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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See Comment page 190

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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

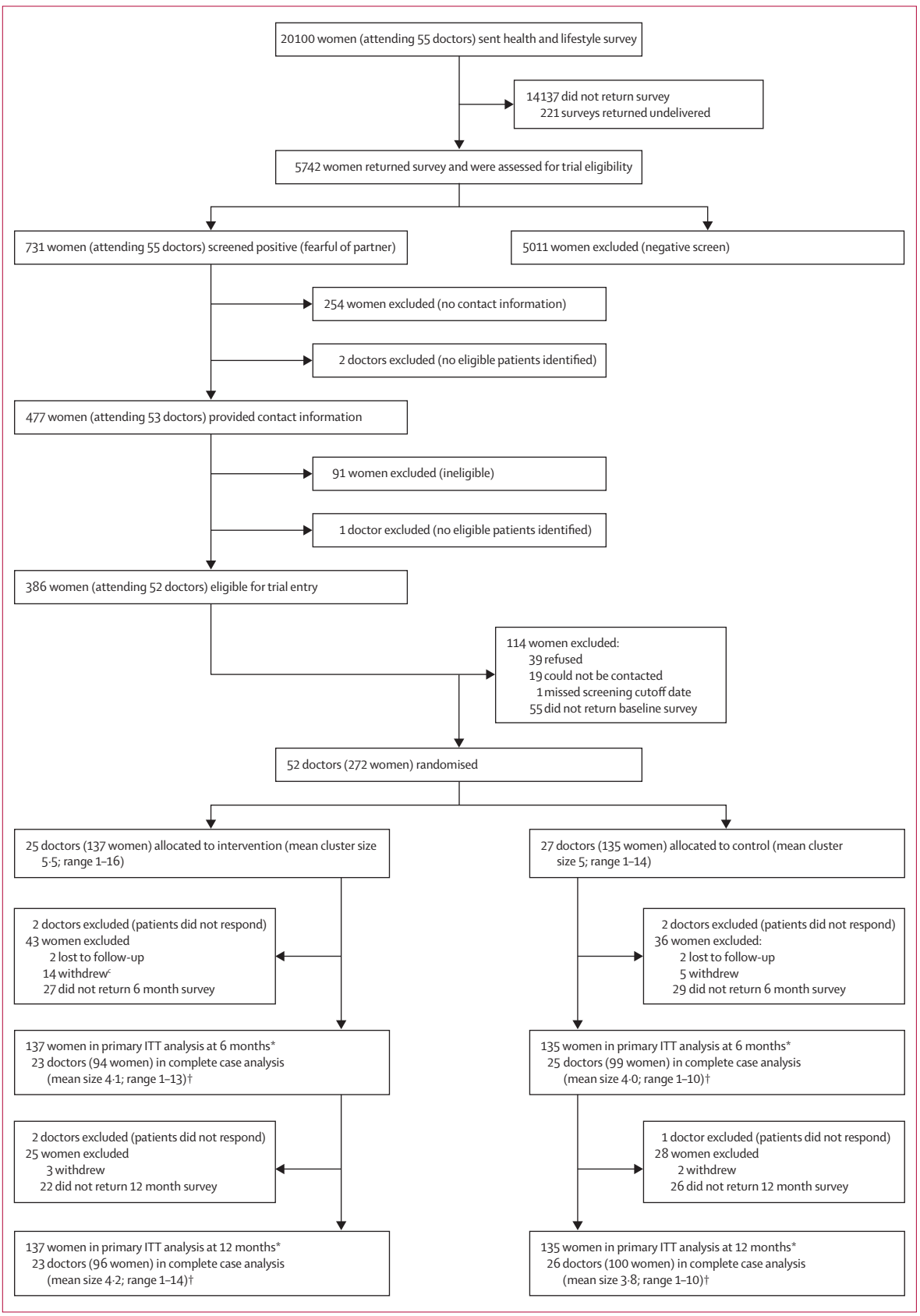

Figure: **Trial profile**
ITT=intention to treat. *Primary analysis imputed missing cases. †Analysis includes women who returned surveys only.

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 pre-specified,[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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