.0)	58.3	(22.2)	54.0	(26.7)	0.99	(0.98 to 1.01)	.451
Environmental QoL											
Baseline	60.0	(14.7)	58.6	(15.9)	54.4	(17.0)	60.5	(14.8)	1.01	(0.99 to 1.02)	.360
6 months	61.6	(14.9)	62.0	(16.5)	62.5	(19.1)	64.3	(16.6)	0.99	(0.97 to 1.02)	.599
12 months	63.0	(16.5)	63.9	(17.5)	65.2	(11.2)	64.5	(16.0)	0.99	(0.98 to 1.01)	.577
Mental Health Status											
Baseline	37.3	(11.6)	35.3	(11.9)	33.3	(12.1)	38.7	(11.7)	1.00	(0.98 to 1.02)	.919
6 months	37.1	(11.5)	37.7	(11.9)	38.4	(12.2)	41.5	(12.6)	0.98	(0.95 to 1.01)	.222
12 months	39.1	(11.8)	40.2	(13.4)	36.1	(13.5)	43.1	(12.0)	1.00	(0.97 to 1.03)	.884
Physical Health Status											
Baseline	49.0	(10.5)	49.0	(10.9)	45.0	(11.4)	50.0	(11.4)	1.01	(0.99 to 1.04)	.334
6 months	48.4	(10.6)	47.4	(12.6)	43.4	(12.8)	49.8	(12.1)	1.01	(0.98 to 1.04)	.491
12 months	47.5	(10.4)	47.1	(11.7)	46.0	(13.0)	48.3	(11.5)	1.00	(0.97 to 1.03)	.996
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**OR**	**(95% CI)**	***p***
Depression caseness											
Baseline	37	(44.1)	42	(51.9)	32	(64.0)	20	(36.4)	0.94	(0.57 to 1.53)	.792
6 months	35	(48.0)	26	(36.6)	10	(40.0)	8	(34.8)	1.22	(0.62 to 2.40)	.555
12 months	45	(57.7)	31	(43.7)	12	(57.1)	8	(32.0)	1.35	(0.69 to 2.64)	.374
Anxiety caseness											
Baseline	58	(69.1)	61	(75.3)	36	(72.0)	37	(67.3)	1.13	(0.66 to 1.94)	.647
6 months	50	(68.5)	49	(69.0)	18	(72.0)	12	(52.2)	1.32	(0.67 to 2.62)	.426
12 months	52	(66.7)	47	(66.2)	14	(66.7)	14	(56.0)	1.27	(0.64 to 2.52)	.490
Abuse caseness											
Baseline	53	(63.9)	62	(77.5)	40	(81.6)	39	(70.9)	0.76	(0.43 to 1.33)	.335
6 months	33	(47.8)	34	(47.9)	10	(40.0)	9	(40.9)	1.35	(0.69 to 2.65)	.379
12 months	32	(42.7)	33	(47.8)	8	(38.1)	11	(45.8)	1.13	(0.57 to 2.22)	.732

Supplementary Table 3. Number of participants who sought help or advice or discussed fear of a partner/ex-partner with a professional, by timepoint and treatment arm[a]

Service	Timepoint	Intervention		Control		Total		Between groups fixed effect			Within groups random effect		
		n	(%)	n	(%)	n	(%)	OR	(95% CI)	*p*	OR	(95% CI)	*p*
Sought help or advice for IPV or relationship issues from an IPV, counselling, religious or legal service[b,c]	Baseline	62	(46.3)	58	(43.6)	120	(44.9)						
	6 months	42	(46.7)	44	(45.8)	86	(46.2)	0.9	(0.3 to 2.3)	.836	1.1	(0.6 to 2.0)	.731
	12 months	41	(42.7)	40	(40.8)	81	(41.8)	0.8	(0.3 to 2.3)	.701	0.9	(0.5 to 1.7)	.713
	24 months	26	(32.1)	33	(39.3)	59	(35.8)	0.4	(0.2 to 1.1)	.081	0.8	(0.5 to 1.4)	.489
Discussed feeling afraid with a health professional other than *weave* doctor[d]	Baseline	93	(69.4)	94	(72.9)	187	(71.1)						
	6 months	52	(55.9)	46	(47.9)	98	(51.9)	1.9	(0.8 to 4.7)	.144	0.2	(0.1 to 0.4)	<.001
	12 months	41	(45.1)	45	(45.5)	86	(45.3)	1.1	(0.4 to 3.0)	.831	0.2	(0.1 to 0.3)	<.001
	24 months	36	(45.6)	33	(40.2)	69	(42.9)	2.1	(0.7 to 6.7)	.199	0.1	(0.0 to 0.3)	<.001

Notes. OR = odds ratio; CI = confidence interval; IPV = intimate partner violence. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location. [b]See Supplementary Tables 4 to 6 for further breakdown of types of services used. [c]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and past 6 months for 6-month timepoint. [d]Timeframe is past 12 months for 12-month and 24-month timepoints, past 6 months for 6-month timepoint, and ever (for current fear of partner/ex-partner) for Baseline.

Supplementary Table 4. Number of times sought help or advice regarding intimate partner violence or relationship issues from intimate partner violence services or women's services, by timepoint and treatment arm[a,b]

Service	Timepoint	Number of times	Intervention n	Intervention (%)	Control n	Control (%)	Total n	Total (%)	Between groups fixed effect OR	Between groups fixed effect (95% CI)	*p*	Within groups random effect OR	Within groups random effect (95% CI)	*p*
IPV or women's face-to-face service	Baseline	1 to 4	5	(3.7)	5	(3.8)	10	(3.8)						
		5 or more	2	(1.5)	5	(3.8)	7	(2.6)						
	6 months	1 to 4	4	(4.4)	1	(1.1)	5	(2.7)	3.6	(0.4 to 32.3)	.258	0.3	(0.1 to 1.5)	.148
		5 or more	1	(1.1)	2	(2.1)	3	(1.6)						
	12 months	1 to 4	2	(2.1)	1	(1.0)	3	(1.6)	1.5	(0.1 to 19.4)	.759	0.2	(0.0 to 1.1)	.058
		5 or more	0	(0.0)	1	(1.0)	1	(0.5)						
	24 months	1 to 4	4	(4.9)	2	(2.4)	6	(3.6)	2.1	(0.3 to 15.7)	.466	0.6	(0.1 to 3.5)	.578
		5 or more	1	(1.2)	2	(2.4)	3	(1.8)						
IPV or women's information telephone helpline	Baseline	1 to 4	11	(8.2)	11	(8.3)	22	(8.3)						
		5 or more	2	(1.5)	1	(0.8)	3	(1.1)						
	6 months	1 to 4	4	(4.4)	1	(1.1)	5	(2.7)	6.4	(0.5 to 85.5)	.162	0.1	(0.0 to 0.5)	.013
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	12 months	1 to 4	5	(5.3)	2	(2.0)	7	(3.7)	3.5	(0.4 to 27.4)	.241	0.1	(0.0 to 0.7)	.019
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
	24 months	1 to 4	5	(6.3)	5	(6.0)	10	(6.1)	0.9	(0.1 to 10.7)	.942	0.5	(0.1 to 4.4)	.571
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
IPV or women's emergency helpline	Baseline	1 to 4	9	(6.8)	10	(7.6)	19	(7.2)						
		5 or more	1	(0.8)	1	(0.8)	2	(0.8)						
	6 months	1 to 4	0	(0.0)	3	(3.2)	3	(1.6)	*Too few cells for analysis*			0.3	(0.1 to 1.3)	.119
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
	12 months	1 to 4	4	(4.2)	2	(2.0)	6	(3.1)	2.0	(0.2 to 17.6)	.521	0.2	(0.0 to 1.2)	.081
		5 or more	0	(0.0)	0	(0.0)	0	(0.0)						
	24 months	1 to 4	0	(0.0)	2	(2.4)	2	(1.2)	0.3	(0.0 to 6.2)	.473	0.2	(0.0 to 3.0)	.269
		5 or more	1	(1.2)	0	(0.0)	1	(0.6)						

Notes. OR = odds ratio; CI = confidence interval; IPV = intimate partner violence. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell. [b]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and past 6 months for 6-month timepoint.

Supplementary Table 5. Number of times sought help or advice regarding intimate partner violence or relationship issues from health, counselling or religious services, by timepoint and treatment arm[a,b]

Service	Timepoint	Number of times	Intervention		Control		Total		Between groups fixed effect			Within groups random effect		
			n	(%)	n	(%)	n	(%)	OR	(95% CI)	*p*	OR	(95% CI)	*p*
General counselling face-to-face service	6 months	1 to 4	16	(17.8)	16	(16.8)	32	(17.3)						
		5 or more	9	(10.0)	16	(16.8)	25	(13.5)						
	12 months	1 to 4	9	(9.5)	13	(13.3)	22	(11.4)	1.3	(0.5 to 3.3)	.633	0.5	(0.2 to 1.1)	.091
		5 or more	12	(12.6)	11	(11.2)	23	(11.9)						
	24 months	1 to 4	9	(11.1)	11	(13.3)	20	(12.2)	0.7	(0.2 to 2.6)	.598	0.6	(0.2 to 1.6)	.302
		5 or more	5	(6.2)	11	(13.3)	16	(9.8)						
General counselling telephone helpline	Baseline	1 to 4	17	(12.8)	22	(16.7)	39	(14.7)						
		5 or more	2	(1.5)	4	(3.0)	6	(2.3)						
	6 months	1 to 4	8	(8.9)	9	(9.6)	17	(9.2)	1.5	(0.4 to 6.6)	.570	0.3	(0.1 to 0.7)	.004
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	12 months	1 to 4	7	(7.4)	8	(8.2)	15	(7.8)	1.4	(0.2 to 8.9)	.693	0.2	(0.1 to 0.8)	.027
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	24 months	1 to 4	0	(0.0)	6	(7.1)	6	(3.6)	0.2	(0.0 to 1.0)	.053	0.3	(0.1 to 0.8)	.023
		5 or more	2	(2.5)	1	(1.2)	3	(1.8)						
Religious professional	Baseline	1 to 4	8	(6.0)	10	(7.6)	18	(6.8)						
		5 or more	3	(2.2)	2	(1.5)	5	(1.9)						
	6 months	1 to 4	4	(4.4)	5	(5.4)	9	(4.9)	0.9	(0.1 to 10.1)	.910	0.3	(0.0 to 2.5)	.289
		5 or more	0	(0.0)	1	(1.1)	1	(0.6)						
	12 months	1 to 4	6	(6.3)	8	(8.2)	14	(7.3)	0.5	(0.1 to 4.0)	.492	1.8	(0.4 to 7.8)	.457
		5 or more	1	(1.1)	3	(3.1)	4	(2.1)						
	24 months	1 to 4	5	(6.2)	5	(6.1)	10	(6.1)	0.3	(0.0 to 3.1)	.295	1.7	(0.5 to 6.0)	.426
		5 or more	0	(0.0)	2	(2.4)	2	(1.2)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell. [b]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and in past 6 months for 6-month timepoint.

Supplementary Table 6. Number of times sought help or advice regarding intimate partner violence or relationship issues from police or services, by timepoint and treatment arm[a,b]

Service	Timepoint	Number of times	Intervention n	Intervention (%)	Control n	Control (%)	Total n	Total (%)	Between groups fixed effect OR	Between groups fixed effect (95% CI)	*p*	Within groups random effect OR	Within groups random effect (95% CI)	*p*
Police	Baseline	1 to 4	30	(22.7)	18	(14.1)	48	(18.5)						
		5 or more	0	(0.0)	5	(3.9)	5	(1.9)						
	6 months	1 to 4	10	(11.1)	10	(10.9)	20	(11.0)	0.8	(0.2 to 3.9)	.775	0.4	(0.1 to 1.4)	.159
		5 or more	1	(1.1)	1	(1.1)	2	(1.1)						
	12 months	1 to 4	9	(9.6)	8	(8.2)	17	(8.9)	0.7	(0.1 to 3.5)	.651	0.3	(0.1 to 1.0)	.043
		5 or more	1	(1.1)	1	(1.0)	2	(1.0)						
	24 months	1 to 4	9	(11.3)	9	(10.7)	18	(11.0)	0.5	(0.1 to 2.6)	.405	0.5	(0.2 to 1.4)	.186
		5 or more	0	(0.0)	1	(1.2)	1	(0.6)						
Other legal services (e.g. lawyer)	Baseline	1 to 4	27	(20.3)	24	(18.3)	51	(19.3)						
		5 or more	7	(5.3)	9	(6.9)	16	(6.1)						
	6 months	1 to 4	11	(12.2)	10	(10.6)	21	(11.4)	1.0	(0.3 to 3.7)	.995	0.4	(0.2 to 0.9)	.031
		5 or more	3	(3.3)	5	(5.3)	8	(4.4)						
	12 months	1 to 4	14	(14.9)	10	(10.2)	24	(12.5)	1.5	(0.3 to 6.7)	.631	0.4	(0.1 to 1.2)	.110
		5 or more	4	(4.3)	4	(4.1)	8	(4.2)						
	24 months	1 to 4	8	(10.0)	12	(14.5)	20	(12.3)	0.5	(0.2 to 1.3)	.144	0.7	(0.3 to 1.6)	.457
		5 or more	4	(5.0)	6	(7.2)	10	(6.1)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell. [b]Timeframe is past 12 months for Baseline, 12-month and 24-month timepoints, and in past 6 months for 6-month timepoint.

Supplementary Table 7. Number of overall visits to non-*weave* doctors and nurses, by timepoint and treatment arm (includes general visits not related to intimate partner violence or relationship issues, as well as visits that were related to partner violence or relationship issues)[a]

Practitioner	Timepoint	Number of visits	Intervention		Control		Total		Between groups fixed effect			Within groups random effect		
			n	(%)	n	(%)	n	(%)	OR	(95% CI)	*p*	OR	(95% CI)	*p*
Family doctor not enrolled in *weave* trial	Baseline	1 to 4	67	(50.8)	63	(49.2)	130	(50.0)						
		5 or more	26	(19.7)	34	(26.6)	60	(23.1)						
	12 months	1 to 4	52	(55.9)	49	(50.5)	101	(53.2)	0.9	(0.4 to 2.3)	.844	1.3	(0.6 to 2.9)	.442
		5 or more	19	(20.4)	28	(28.9)	47	(24.7)						
	24 months	1 to 4	43	(53.8)	42	(52.5)	85	(53.1)	1.5	(0.8 to 2.9)	.217	1.0	(0.6 to 1.6)	.967
		5 or more	19	(23.8)	19	(23.8)	38	(23.8)						
Primary care nurse	Baseline	1 to 4	29	(21.5)	16	(12.3)	45	(17.0)						
		5 or more	4	(3.0)	3	(2.3)	7	(2.6)						
	12 months	1 to 4	13	(14.0)	18	(18.4)	31	(16.2)	0.4	(0.1 to 1.3)	.112	1.7	(0.6 to 4.6)	.278
		5 or more	4	(4.3)	2	(2.0)	6	(3.1)						
	24 months	1 to 4	10	(12.4)	12	(15.4)	22	(13.8)	0.6	(0.2 to 2.0)	.377	1.2	(0.4 to 3.2)	.769
		5 or more	5	(6.2)	1	(1.3)	6	(3.8)						
Hospital doctor	Baseline	1 to 4	44	(32.4)	41	(31.8)	85	(32.1)						
		5 or more	6	(4.4)	6	(4.7)	12	(4.5)						
	12 months	1 to 4	22	(23.2)	20	(20.4)	42	(21.8)	0.9	(0.3 to 2.6)	.903	0.6	(0.3 to 1.1)	.108
		5 or more	4	(4.2)	6	(6.1)	10	(5.2)						
	24 months	1 to 4	18	(22.8)	21	(26.9)	39	(24.8)	0.8	(0.4 to 1.7)	.601	0.8	(0.5 to 1.3)	.407
		5 or more	4	(5.1)	3	(3.9)	7	(4.5)						
Hospital nurse	Baseline	1 to 4	22	(16.2)	20	(15.3)	42	(15.7)						
		5 or more	5	(3.7)	7	(5.3)	12	(4.5)						
	12 months	1 to 4	14	(14.9)	13	(13.3)	27	(14.1)	1.0	(0.4 to 2.6)	.975	0.8	(0.4 to 1.8)	.651
		5 or more	3	(3.2)	5	(5.1)	8	(4.2)						
	24 months	1 to 4	13	(16.1)	14	(17.3)	27	(16.7)	0.8	(0.3 to 2.4)	.734	1.2	(0.5 to 2.6)	.705
		5 or more	3	(3.7)	5	(6.2)	8	(4.9)						
Specialist doctor	Baseline	1 to 4	45	(33.1)	47	(36.4)	92	(34.7)						
		5 or more	14	(10.3)	14	(10.9)	28	(10.6)						
	12 months	1 to 4	31	(32.6)	36	(36.7)	67	(34.7)	0.9	(0.4 to 2.1)	.769	0.9	(0.6 to 1.5)	.798
		5 or more	9	(9.5)	10	(10.2)	19	(9.8)						
	24 months	1 to 4	28	(35.0)	35	(43.2)	63	(39.1)	1.2	(0.5 to 3.1)	.644	0.8	(0.5 to 1.5)	.492
		5 or more	8	(10.0)	3	(3.7)	11	(6.8)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values, calculated using mixed effects ordinal logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location.

Supplementary Table 8. Number of visits to domestic violence, mental health, social work, and drug and alcohol practitioners, by timepoint and treatment arm (includes general visits not related to intimate partner violence or relationship issues, as well as visits that were related to partner violence or relationship issues)[a]

Practitioner	Timepoint	Number of visits	Intervention n	(%)	Control n	(%)	Total n	(%)	Between groups fixed effect OR	(95% CI)	p	Within groups random effect OR	(95% CI)	p
Domestic violence worker[b]	Baseline	1 to 4	6	(4.5)	9	(6.9)	15	(5.7)						
		5 or more	3	(2.3)	2	(1.5)	5	(1.9)						
	12 months	1 to 4	5	(5.4)	1	(1.0)	6	(3.2)	2.8	(0.2 to 41.0)	.450	0.2	(0.0 to 2.7)	.250
		5 or more	0	(0.0)	2	(2.0)	2	(1.1)						
	24 months	1 to 4	2	(2.5)	2	(2.5)	4	(2.5)	0.9	(0.1 to 11.0)	.906	0.5	(0.1 to 4.1)	.535
		5 or more	2	(2.5)	2	(2.5)	4	(2.5)						
Social worker	Baseline	1 to 4	9	(6.6)	12	(9.2)	21	(7.9)						
		5 or more	4	(2.9)	5	(3.8)	9	(3.4)						
	12 months	1 to 4	4	(4.3)	3	(3.1)	7	(3.7)	2.6	(0.4 to 18.3)	.325	0.3	(0.1 to 1.4)	.126
		5 or more	3	(3.2)	3	(3.1)	6	(3.1)						
	24 months	1 to 4	7	(8.6)	3	(3.8)	10	(6.2)	4.0	(0.6 to 28.2)	.158	0.4	(0.1 to 1.6)	.182
		5 or more	3	(3.7)	2	(2.5)	5	(3.1)						
Psychologist	Baseline	1 to 4	16	(11.9)	14	(11.0)	30	(11.5)						
		5 or more	29	(21.5)	37	(29.1)	66	(25.2)						
	12 months	1 to 4	14	(14.9)	19	(19.6)	33	(17.3)	1.1	(0.4 to 2.9)	.871	0.6	(0.3 to 1.4)	.278
		5 or more	14	(14.9)	20	(20.6)	34	(17.8)						
	24 months	1 to 4	13	(16.1)	12	(15.2)	25	(15.6)	0.7	(0.2 to 2.3)	.609	0.9	(0.4 to 1.8)	.755
		5 or more	13	(16.1)	21	(26.6)	34	(21.3)						
Psychiatrist	Baseline	1 to 4	9	(6.6)	8	(6.2)	17	(6.4)						
		5 or more	9	(6.6)	13	(10.1)	22	(8.3)						
	12 months	1 to 4	2	(2.2)	3	(3.1)	5	(2.6)	3.4	(0.3 to 36.2)	.305	0.2	(0.0 to 1.1)	.073
		5 or more	8	(8.6)	5	(5.1)	13	(6.8)						
	24 months	1 to 4	4	(4.9)	2	(2.5)	6	(3.7)	1.5	(0.1 to 22.3)	.772	0.2	(0.0 to 1.7)	.156
		5 or more	4	(4.9)	4	(5.0)	8	(5.0)						
Counsellor / family therapist	Baseline	1 to 4	21	(15.8)	19	(14.7)	40	(15.3)						
		5 or more	23	(17.3)	29	(22.5)	52	(19.9)						
	12 months	1 to 4	13	(14.0)	18	(18.2)	31	(16.2)	1.1	(0.4 to 2.8)	.893	0.4	(0.3 to 0.8)	.003
		5 or more	10	(10.8)	8	(8.1)	18	(9.4)						
	24 months	1 to 4	12	(14.8)	14	(17.3)	26	(16.1)	0.3	(0.1 to 1.1)	.074	0.8	(0.5 to 1.5)	.528
		5 or more	4	(4.9)	14	(17.3)	18	(11.1)						
Alcohol or drug worker	Baseline	1 to 4	3	(2.2)	4	(3.1)	7	(2.6)						
		5 or more	1	(0.7)	3	(2.3)	4	(1.5)						
	12 months	1 to 4	3	(3.2)	1	(1.0)	4	(2.1)	*Too few participant per cell for analyses*			*Too few participant per cell for analyses*		
		5 or more	1	(1.1)	0	(0.0)	1	(0.5)						
	24 months	1 to 4	2	(2.5)	0	(0.0)	2	(1.3)						
		5 or more	1	(1.3)	1	(1.3)	2	(1.3)						

Notes. OR = odds ratio; CI = confidence interval. [a]Comparisons are presented as odds ratios, with 95% CIs and *p*-values; Except where otherwise specified, comparisons were calculated using mixed effects ordinal logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location. [b]Comparisons calculated using mixed effects binary logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Number of visits were collapsed into binary visit/no-visit variables for these analyses, due to the small number of participants in each cell.

Supplementary Table 9. Primary outcomes at baseline and 24 months, by study arm, when excluding intervention participants who did not attend counselling[a]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	N	M (SD)	Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
Physical QOL (WHOQOL-Bref)	Baseline	66	57.5 (20.6)	135	58.3 (17.5)				
	24 months	43	60.2 (23.3)	85	63.9 (19.1)	-0.1 (-5.4 to 5.2)	.972	3.1 (0.7 to 5.5)	.010
Psychological QOL (WHOQOL-Bref)	Baseline	66	48.7 (18.5)	135	48.4 (18.1)				
	24 months	43	54.0 (20.9)	85	55.6 (17.5)	0.2 (-4.8 to 5.3)	.930	5.5 (3.1 to 7.9)	<.001
Social QOL (WHOQOL-Bref)	Baseline	67	44.2 (22.6)	135	47.0 (24.6)				
	24 months	43	51.9 (23.4)	84	54.3 (23.2)	0.8 (-6.9 to 8.5)	.846	6.8 (3.1 to 10.4)	<.001
Environmental QOL (WHOQOL-Bref)	Baseline	66	57.4 (14.7)	135	58.0 (15.8)				
	24 months	43	62.1 (18.9)	85	65.6 (15.8)	-0.5 (-4.4 to 3.3)	.792	6.3 (4.3 to 8.3)	<.001
Mental health status (SF-12)	Baseline	66	36.4 (11.8)	129	35.9 (11.9)				
	24 months	41	37.9 (13.6)	79	41.4 (11.3)	-3.0 (-6.6 to 0.7)	.113	5.0 (2.6 to 7.4)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval; QOL = quality of life; WHOQOL-Bref = World Health Organization Quality of Life Brief Version; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance; estimated ICCs are not shown, as all were <0.0001.

Supplementary Table 10. Secondary outcomes at baseline and 24 months, by study arm, when excluding intervention participants who did not attend counselling[a]

		Study arm				ICC	Between groups fixed effect		Within groups random effect	
		Intervention		Control						
		n	n (%)	n	n (%)		OR (95% CI)	*p*	OR (95% CI)	*p*
IPV caseness (CAS)[b]	Baseline	66	49 (74.2)	132	93 (70.5)	0.037				
	24 months	43	19 (44.2)	81	34 (42.0)		0.7 (0.2 to 2.5)	.54	0.1 (0.1 to 0.4)	<.001
Depression caseness (HADS)[c]	Baseline	66	36 (54.6)	134	69 (51.5)	<0.001				
	24 months	42	21 (50)	84	35 (41.7)		0.9 (0.3 to 2.6)	.81	0.6 (0.3 to 1.1)	.111
Anxiety caseness (HADS)[c]	Baseline	66	52 (78.8)	134	94 (70.2)	0.014				
	24 months	43	27 (62.8)	84	51 (60.7)		0.4 (0.1 to 1.3)	.12	0.5 (0.2 to 1.0)	.038
PTSD caseness (PCL-C)[d]	24 months	43	13 (30.2)	85	25 (29.4)	-	1.1 (0.5 to 2.7)	.80	-	
Physical symptom caseness[e]	24 months	43	24 (55.8)	85	43 (50.6)	-	1.2 (0.6 to 2.3)	.56	-	
		n	M (SD)	n	M (SD)		Mean difference (95% CI)	*p*	Mean change (95% CI)	*p*
Physical health status (SF-12)	Baseline	66	47.7 (10.9)	129	47.6 (10.9)	<0.001				
	24 months	41	46.2 to 11.3	79	46.1 (11.6)		1.8 (-1.7 to 5.3)	.31	-2.8 (-4.9 to -0.7)	.009

Notes. ICC = intra-cluster correlation; CI = confidence interval; OR = odds ratio; CAS = Composite Abuse Scale; HADS = Hospital Anxiety and Depression Scale; PTSD = posttraumatic stress disorder; PCL-C = PTSD Checklist – Civilian Version; M = mean; SD = standard deviation; SF-12 = 12-item Short Form Health Survey. [a]Results are presented as mean differences or odds ratios, with 95% CIs and *p*-values, calculated using mixed effects linear regression or logistic regression with robust standard errors, allowing for clustering effect and rural vs urban practice location; Intra-cluster correlations (ICCs) for outcomes at baseline were estimated using one-way analysis of variance. [b]CAS total score ≥ 7. [c]HADS subscale score ≥ 8. [d]PCL-C score ≥ 50; Not measured at baseline. [e]Experienced at least physical symptoms on checklist, in the past four weeks; Not measured at baseline.

Supplementary Table 11. Level of fear of partner/ex-partner at baseline and 24 months, by treatment arm, including all available data from all participants[a,b]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	n	M (SD)	Coeff (95% CI)	*p*	Coeff (95% CI)	*p*
Fear level in the last two weeks	Baseline	135	32.7 (27.0)	131	30.0 (28.0)				
	24 months	81	25.3 (32.5)	84	23.1 (28.2)	-3.0 (-11.0 to 5.1)	.467	-5.5 (-10.9 to -0.2)	.042
Fear level 6 months ago	Baseline	136	47.5 (30.9)	133	49.1 (30.7)				
	24 months	81	33.8 (31.6)	84	28.3 (30.5)	5.8 (-3.2 to 14.8)	.209	-19.4 (-26.1 to -12.6)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval. [a]Fear level was measured on a 100-point visual analogue scale ranging from 0 (not at all afraid) to 100 (very afraid). [b]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location.

Supplementary Table 12. Level of fear of partner/ex-partner at baseline and 24 months, by treatment arm, when excluding intervention participants who did not attend counselling intervention[a,b]

		Study arm				Between groups fixed effect		Within groups random effect	
		Intervention		Control					
		n	M (SD)	n	M (SD)	Coeff (95% CI)	*p*	Coeff (95% CI)	*p*
Fear level in the last two weeks	Baseline	65	32.6 (27.7)	131	30.0 (28.0)				
	24 months	43	30.4 (34.5)	84	23.1 (28.2)	1.7 -(7.9 to 11.2)	.733	-5.5 -(10.9 to -0.1)	.045
Fear level 6 months ago	Baseline	66	51.1 (30.0)	133	49.1 (30.7)				
	24 months	43	37.0 (30.9)	84	28.3 (30.5)	5.2 (-5.6 to 16.0)	.345	-19.4 (-26.1 to -12.6)	<.001

Notes. M = mean; SD = standard deviation; CI = confidence interval. [a]Fear level was measured on a 100-point visual analogue scale ranging from 0 (not at all afraid) to 100 (very afraid). [b]Results are presented as mean differences, with 95% CIs and *p*-values, calculated using mixed effects linear regression with robust standard errors, allowing for clustering effect and rural vs urban practice location.

CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	2-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6-8
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	8
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	9-10 (& Supplement)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N/A
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	9
	4b	Settings and locations where the data were collected		9, 11
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	10-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	11-12

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	12, 16-17 (see also six to twelve months outcomes paper, reference 15)
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		10 (see also six to twelve months outcomes paper, reference 15
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	10

	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	9
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		10
	11b	If relevant, description of the similarity of interventions		N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	12-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		N/A
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1 & p.11
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		9, 11
	14b	Why the trial ended or was stopped		N/A

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Supplement (see also (see also six to twelve months outcomes paper, reference 15)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Table 1 (p.16), Table 2 (p.17), Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Table 1 (p.16), Table 2 (p.17)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		N/A See also pp. 9, 15 & Supplement
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		18-20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant		18-21

		evidence	
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	9
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3

** Note: page numbers optional depending on journal requirements*