PreDove

Barts and The London
Queen Mary's School of Medicine and Dentistry

Prevention of domestic violence (PreDoVe)

A pilot randomised controlled trial of a primary care based intervention in primary care

Report to the Nuffield Foundation

Gene Feder, Gill Foster, Sandra Eldridge, Jean Ramsay, Anne Spencer
on behalf of the PreDoVe steering group

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I. Background and Aims

Domestic violence (DV) or intimate partner violence against women is a major public health problem resulting in injury and long term health problems. Extending a previous systematic review,[1] we have recently reviewed all controlled intervention studies based in or relevant to health care settings.[2] Fifteen studies of system-centred interventions were included, ten of which were conducted in health care settings. Overall, we found that system-centred interventions can increase referral rates in the short-term, although evidence from the studies with longer term follow-up suggests that reinforcement and training of new staff is needed to sustain this effect. Twenty studies of woman-centred interventions were reviewed, including nine interventions for advocacy and ten that evaluated psychological interventions (counselling or psychological therapy). Evidence from the advocacy studies suggests that this form of intervention, particularly for women who have actively sought help from professional services or are in a refuge setting, can reduce abuse, increase social support and quality of life, and lead to increased use of safety behaviours and accessing of community resources. Evidence from evaluations of psychological interventions suggests that these may be effective in reducing depression in women with a history of partner abuse, although it is unclear to what extent this is in addition to spontaneous resolution as time from abuse elapses.

The virtual absence of randomised controlled trials of health care based interventions for partner violence, of robust studies within primary care and of controlled studies in the UK, led us to design a randomised controlled trial of a complex intervention within general practice to improve outcomes for women experiencing intimate partner violence. It would have been premature to directly proceed to the full trial without ensuring that all the intervention and evaluation components of the design are acceptable, feasible and appropriate.[3] To this end, funded by the Nuffield Foundation, we carried out a pilot study to test the feasibility of conducting a randomised controlled trial of a system based intervention to reduce abuse and improve quality of life and mental health outcomes for women who have experienced partner abuse in the past year. This report summarises the results of this pilot

Aims

1. Assess the feasibility and acceptability of a general practice-based domestic violence intervention programme.
2. Assess the feasibility of a randomised controlled trial design to evaluate outcomes of the intervention.

II. Objectives of the pilot study

Aim 1

a) Assess the feasibility and acceptability of implementing a domestic violence programme in a general practice setting, including practice-based education of health professionals, patient information about domestic violence in the waiting room, prompting via the electronic medical record of questions about abuse in practices, and provision of referral pathways to domestic violence advocacy and specialist counselling
b) Assess adherence of clinicians to the programme with measurement of process variables.
c) Formulate policy recommendations on role of domestic violence advocacy in primary care settings

Aim 2

a) Recruit three practices in east London for implementation of a domestic violence prevention programme including screening, advocacy and mental health care.
b) Recruit one practice in east London that will not get the programme but in which we will recruit patients for follow up.
c) Assess the feasibility of identifying and recruiting a sample of women from a multi-cultural population who have experienced domestic violence in the past year.
d) Assess the feasibility and acceptability of administering baseline questionnaires to the sample of women, administering repeat questionnaires over a 6-month period, and the acceptability of further, long term follow up.
e) Collect outcome variable data that will allow an accurate estimate of sample size for the main trial.
f) Evaluate cost effectiveness of the intervention

g) Assess the likely effectiveness of the intervention and possible improvements to the intervention using modelling

III. Aim 1: feasibility and acceptability of the intervention and adherence of the participating clinicians

Intervention model

The intervention was multi-faceted:

- domestic violence education and training for participating health professionals
- screening for abuse by health professionals of women attending primary care
- an information campaign in participating practices (posters and leaflets in the waiting room and the women's toilet) highlighting the problem of partner abuse and the support available in the community and through the practice
- provision of immediate support and follow-up from the clinician for women who disclose abuse
- referral by the clinician or self-referral, to a practice-based advocate seconded for the pilot from Victim Support
- referral by the clinician to a clinical psychologist seconded for the pilot from Tower Hamlets PCT clinical psychology service

III.1. Methods

III.1.1. Practice based DV education and follow up

Training sessions were held in the three intervention practices. All practice staff were invited: general practitioners, health visitors, practice nurses, midwives, counsellors and practice managers. The sessions lasted two hours. The trainers included the principal investigator (a GP researcher), a domestic violence (DV) advocate and a clinical psychologist seconded from Tower Hamlets victim support and PCT respectively. Sessions involved presentations by the trainers, facilitated discussion, and role-play in small groups focused on asking about abuse. The role-play scenarios were based on patients who had disclosed domestic violence in a general practice setting. The training was eligible for Post Graduate Educational Allowance (discontinued in April 2004). All participants received a training manual.

The education sessions were followed up with regular meetings between practice staff and the DV advocate, who had a facilitation role. Each practice nominated a key person who could liaise with the advocate. New staff or staff unable to attend the education session was invited to meet with the DV advocate to discuss the project in detail. In addition, the DV advocate performed regular audits of identification and referral rates and results were fed back at practice team meetings to encourage discussion of issues or difficulties. The intervention team supported the DV advocate by meeting regularly to discuss progress and offer solutions to any difficulties arising that related to the intervention.

We carried out a qualitative evaluation with an intensity sample of clinicians to determine what participants thought about all aspects of the trial: the education sessions, their experiences of asking women about domestic violence, their experiences of using the HARK template and their experiences of the process of referral to an outside agency.

III.1.2. Identification of women experiencing partner violence

During the training session we discussed with practice teams what policy they wanted to implement on questioning women about abuse. The discussion centred on who, and when, to ask about partner violence. Our goal was that clinicians would routinely ask all women, however, we were aware that this was unlikely to be acceptable.[4] The doctors and nurses participating in the education sessions agreed to selective questioning. We suggested that clinicians ask women attending new patient checks, antenatal visits, well women clinics and family planning clinics or when women presented with signs or symptoms associated with abuse.

Our research group developed a four item screening tool from the Abuse Assessment screen [5]. The four components of the tool represent the emotional, physical, sexual and fear dimensions of partner violence.

role was to assess the woman's needs and put her in contact with the relevant agencies, such as social services, police or housing departments. The advocate also had an active role in supporting practices in implementation of questioning and referral, including reporting back use of the HARK template.

III.1.7. Content of psychological intervention

Clinicians were encouraged to refer women who they thought would benefit from a psychological intervention based on cognitive behaviour therapy. Women were offered an appointment with the psychologist within four weeks of the referral. Following an initial assessment to establish that referral criteria were met and that the help they sought for psychological intervention was appropriate, women were offered 6-12 sessions. The focus of treatment was client-led on a continuum from crisis intervention and safety planning at one end through to psychological well-being and mental health promotion at the other. The role of the psychologist extended to writing supporting applications and detailed psychological assessments of mental health status for housing departments and liaising with other health service staff.

III.2. Results

III.2.1. Practice-based DV education

The 2 hour education sessions were attended by more three quarters of the general practitioners and practice nurses in both of the larger intervention practices and by all in the smaller practice. No midwives attended any of the sessions in any of the practices and health visitors only attended sessions in the larger practice. The DV advocate kept in regular contact with the key person that each practice had nominated for liaison. Some staff members of one of the larger practices requested further training immediately following the education session. They requested supplementary training using role-play to practice asking women about abuse and how to respond to women who disclosed abuse. This was undertaken by the DV advocate and the psychologist. Four months after the education session the DV advocate returned to one of the practices to carry out further formal training session, as new members of staff had commenced working. In the other two practices she returned at least twice to meet with some of the primary care team to reinforce the training.

We carried out semi-structured interviews with four GPs and five nurse practitioners to explore their perceptions of the intervention. Views about the education session were generally positive. Informants felt that the training had increased their awareness of the extent and consequences of domestic violence. Most of the informants said that a formal follow up session would have been useful at a much later date (those who specified a time frame requested annual training). One GP informant voiced that she felt unsure of how to proceed after the education session.

III.2.2. Monitoring of HARK template use

6950 women aged over 15 years consulted a doctor or nurse in the three practices during the 12 month study period. Use of the template varied between and within practices. In total 435 women were asked about partner abuse using the template. The proportion of positive disclosures for those who were asked about abuse varied almost 10 fold. (appendix 2, table 1). In one practice very few women were being asked about abuse but a large proportion of those asked were positive. It was discovered that there was a problem with the links to the template, resulting in failure to capture some use of the template when women were negative for HARK. During the interviews with clinicians from that practice, all had said that they had used the template and had referred at least one woman to the advocate or psychologist. A few women were asked about partner abuse without use of the HARK template (see appendix 2 table1). We did not have ethical approval to look at the records of these women and therefore cannot explore reasons why the template was not used.

III.2.3. Referrals

i) Recorded on template: 18 to the DV advocate and 12 to the psychologist. In three cases the clinician had referred a woman to both the DV advocate and the psychologist. In one practice four referrals to the psychologist were recorded but no direct referrals from that practice were received.

(ii) Victim Support data: there were no self-referrals from any of the practices for women experiencing abuse. There were two self-referrals as a result of the leaflet campaign (one man and one non-partner family violence) and one from the tear-off notices in the women's toilets (also arising from non-partner family violence). No self or clinician referrals were received from the control practice, however two women

from the control practice were referred by the Community Safety Unit (CSU). Their decision to go to the police was not informed by either seeing our leaflets or talking to a clinician about DV.

iii) Data from the DV advocate and the psychologist are shown in table 2. There were three cross-referrals between the advocate and psychologist. Practice 3 referred one woman who disclosed partner violence to another psychologist who referred her to the PreDoVe psychologist.

	Practice 1	Practice 2	Practice 3	Total
DV-Advocate	6	20	6	32
Psychologist	14	4	0	18

Table 1: Number of referrals to the DV advocate and psychologist from each practice

III.2.4. Outcome of referrals to the DV advocate

Eight clients required crisis intervention involving emergency housing support. One of the women went straight into a refuge; the remaining seven women were re-housed via the Homeless Persons Unit. In six of these cases the abuse had escalated; two of the women were pregnant and were afraid of losing their unborn child. Twenty one women were not in need of crisis intervention but asked for referrals to other agencies and/or emotional support. Of these, eight clients were referred to other agencies (solicitors, single mother and toddler group, counselling, MP). Three clients decided that they were not ready yet to talk about what had happened to them, however, they wanted to keep their case open and felt relieved to know that they had the option to contact their caseworker if they need to speak with someone. Of the 21 women, 14 have separated from their husbands or partners, seven women were still in the abusive relationship. Two partners had requested referrals to organisations that work with perpetrators. Three of the referred women were not contactable either by phone or by letter. The respective referring clinicians at the practices were informed.

III.2.4. Outcome of referrals to the psychologist

Two of the 18 referrals had been made in error as the women were not experiencing partner abuse and 1 woman did not fulfil the study criteria as she had experienced the abuse 10 years previously. Eleven attended initial assessment and 8 received treatment. The number of sessions varied from between 3 and 14. The duration of abuse was between 6 months and 23 years.

IV.Aim 2 Feasibility of trial design

IV.1. Methods

IV.1.2. Recruitment of practices

The three intervention practices were recruited purposefully to include a range of characteristics, including partnership size and training status. The control practice (no DV training offered to the practice team) was selected at random from the remaining Tower Hamlets practices. The control practice allowed us to test the feasibility and acceptability of recruiting women trial participants in a practice that did not get the intervention.

IV.1.3. Recruitment of women participants

In the month before the educational session in the practice, research assistants recruited women in the practice waiting rooms of all four practices (intervention and control) for administration of the 30-item Composite Abuse Scale (CAS) [6]and for identification of women experiencing partner violence in the past year and a few demographic questions. One of the researchers was a Bengali/Sylheti speaker. Women were excluded if they were unable to give informed consent for any reason, too unwell to complete the questionnaires, holding babies, accompanied by children aged over four years, accompanied by another adult or unable to speak English or Bengali/Sylheti. The study team developed a protocol for approaching women safely. When women consented to complete the questionnaire they were able to do so in a consulting room or other private space adjacent to the waiting room. All women who completed the questionnaire - whether or not they disclosed abuse - were given information about where to seek support if they were experiencing domestic violence. Women were asked for permission for the research team to

look at their medical or related records. Full consent was obtained and baseline questionnaires administered in a private room after their consultation. If women could not fill in the questionnaire on the same day an appointment was made at a location of their choice and contact details were elicited.

IV.1.4. Follow up of participants

There were two stages to this study. Women who completed stage one were all women who completed the demographic questions and the CAS questionnaire. Stage two involved women who had scored positive for abuse on CAS. The criteria we used were three positive responses with at least one incident of sexual or physical abuse. These women were invited to participate in the second stage of the study which involved completing a baseline questionnaire and agreeing to be followed up by the researcher at three months, six months and for an indefinite period thereafter. Women were asked to give the researchers a range of contact numbers in order that we could maintain contact with them. They were reassured that no confidential information would be disclosed to friends or relatives. The research assistants contacted the participants again by telephone at 3 months and 6 months after recruitment to arrange an appointment and all outcome measures were re-administered.

General practice and related records were examined for a record of abuse and independent data on health service use at 6 months and 12 months after recruitment intervals for all women participating. Follow up interviews were carried out at the practice or in a place that the women felt was safe.

IV.1.5. Outcome and process measures

In the context of a pilot study it was not essential to distinguish our primary from secondary outcomes; however, we wanted to ensure that we tested all potential primary outcome measures for the main trial. We used a range of well validated measures which included the following: (a) abuse measures (physical, emotional, sexual), (b) mental health measures (depression, anxiety and post traumatic stress), (c) quality of life, (d) substance abuse, (e) childhood experience of abuse, (f) child behaviour and health assessment, (g) health care utilisation and contact with advocate, (h) housing status or refuge use. Due to the cultural diversity of the Tower Hamlets population we adapted the outcome measures for the Sylheti speaking population of this study. We used a method of cross-cultural adaptation developed by members of our research group.[7]

Our process measures: attendance of primary care staff at educational sessions, use of HARK template, numbers of abused women identified and documented, referral rates to advocate and psychologist. We also collected process data from the general practice medical records about referral and use of other services.

Our outcome measures:

Abuse: Composite Abuse Scale (CAS); a multidimensional measure of partner abuse that has 4 dimensions - Severe Combined Abuse, Emotional Abuse, Physical Abuse and Harassment. Although CAS is a validated tool, sensitivity to change has not yet been demonstrated. With permission of the authors we re-worded the introduction so that participants were asked about a shorter time period to allow us to measure recent change in abuse. Thus the adapted CAS was used both to identify participants and as an outcome measure.

Mental health: the 21-item Beck Depression Inventory (BDI) is a continuous scale that is sensitive to change and has been widely used as an outcome measure in psychiatric intervention studies.

The Speilberger State-Trait anxiety inventory (STAI) is also sensitive to change and has a short form (6 items) with comparable results to the longer version. To characterise post traumatic stress we used the Impact of Events Scale which is a short questionnaire (15 items) that is widely used to measure outcomes of therapeutic interventions for PTS.

Quality of life: Generic measures have an advantage of comparability to other studies and also extensive validation and reliability testing. We chose two measures: the Short-form Health Survey (SF12), and the Manchester Short Assessment of Quality of Life (MANSA). The SF12 has been used with a variety of patient groups, including abused women, and has been shown to be sensitive to change. The MANSA is a brief 15 item-instrument for assessing quality of life; it focuses on satisfaction with life as a whole and with life domains.

Substance abuse: TWEAK is a 5-item scale to measure alcohol use [8]. It has been used to detect high alcohol in various populations, including pregnant women, people who abuse alcohol receiving treatment, patients attending outpatient clinics and the general population. The Drug Abuse Screening Test (DAST-10) comprises 10 items and elicits information about possible involvement with drugs during the last 12

months. It has been administered to both psychiatric and non-psychiatric groups. Childhood experience of abuse

Childhood experiences of physical and sexual abuse were measured using 4 items from the Childhood Experiences of Violence Questionnaire (CEVQ).

Child behaviour and health assessment: The Strengths and Difficulties Questionnaire (SDQ) is a 25-item scale that measures five dimensions of children's behaviour, emotions and relationships. In our study, abused mothers were asked to complete separate questionnaires for each of their children aged 3-15 years of age.

IV.1.6 Pre-piloting of new trial design

When it became clear that the trial design was not feasible (see section IV.2.7), we pre-piloted a revised design. This was also based on recruitment of women patients from waiting rooms, but tested a different hypothesis: that direct referral to a domestic violence advocate would be beneficial in terms of health and quality of life. This was no longer testing the effect of a system (practice)-based intervention. The recruitment method was identical. Once a woman consented to participation she was randomised either to direct referral to an advocacy service (Hackney Women's Aid) or information about domestic violence services. The same baseline/outcome questionnaires were used, with one addition: the domestic violence survivor assessment tool.

IV.2. Results

IV.2.2. Recruitment of practices

Two of the intervention practices were large group practices with list sizes of approximately 10,000. The third practice was smaller with 2 GPs and 2 practice nurses and a list size of approximately 6000. The control practice was a large group practice with a list size of 8700.

IV.2.3. Recruitment of women participants

Researchers covered an average of 31 sessions in each practice over a 5 week period prior to the education session. Over the five month recruitment period, 2213 potentially eligible women aged more than 15 years consulted at intervention practices, 1423 while the researchers were in present in the waiting room. Two hundred and sixty-one (18%) of these women were interviewed by a researcher. 52 (20%) of these women scored positive for abuse on the CAS questionnaire. Fifty four percent of these women consented to take part in the study. [1] See appendix 4, tables 4 and 5 for demographic details of women from the intervention and control practice of these 28 (11%) were recruited to the study. Four hundred and thirty-five women attending in the 12 month data collection period (6.3% of 6950 women attending) were asked about abuse by health professionals and 44 were referred to a psychologist or advocate. The overlap between those affected by the intervention and those recruited to our study was, however, very small: of those women who allowed their records to be examined (24/28), only three were positively identified as a result of a health professional asking; one woman disclosed without being asked; only one recruited woman was referred. Most recruited women were not affected by the intervention. (see appendix 3, table 3: Number of women approached and recruited per practice).

There were a total of 1435 women who were eligible to be approached according to our criteria, of these 74% were approached by a researcher. Thirty five percent of those approached were deemed ineligible because they either: didn't speak English, had not been involved in a relationship in the previous 12 months, were not registered with the practice or were under 16 years old. Of the remaining 689 women, 306 (44%) agreed to be interviewed in the private room. Only 5 women declined to complete stage 1 after being informed about the nature of the study. Two hundred and sixty one women successfully completed stage 1 in the intervention practices.

In order to address the exclusion of women who did not speak English, most of whom spoke Sylheti or Bengali, a Bangladeshi research assistant tried to recruit women using a translated CAS for stage 1. In the equivalent of 5 days recruitment in two practices 170 Bangladeshi women attended and 33 were

[1] In the early stages of the study we discovered that high numbers of women scored positive for abuse according to the criteria of 3 positive responses on the scale. In many cases women had scored positive on 3 emotional abuse items and when they were invited to proceed to stage 2 were surprised and in some cases offended when a suggestion of abuse was made. A decision was made by the steering group to change the criteria to: 3 positive responses at least 1 of which should include physical or sexual abuse.

approached (19%), but only two (6%) were recruited to stage . One of these women was recruited to the pilot trial. The main problem in approaching women was that the majority (71%) were accompanied and hence ineligible. We do not have a good explanation for the low recruitment of eligible Bangladeshi women to stage 1.

IV.2.4. Follow up of participants

Researchers had asked women for a variety of contact phone numbers, however, the majority of women only gave 1 phone number, or a mobile phone number and their own land-line number. Several women stated that they did not wish family members to be contacted or run the risk of them finding out about the abuse despite assurance from the researchers. Researchers met with women at their practice, at a time that was convenient for them. Two women completed the questionnaires at a local café and 1 woman was interviewed at home.

From the control practice 1 woman was followed up at 6 months, 1 woman dropped out at 3 months and 1 woman had difficulty arranging an appointment at 3 and 6 months.

	3 months (n=28)	6 months (n=25)
Followed up	17 (60%)	13 (52%)
Missed	5	2
Dropped out	2	4
Left area	1	0
No contact	3	6

Table 2: Follow up of women from intervention practices

IV.2.5. Baseline questionnaires

Only one woman failed to complete the baseline questionnaires. She was unable to fill in the questionnaire herself therefore it was completed by the researcher asking the questions, the woman became distressed but insisted on continuing with the questions because "it might help someone else". The interview was discontinued when the GP called the patient and she did not return to the private room following the GP consultation.

Beck Depression inventory: 14 (45 %) of those recruited scored more than 17 on the BECK depression inventory, of these 5 were moderately depressed, 6 were severely depressed and 1 was extremely depressed.

TWEAK: a score of 3 or more is positive for alcoholism/heavy drinking, 30 women completed the questionnaire, 60% were positive for heavy drinking.

DAST: 7 women scored positive for drug abuse, 1 of whom had substantial drug abuse.

CEVQ: 11 (37%) scored positive for childhood severe physical abuse, 1 woman scored positive for severe sexual abuse and 4 women scored positive for severe sexual *and* physical abuse.

Impact of events scale: Only 4 out of 30 women scored negative for stress, 9 women (29%) were moderately stressed and 10 (32%) were severely stressed.

IV.2.6. Medical record search of consultations

Intervention practices: Twenty four women out of 28 gave consent for the researcher to review their medical records. All women returned to the practice for at least one consultation in the 12 months following recruitment. The number of consultations ranged from 3 to 44 (median 8). Four women were asked about abuse using the HARK template, 3 of these had a positive recording. Two of these women already had a history of abuse known to the practice. None of the women were referred to the DV advocate or psychologist. One woman who was positive on HARK had a referral to a psychologist other than the study psychologist. In the control practice women recruited to the pilot consulted between 3 and 14 times. None of them disclosed abuse and none of them were referred to a counsellor or psychologist.

IV.2.7. Feasibility of research design

Over the five month recruitment period, 1435 potentially eligible women aged more than 15 years consulted at intervention practices while the researchers were present in the waiting room. Two hundred and sixty-one (18%) of these women were interviewed by a researcher of these 28 (11%) were recruited to the study. Four hundred and thirty-five women attending in the 12 month data collection period (6.3% of 6950 women attending) were asked about abuse by health professionals and 44 were referred to a psychologist or advocate. The overlap between those affected by the intervention and those recruited to

our study was, however, very small: of those recruited women who allowed their records to be examined (24/28), only three were positively identified as a result of a health professional asking; one woman disclosed without being asked; only one recruited woman was referred. Most recruited women appeared not to be affected by the intervention.

We constructed a simple model to assess the likely impact of the intervention on recruited women in the main trial. We assumed (i) the pilot study rates for different processes described above hold in the main trial, (ii) 14% of women who attend are abused, (iii) the likelihood of recruiting a woman to the trial is *independent* of the likelihood of her disclosing abuse to a health professional. Using these assumptions, we estimate that only 4.5% of our recruited women will be identified and referred by health professionals .This corresponds closely with our observed pilot results.

What identification and recruitment rates would we need in the main trial to ensure that a much larger proportion of recruited women are actually affected by the intervention? Changing the recruitment rate makes no difference to the proportion of recruited women affected by the intervention, but increasing the rates at which general practitioners ask about abuse from 6.3 % to 50% and the rate at which they refer women from 11% to 14% increases the proportion of study participants affected by the intervention to 50% (Appendix table 6). The increase in rate of enquiry dominates this result. Increases of this magnitude are unlikely even with a much more intense practice based intervention. [1]. We therefore conclude that we are unlikely to be able to detect a noticeable impact of the intervention amongst trial participants using our proposed research design.

Table 3 shows rates for processes carried out by health professionals, separately for the three intervention practices. The proportions of women who were asked about abuse using HARK, and the proportion of these found positive on HARK vary considerably between practices. This suggests that HARK is being used differently in the three practices. In no practice is it being used as a screening tool, and in practice two, where the rate of asking is extremely low compared with the other practices, but the proportion of asked women who are HARK positive is substantially higher, the tool may often be used only after a woman has disclosed or when the health professional already suspects abuse. This is not a robust result because it is likely that not all episodes of HARK template use were recorded by that practice's system. (see p.2 para 3) There is much less variation between practices in the estimated proportion of abused women identified using HARK.

	total	practice 1	practice 2	practice 3
proportion of abused women identified by practice	4.4%	3.6%	4.8%	4.3%
Proportion of women (all women) asked	6.2%	13.7%	1.8%	8.4%
proportion of asked women who were positive on HARK	9.9%	3.7%	38.1%	7.2%

Table 3: Estimates of transition probabilities for three practices, and overall

Table 3 showed the number of referrals estimated using data from different sources. Unfortunately we were unable to identify which of these women had a positive HARK identification. Clearly, a woman who is referred must have disclosed to the GP, but some women may disclose outside the use of HARK. Although we are aware (through computer searches of relevant Read codes) that 17 women were identified in intervention practices without the use of HARK, we do not know if there were more, whether any were referred and whether their identification was due to the intervention. In the control practice, searching on the same codes, we found no disclosure of domestic violence in our study period. The psychologist linked to that practice reported no referrals for women experiencing partner violence in the past year.

IV.2.8. Cost effectiveness model

We constructed a simple model for the PreDoVe intervention using costs from our pilot, projected outcomes from the referral of women to advocacy and psychological interventions and assumptions about utilities of different outcomes. The results of the model show an incremental cost effectiveness ratio (ICER) of -£35,686. The intervention is both potentially beneficial and cheaper than normal care, driven by the savings in terms of reduced crime. This model does not prove cost-effectiveness of the intervention, because we can only be confident about benefit if we do the main trial. Moreover, we need to add distributions so we can estimate the precision of the model and test its sensitivity to variation in the

assumptions when these were not based directly on data. Nevertheless, even this simple model shows that this type of intervention is likely to be cost-effective, if we can show clinical effectiveness.

IV.2.9 Pre-piloting of new trial design

51 of 147 eligible women were interviewed by a researcher. Four (8%) scored positive for abuse on the CAS questionnaire. Three consented and two were randomised to the referral to the Hackney Women's Aid (NIA) advocate and one to normal care. As this recruitment took place at the end of our study we do not yet have follow up data on these three participants.

V. Conclusion

V.1. Academic/service provider collaboration

A central feature of the intervention model was linking general practice responses to women experiencing domestic violence to a broader community response and community resources. One of the achievements of this pilot was making this link through a challenging and productive collaboration between health service researchers, domestic violence service providers and a primary care trust. Non-academic collaborators were involved in the design of the pilot, its management and its analysis. The training sessions were jointly run by members of the steering group. Monthly steering group meetings were a forum for mutual education of its members: academic partners learned about the complexities of service provision for women experiencing partner violence and service providers learned about the demands of randomised controlled trial research methods. The strength of this collaboration is a good basis for a full trial and other projects.

V.2. To what extent did we fulfil our aims?

We achieved both our aims.

V.2.1 Aim 1: Assess the feasibility and acceptability of a general practice-based domestic violence intervention programme

The intervention proved feasible and acceptable to the three intervention practices, as judged by the number of women recorded with recent experience of partner violence and referrals to the domestic violence advocate or psychologist, as well as the interviews with informants. The *magnitude* of the intervention's effect was modest. Nevertheless, if we knew that identification and referral benefited individual women, then the overall rate would result in substantial public health gain if rolled out to all general practices.

V.2.2 Aim 2**:** Assess the feasibility of a randomised controlled trial design to evaluate outcomes of the intervention.

The design we tested, whereby the intervention takes place at a practice level and trial participants are recruited independently of the intervention among women attending the practice, did not work. We have shown with a simple model that even the most optimistic estimate of increased identification and referral of women that one could expect with a more intense educational intervention would not be sufficient for an efficient trial in which the primary outcomes are improvements in women's health or quality of life. Our model also shows that improved recruitment of participants would not substantially change this conclusion. The design would work if the outcomes were identification and referral of women experiencing violence, but we believe there is already sufficient international (although not UK) evidence that system based interventions can have this effect.[1] We completed our study by testing another trial design to answer a question about the effectiveness of advocacy. Our initial finding is that it may be feasible to recruit women with recent experience of partner violence and individually randomise them within this design.

V.3 Outputs of PreDoVE

We have presented our findings to London wide (London Society for Academic Primary Care conference February 2005), national (Domestic violence and health research forum March 2005) and international meetings (WONCA Europe conference June 2004, Family Violence Prevention Fund scientific conference Boston November 2004). We will submit a methodological paper based on this study to a specialist journal

and a separate paper reporting the cost-effectiveness model. We will continue working on the design of a randomised controlled trial focusing on the effectiveness of advocacy referral from a primary care setting,

PreDoVe steering group and acknowledgements

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Appendices to PreDoVe report

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Table 1: Appearance of HARK template on electronic medical record in intervention practices

		Date last used
Do you want to use the HARK template?	Yes No	
Humiliate?	Yes No	
Afraid?	Yes No	
Rape?	Yes No	
Kick?	Yes No	
Refer to advocate?	Yes No	
Refer to psychologist?	Yes No	

Table 2: Enquiries about partner violence

Women 16+ attending **(Total No. of women in practice)**	Practice 1 1601 (5086)	**Practice 2** 3542 (5146)	**Practice 3** 1807 (2851)
Used template	219 (14%)	63 (2%)	152 (8%)
Hark +	**8**	**24**	**11**
Hark+/used	**4%**	**38%**	**7%**
Enquired without use of HARK template	**9**	**5**	**3**

Table 3: Number of women approached and recruited per practice.

	Practice 1	**Practice 2**	**Practice 3**	**Control Practice**	**Total**
No. of women eligible to approach	566	409	235	225	1435
No. of women approached	444	325	163	130	1062 (74%)
No. declined Stage 1	193	85	47	58	383
No. excluded according to criteria	107	147	87	32	373
Refused in private room	2	3	0	0	5
Completed CAS	142	90	29	40	301
CAS positive	23 (16%)	21 (23%)	8 (27%)	9 (22%)	61 (20%)
Declined Stage 2	8	9	7	6	30 (49 %)
Recruited to Stage 2	15 (65%)	12 (57%)	1 (12%)	3 (50%)	31 (51%)

Table 4 Women completing stage 1 from intervention practices

	CAS negative N=209	Recruited Stage 2 N=28	Declined Stage 2 N=24	Total N=261
Age (mean)	36	31	32	33
Ethnicity: White	150 (72%)	19 (68%)	12 (50%)	181 (69%)
Black	10	0	1	11 (4%)
Asian	32 (15%)	3 (11%)	7 (29%)	42 (16%)
other	17	5	3	25 (10%)
Employment:				
Paid employ	113 (54%)	14 (50%)	12 (50%)	139 (53%)
Unemployed	25 (12%)	6 (21%)	2 (8%)	33 (13%)
Housewife	37 (18%)	5 (19%)	7 (29%)	49 (19%)
Studying	20	1	2	23
Retired	7	1	0	8
Other	7	1	1	9
Employment hours:	(n=113)	(n=14)	(n=12)	(n=139)
< 15 hours/wk	4	2	2	8
16-40 hours/wk	86 (76%)	10 (71%)	8 (66%)	104 (75%)
41 or more	23	2	2	27
Housing:				
Owned	90 (43%)	5 (18%)	4 (17%)	99 (38%)
Council/HA	76 (36%)	16 (57%)	14 (58%)	106 (41%)
Private rent	42 (20%)	7 (5%)	5 (21%)	54 (21%)
Hostel	1	0	1	2

Table 5: Women completing stage 1 from Control practice

	CAS negative N=31	Recruited Stage 2 N=3	Declined Stage 2 N=6	Total N=40
Age (mean)	43	39	24	35
Ethnicity: White	25 (81%)	3	4	32 (80%)
Black	3		1	4 (10%)
Asian	2		1	3
other	1			1
Employment:	(n=29)			(N=38)
Paid employ	13 (45%)		3 (50%)	16 (42%)
Unemployed	5 (17%)	2	1	8 (21%)
Housewife	5 (17%)		1	6 (16%)
Studying	0		1	1
Retired	6			6
Other		1		1
Employment hours:	(n=13)		(n=3)	(n=16)
< 15 hours/wk	2		1	3
16-40 hours/wk	10 (78%)		2	12
41 or more	1			1
Housing:			(N=5)	(N=39)
Owned	7 (22%)		2	9
Council/HA	18 (58%)	3	2	23 (59%)
Private rent	5 (16%)		1	6
Other	1			1

Table 6: Effect of increased recruitment or clinician enquiry rates on proportion of recruited women who are asked about domestic violence

	Actual	Increase in research interview rate/ recruitment rate	Increase in asking rate/ referral rate	Increase in both
Research interview rate	12%	25%	12%	25%
Recruitment rate	11%	14%	11%	14%
Asking rate	6.3%	6.3%	50%	50%
Referral rate	10%	10%	14%	14%
Proportion of study participants affected by intervention	4.5%	4.5%	50%	50%