Identification and Referral to Improve Safety (IRIS) of women experiencing domestic violence with a primary care training and support programme: a cluster randomised controlled trial

Gene Feder, Roxane Agnew Davies, Kathleen Baird, Danielle Dunne, Sandra Eldridge, Chris Griffiths, Alison Gregory, Annie Howell, Medina Johnson, Jean Ramsay, Clare Rutterford, Debbie Sharp

Summary

Background Most clinicians have no training about domestic violence, fail to identify patients experiencing abuse, and are uncertain about management after disclosure. We tested the effectiveness of a programme of training and support in primary health-care practices to increase identification of women experiencing domestic violence and their referral to specialist advocacy services.

Methods In this cluster randomised controlled trial, we selected general practices in two urban primary care trusts, Hackney (London) and Bristol, UK. Practices in which investigators from this trial were employed or those who did not use electronic records were excluded. Practices were stratified by proportion of female doctors, postgraduate training status, number of patients registered, and percentage of practice population on low incomes. Within every primary care trust area, we randomised practices with a computer-minimisation programme with a random component to intervention or control groups. The intervention programme included practice-based training sessions, a prompt within the medical record to ask about abuse, and a referral pathway to a named domestic violence advocate, who also delivered the training and further consultancy. The primary outcome was recorded referral of patients to domestic violence advocacy services. The prespecified secondary outcome was recorded identification of domestic violence in the electronic medical records of the general practice. Poisson regression analyses accounting for clustering were done for all practices receiving the intervention. Practice staff and research associates were not masked and patients were not aware they were part of a study. This study is registered at Current Controlled Trials, ISRCTN74012786.

Findings We randomised 51 (61%) of 84 eligible general practices in Hackney and Bristol. Of these, 24 received a training and support programme, 24 did not receive the programme, and three dropped out before the trial started. 1 year after the second training session, the 24 intervention practices recorded 223 referrals of patients to advocacy and 24 control practices recorded 12 referrals (adjusted intervention rate ratio 22·1 [95% CI 11·5–42·4]). No adverse events were recorded.

Interpretation A training and support programme targeted at primary care clinicians and administrative staff improved referral to specialist domestic violence agencies and recorded identification of women experiencing domestic violence. Our findings reduce the uncertainty about the benefit of training and support interventions in primary care settings for domestic violence and show that screening of women patients for domestic violence is not a necessary condition for improved identification and referral to advocacy services.

Funding Health Foundation.

Introduction

Domestic violence damages health.\(^7\) Survivors have chronic health problems including: gynaecological disorders,\(^8\) chronic pain,\(^9\) neurological symptoms,\(^8\) gastrointestinal disorders,\(^8\) and self-reported heart disease.\(^10\) The most prevalent effect is on mental health, including persistent post-traumatic stress disorder, depression, anxiety, suicidal ideation, and substance misuse.\(^11-13\) Health-care services, particularly primary care, can be a survivor’s first or only point of contact with professionals\(^14\) and abused women identify doctors as the professionals from whom they would most like to seek support.\(^14\) The magnitude of the health consequences of domestic violence contrasts...
with its virtual invisibility within primary health care; in one questionnaire study based in general practice only 15% of women with a history of domestic violence had any reference to violence in their medical record. If women disclose domestic violence to a clinician, there is evidence of an inappropriate, poor quality response. Doctors and nurses are largely unaware of appropriate interventions and have seldom received effective or, in the UK, any training about domestic violence.

Findings from a systematic review of 15 controlled studies showed that training and organisational change within health-care systems can increase the identification of women experiencing domestic violence by health-care professionals, but revealed uncertainty about the effect of these interventions on referral to specialist services for domestic violence or other outcome measures beyond identification. In an update to that review up until December 2009, we found four more randomised controlled trials of health-care system interventions of training and screening in health-care settings, with equivocal evidence of improved referrals to specialist domestic violence services and mixed evidence of benefit to women screening positive for intimate partner violence. Overall, the effectiveness of domestic violence training models for primary care clinicians, particularly outside north America, remains uncertain.

Our aim in this trial was to test the effectiveness of a programme of training and support to improve the response of primary health-care practices to domestic violence. The programme focused on the identification of women experiencing domestic violence, an appropriate initial response by clinicians, and referral to a specialist advocacy service, if that was what the woman wanted. Domestic violence advocacy includes provision of legal, housing, financial and safety planning advice, and facilitation of access to community resources, such as refuges or shelters, emergency housing, and psychological support. Advocacy for women with recent experience of domestic violence reduces risk of further physical violence, improves quality of life, and can improve mental health outcomes.

Methods
Study design and participants
The protocol for this study is available online.

General practices in two urban primary care trusts (administrative bodies contracting all NHS general practice services in geographically specified areas), one in the south west of England (Bristol) and the other in east London (Hackney), UK, were eligible for participation. Exclusion criteria were investigators of this study working in the practices or the practices not using electronic records. The Identification and Referral to Improve Safety (IRIS) programme had ethics approval from the South East Research Ethics Committee (REC Reference: 07/MRE01/65). No consent was required for outcome data extraction from medical records.

Randomisation and masking
To ensure inclusion of practices with a range of characteristics, we stratified them by four characteristics (proportion of whole time equivalent female doctors, general practice postgraduate training status, number of patients registered with the practice, and percentage of the practice population on low incomes defined by the low income scheme index), then ordered them randomly within strata and invited them to participate in the trial sequentially within each strata by email or letter. Practices were informed that, if allocated to the control group, they would be offered training once the trial was completed (waiting list control design).

We chose a cluster randomisation design because our intervention was aimed at primary care teams, not individual clinicians or patients. Within every primary care trust area we randomised practices with a computer minimisation programme, with a random component (Minim Version 1.3), maintaining allocation concealment. JR ran the minimisation programme for every practice after they were recruited and then informed the research associates of the allocation. The minimisation variables were the same as the stratification variables. Due to the nature of the intervention, practice staff could not be masked to allocation status. Most researchers were not masked but an independent researcher outside the study team who searched the records of some practices was masked. Because the intervention was targeted at clinicians and administrators and no consent was required for outcome data extraction from medical records, as agreed by the research ethics committee, patients were not aware they were part of a research study.

Procedures
The main component of the intervention consisted of two 2-h multidisciplinary training sessions, targeted at the clinical team. The training sessions were designed to improve the response of clinicians to women being abused through improved identification, support, and referral to specialist agencies. These sessions incorporated case studies and practice in asking about violence and responding appropriately. They were delivered by an advocate educator based in one of the two collaborating specialist agencies (Next Link and the nia project), and either a clinical psychologist specialising in domestic violence or an academic family doctor. The advocate educators were experienced domestic violence advocates and trainers. The psychologist and academic family doctor had backgrounds in domestic violence research and training. Presentations and interactive sessions were standardised and every practice was given a handbook with additional materials. There was no quality assessment of the training nor measurement of fidelity. The advocate educator was central to the intervention, combining a role in training and support to the practices with provision of advocacy to women referred from the practices. The training sessions were followed by quarterly to half yearly
Our primary outcome was the number of referrals to a specialist domestic violence agency of women aged 16 years and older in the electronic medical records of the general practice. This outcome was measured for the 12 months preceding the first training session and for 12 months following the second training session in intervention practices. The pre-specified secondary outcome reported here was recorded identification of domestic violence in the electronic medical records of the general practice, measured for the same period as the primary outcome. A post-hoc secondary outcome was referral of women registered in trial practices received by the two collaborating specialist domestic violence agencies, including self referral, referral received from clinicians in a practice, and referrals from other agencies. Although during the trial Next Link received most domestic violence referrals in Bristol and the nia project in Hackney, we had initially planned to combine referrals received in these agencies with referrals from trial practices received in other domestic violence agencies in the two localities. This combination was meant to minimise potential bias towards referrals from intervention practices to Next Link and the nia project. Ultimately, the other agencies were unable to systematically obtain practice-specific referral data; and we therefore asked them to enumerate how many direct referrals in total they had received from any general practice in the whole locality (ie, not confined to trial practices) during the duration of the trial. This analysis aimed to assess whether the primary outcome and the post-hoc secondary outcome analyses might have biased the result in favour of intervention practices.

For the outcomes of identification and referral, the denominator was the total number of women registered in intervention and control practices. Outcome events in the practices were detected through searches for domestic violence-related codes in databases of medical records. The free text in all records with those codes was scrutinised for identification and referral events. When the free text or coded data in the record met pre-specified criteria (available from authors), an identification or referral event was entered onto a data form. Outcome events in the specialist agencies (referrals received) were extracted from data logs kept in the agencies. A secondary outcome specified in our protocol,28 measurement of clinician preparation, knowledge, and self-reported practice with regards to domestic violence will be reported in a separate article, as will be the detailed cost-effectiveness analysis specified in our protocol.

The main potential adverse event from the trial was breach of patient confidentiality from researchers extracting data of patients in practices or in the communication between clinicians and IRIS advocate educators. We asked the practices and the domestic violence agencies to report any breach of confidentiality to the principal investigator (GF). We also asked practices to report any issues they had in the response of the agencies to referrals.

To ensure comparability in timing of data collection, we paired control and intervention practices by number of registered patients and training status and obtained the data from each pair simultaneously. Research associates collecting data could not be masked to allocation status, because IRIS posters and leaflets were visible in intervention practices. Additionally, they could recognise the IRIS template in the medical record that prompted clinicians in the intervention practices to ask about abuse. Disclosure and referral data from general-practice records were double entered onto the study database. If the research associates were uncertain about whether an event was in the record, this was referred to an independent outcome panel for a decision. For every case, the panel (a primary care domestic violence researcher, a general practitioner, and a health economist) was masked to group assignment and identity of the practice. We assessed the reliability of data extraction by research associates by comparing it with extraction by an independent researcher outside the study team, masked to group assignment, who searched the records of the practices and the domestic violence agencies to report any breach of confidentiality to the principal investigator (GF). We also asked practices to report any issues they had in the response of the agencies to referrals.
### Table 1: Characteristics of practices randomised compared with those of practices that declined

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Randomised (n=48)</th>
<th>Declined† (n=31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered patients</td>
<td>7424 (4322–8830)</td>
<td>5524 (3044–8211)</td>
</tr>
<tr>
<td>Female doctors within a practice (%)</td>
<td>45·3 (10·6–53·5)</td>
<td>47·9 (32·5–66·5)</td>
</tr>
<tr>
<td>Postgraduate training practice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>29 (60%)</td>
<td>14 (50%)</td>
</tr>
<tr>
<td>No</td>
<td>19 (40%)</td>
<td>14 (50%)</td>
</tr>
<tr>
<td>Registered patients on low income (%)</td>
<td>32 (13–34)</td>
<td>29 (9–30)</td>
</tr>
</tbody>
</table>

Data are median (interquartile range) or n (%). †Three results missing for teaching practice and list size. Six missing for income, seven missing for percentage of female doctors.

### Statistical analysis

We tested the hypothesis that the intervention would increase identification of women experiencing domestic violence and their referral to domestic violence agencies. With 24 intervention practices and 24 control practices, with the assumption of an identification rate of 1% in control practices (a conservative estimate based on our survey of 12 east London practices) and an intraclass correlation coefficient of 0·03, we would be able to detect a difference of 3·2% in the identification rate with a power of 80% at a significance level of 0·05. This calculation assumed an average of 1600 women in the relevant age group in every practice, and took account of variation in cluster size. With this number of practices, we would be able to reliably detect a three-fold difference between intervention and control practices in the referral of women disclosing abuse to domestic violence advocacy services.

We used Poisson regression models to analyse outcome events in the practices. Our independent variable was the number of referrals or identifications for every cluster. We included the number of women aged 16 years or older as the exposure and practice as a random effect to account for the clustered nature of the data. Analysis was done for all practices for which we obtained baseline data, adjusted for minimisation factors but not for practice baseline rates, since these did not improve the precision of our treatment estimate. All analyses were done in Stata 10.1.

This study is registered with Current Controlled Trials, ISRCTN74012786.

### 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.

### Results

The intervention was delivered between Sept 1, 2007, and Sept 30, 2008. 51 (62%) of 82 eligible practices agreed to participate (figure 1). These practices had a similar proportion of female doctors, but were larger, had a higher proportion of patients on low incomes, and had a higher proportion of postgraduate teaching than did practices that declined participation (table 1). Of the 51 randomised practices, three dropped out before we obtained baseline data. Table 2 shows the baseline demographic characteristics (including minimisation factors) of participating practices and recorded identification and referral rates in the 12 months before the intervention. These characteristics were well balanced in the two study groups and in the two localities (table 2) and for every site (data not shown).

The outcome panel assessed 118 uncertain recordings: 15 uncertain recordings of referral (five deemed to be referrals and ten not), 100 uncertain identifications of domestic violence (47 deemed positive identifications and 53 not), and three recordings of domestic violence for which there was uncertainty whether a clinician or an outside agency had identified the woman (two were deemed to be identified by the clinician and one not). Comparison of the data sets for referral and identification extracted by trial research associates with those extracted by an independent researcher showed six discrepancies. These discrepancies easily resolved in favour of the original dataset when the discrepancies were discussed and with no favouring of either group.
Table 3: Numbers and incident rate ratios for recorded referrals and identifications of women experiencing domestic violence in general practice and domestic violence referrals received by specialist agencies, 12 months after intervention

<table>
<thead>
<tr>
<th>Control (n=24)</th>
<th>Intervention (n=24)</th>
<th>Total (n=48)</th>
<th>Unadjusted intervention group incident rate ratio (95% CI)</th>
<th>Adjusted* intervention group incident rate ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of eligible women</td>
<td>73 347</td>
<td>70 521</td>
<td>143 868</td>
<td>...</td>
</tr>
<tr>
<td>Number of eligible women per practice</td>
<td>3088 (2043–4173)</td>
<td>2945 (1747–4083)</td>
<td>3013 (1804–4168)</td>
<td>...</td>
</tr>
<tr>
<td>Recorded referral in the general practice electronic medical record</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td>12</td>
<td>223</td>
<td>235</td>
<td>21.0 (10.7–41.1)</td>
</tr>
<tr>
<td>Number per practice</td>
<td>0 (0–1)</td>
<td>9 (4–14)</td>
<td>2 (0–9)</td>
<td>...</td>
</tr>
<tr>
<td>Recorded disclosure of domestic violence in the general practice electronic medical record</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td>236</td>
<td>641</td>
<td>877</td>
<td>3.4 (2.1–5.4)</td>
</tr>
<tr>
<td>Number per practice</td>
<td>5 (2–20)</td>
<td>25 (9–40)</td>
<td>13 (3–29)</td>
<td>...</td>
</tr>
<tr>
<td>Referrals received by specialist domestic violence agencies (Next Link and the nia Project)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td>40</td>
<td>238</td>
<td>278</td>
<td>6.6 (4.1–10.7)</td>
</tr>
<tr>
<td>Number per practice</td>
<td>0.5 (0.0–3.0)</td>
<td>9.0 (5.0–14.8)</td>
<td>3.5 (0.0–9.0)</td>
<td>...</td>
</tr>
</tbody>
</table>

Data are median (interquartile range) unless otherwise stated. A random effect has been fitted for practice. *Analysis has been adjusted for area stratification and for minimisation factors. Intra cluster correlation: recorded referral=0.0008; recorded disclosure=0.003.

Table 3 shows the absolute number of recorded referrals and identifications in the two trial groups and the intervention incident rate ratios. 12 months after the second training session, the number of referrals to domestic violence agencies recorded in medical records in the intervention practices was 21 times larger than that recorded in the control practices. The 223 recorded referrals overestimate the number of direct referrals sent by the clinicians, at least in the intervention practices, since the advocate educators in the specialist domestic...
Articles

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domestic violence agencies and on recorded identi-
substantial effect on recorded referrals to specialist
The IRIS training and support intervention had a
Discussion
were referred directly to another advocate or agency
made with 55 (30%). Of the remaining 129, 67 (52%) had
contact could not be made with 55 (30%). Of the remaining 129, 67 (52%) had phone support sessions with the advocate before onward referral to another advocate or external agency, 35 (27%) had face-to-face sessions with the advocate, 25 (19%) had a mixture of phone and face-to-face sessions, and 13 (10%) were referred directly to another advocate or agency without initial contact.

Discussion
The IRIS training and support intervention had a substantial effect on recorded referrals to specialist domestic violence agencies and on recorded identification of women experiencing domestic violence, albeit from a low baseline. The primary outcome, a record of referral to a domestic violence agency within the electronic general practice medical record over-estimated actual referral, because clinicians might have recorded a referral when they gave the patient an IRIS card or telephone number. However, the primary outcome did not detect the full potential effect of the intervention either, which included self-referral for women who had disclosed abuse to clinicians but did not want to be referred by them or for those who had read the IRIS publicity in the intervention practices. In the analysis of any referrals, including self-referrals, to the two collaborating domestic violence agencies, the magnitude of the intervention’s effect is lower than that in the analysis of the primary outcome as we expected. However, the seven-fold difference between intervention and control practices remains substantial. Recorded identification of women being abused was three times larger in the intervention group than that in the control group. The ratio of women in the intervention practices with a record of disclosure to referral was 2.8 (compared with a disclosure:referral ratio of 20 in control practices).

Figure 2: Box plot of identification and referrals to advocacy agencies of women experiencing domestic violence
Vertical lines denote interquartile range.

Panel: Research in context
Systematic review
We updated two previous systematic reviews17,25 of controlled studies testing system level interventions in health-care settings to improve referrals and other outcomes for women experiencing domestic violence. We searched Medline, Embase, Cinahl, British Nursing Index, and PsycINFO from Sept 30, 2004, to Dec 31, 2009, using the same search terms as our previous reviews. There were no language restrictions. We found that training and organisational change within health-care systems can increase the identification of women experiencing domestic violence but revealed uncertainty about the effect of these interventions on referral to specialist services for domestic violence or other outcome measures beyond identification.

Interpretation
Our trial compared the effect of a training and support programme in primary care settings on referrals to domestic violence services with no programme. The substantial difference in referrals is strong evidence that the intervention improves the response of clinicians to women experiencing domestic violence and enables access to domestic violence advocacy that can reduce re-victimisation and improve quality of life and possibly mental health outcomes. Our findings reduce the uncertainty about the benefit of domestic violence training and support interventions in primary care settings, particularly outside north America, and show that screening is not a necessary condition for benefit.
IRIS was adequately powered to detect important differences in identification and referral of women experiencing domestic violence, with assiduous capturing of these events. We showed that the IRIS programme increased identification and referral and that clinician behaviour with regards to domestic violence, a major public health and health-care issue that has largely been ignored in clinical practice, can be changed. Although the relative difference between the intervention and control groups was large, the absolute difference was modest. A limitation of the study was the use of a measure of primary outcome that is a proxy for patient’s benefit. A systematic review of controlled studies up to September, 2009, concluded that advocacy was likely to be an effective intervention and support for women victims of intimate partner violence. A Cochrane review of ten randomised controlled trials of advocacy for intimate partner abuse up to July 2008, concluded that intensive advocacy could reduce physical abuse, although its effect on mental health, although reported as positive in most trials, was equivocal. Nevertheless, the overall weight of evidence from controlled studies, and from qualitative studies, favours benefit to women who are referred to advocacy. Not all women referred for advocacy in our study received it, however. Overall, the intensity of contact between referred patients and a domestic violence advocate was consistent with that received in trials of domestic violence advocacy and other controlled studies, although the quality of the advocacy that women received is unknown. Other limitations of the IRIS trial included a three-month period when self-referral data were not obtained in one of the collaborating domestic violence agencies and the absence of systematic referral data from other agencies, although these limitations did not affect the analysis of the primary or secondary outcome.

A distinctive feature of the IRIS model was that it was not based on screening, unlike most other trials of interventions to improve the management of domestic violence in health-care settings at the system level. Yet, it showed a similar magnitude of effect on identification of women experiencing violence. Most previous studies have been set in antenatal clinics or accident and emergency departments (panel). A similar trial based on primary care in the USA showed no effect on referral, possibly because the intervention had neither prompts in the medical record to ask about abuse nor a simple referral pathway to specialist advocacy support. A unique and probably essential feature of the IRIS model was the hybrid role of an advocate educator, who both trained practices in the identification of, and response to, women experiencing domestic violence, and who became the named advocate to whom clinicians could refer. The IRIS model was rooted in a close partnership with third-sector specialist agencies, linking primary care into an inter-sectoral response to violence against women. This model is potentially transferable to middle-income and low-income countries, although some of its aspects would need modification and its effect in different settings would need to be assessed. Particularly, the absence of an electronic medical record in primary care in many countries would require another method to prompt clinicians to ask about domestic violence.

Another important challenge to implementation of the programme in a resource-poor setting is the patchy provision or absence of domestic violence advocacy services. In the UK, the model is sustainable outside of a research context. In Hackney, where the IRIS programme was commissioned in the year after the trial ended, 46 women were directly referred by clinicians in the intervention practices and 74 women registered in those practices contacted agencies of domestic violence through other routes.

Worldwide, clinicians within primary care and other health-care settings are not responding adequately to domestic violence. In this study, we show the effectiveness of a brief intervention of training and support with a simple referral pathway to domestic violence advocacy.

Contributors
All authors were members of the trial management group and contributed to data interpretation and to revision and refinement of the final manuscript. GF and RA-D had the original idea for the study. GF led the study and drafted the report. CG, DS, GF, RAD, and SE participated in the design of the trial. AH, GF, MJ, and RAD participated in the design of the intervention. AG participated in the design of the database. DS and GF participated in practice recruitment. JR participated in the randomisation. AG and DD participated in data collection and entry. AH, KB, and MJ participated in the delivery of intervention. RAD supervised the intervention. JR supervised data collection. CR participated in the data analysis and draft of display items. SE supervised the analysis.

Conflicts of interest
AH and MJ were domestic violence advocate educators and now are employed to promote the commissioning of the IRIS model in the UK. The other authors declare that they have no conflicts of interests.

Acknowledgments
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References


