Advocacy interventions to reduce or eliminate violence and promote the physical and psychosocial well-being of women who experience intimate partner abuse

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The Campbell Collaboration Social Welfare Group

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Protocol information

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Background

Description of the condition

Intimate partner abuse

For the purpose of this review, intimate partner abuse (often termed domestic violence) is defined as abuse of a woman by a male or female partner who currently is, or formerly was, in an intimate relationship with the woman. Intimate partner abuse perpetrated by women or men against male partners or ex-partners also occurs but it is not included in this review because the outcomes, and possibly the risks for partner violence perpetration by each gender, are likely to be different and should not therefore be included in the same review. The majority of abuse with serious health and other consequences is that committed by men against their female partners (Henwood 2000). Abuse perpetrated by ex-partners is included in the review since often a woman is at greatest risk when she is preparing to leave or has just left her partner. It is estimated that between 65% and 75% of women killed by abusive partners are killed while leaving or after already leaving the relationship (Wilson 1993). Intimate partner abuse may take various forms, including physical violence (ranging from slaps, punches and kicks to assaults with a weapon, choking and homicide), sexual violence (such as forced sex, or forced participation in sexual acts), emotionally abusive behaviours (such as stalking, surveillance, threats of abuse, threats to remove children from the household, prohibiting a woman from seeing her family and friends, ongoing belittlement or humiliation, or intimidation), economic restrictions (such as preventing a woman from working, confiscating her earnings, restricting access to funds), and other controlling behaviours (Watts 2002). Additionally, disabled women in abusive relationships may experience withholding of orthotic equipment, medications, transportation, or essential assistance with personal tasks, such as dressing or getting out of bed (Nosek 1998). The different forms of abuse often co-exist, but they may also present in isolation (Taft 2001). Partner abuse may also co-exist with other forms of violence within families, such as child abuse or elder abuse, but such abuse is not the focus of this review.

Prevalence of intimate partner abuse

The 2001 British Crime Survey found that 20% of women in England and Wales reported being physically assaulted by a current or former partner at some time in their lives; and when threats, financial abuse and emotional abuse were included in the definition of intimate partner abuse the prevalence rose to 25% of women (Walby 2004a). Research in the United States indicates that nearly one in three adult

women experience at least one physical assault by a partner during adulthood and four million American women experience a serious assault by a partner during an average 12-month period (APAPTFVF 1996). The prevalence of intimate partner abuse among those women seeking health care is higher than that of the general population. In a primary care study, we found a lifetime experience of physical and sexual violence of 41%, with 17% of women experiencing such violence in the past year (Richardson 2002). Abuse of women by their partners is a world-wide phenomenon (Watts 2002). Fifty-one cross-sectional population surveys conducted in various countries on behalf of the World Health Organisation show a lifetime prevalence of between 10%-50% and between 3%-52% for the experience of physical violence in the previous year (WHO 2001; Heise 1999). Disabled women may be at even greater risk of being abused. In a North American sample of women with physical disabilities, 62% reported having experienced emotional, physical, or sexual abuse in their lifetimes (Nosek 1998).

The impact of intimate partner abuse on health of women

Intimate partner abuse can have short-term and long-term negative health consequences for survivors, even after the abuse has ended (Campbell 2002). World Development Reports (World Bank 2006) and statements from the United Nations (Ingram 2005) emphasise that such violence is a significant cause of death and disability on a world-wide scale and the World Health Organisation (Krug 2002) highlights violence against women as a priority health issue.

In 1997, two women in England and Wales were killed each week by their current or former partners (HMSO 1998), a figure that represents 47% of all female homicides for that year (HMSO 1997). In the United States and Canada, 31%-60% of murders of women during the 1990's were committed by intimate partners (Craven 1997; Crawford 1997; Brock 1999). Percentages may be even higher in less industrialised countries, but there is little global data on the murder of abused women (Gartner 1990).

Physical health of abused women

Intimate partner abuse is one of the most common causes of non-fatal injury in women. In the USA a review estimated that 50% of all acute injuries and 21% of all injuries in women requiring urgent surgery were the result of partner abuse (Guth 2000).

Abused women also experience many chronic health problems. The most consistent and largest physical health difference between

abused and non-abused women is the experience of gynaecological problems (e.g. sexually-transmitted diseases, vaginal bleeding and infection, genital irritation, chronic pelvic pain, urinary-tract infections) (Campbell 2002). Population based studies from the United States show that the likelihood of abused women exhibiting these symptoms are three times greater than average (McCauley 1995). Other conditions include chronic pain (e.g. headaches, back pain) and central nervous system symptoms (e.g. fainting and seizures), (Campbell 2002; DiazOlavarrieta 1999), self-reported gastrointestinal symptoms (e.g. loss of appetite, eating disorders) and diagnosed functional gastrointestinal disorders (e.g. irritable bowel syndrome) (DiazOlavarrieta 1999; Coker 2000), and self-reported cardiovascular symptoms (e.g. hypertension, chest pain) (Tollestrup 1999).

Health of abused women during pregnancy

Research evidence shows that intimate partner abuse continues when a woman becomes pregnant - indeed, it may even escalate (Gazmararian 2000; Mezey 1997). A review by Campbell shows that prevalence rates of abuse during pregnancy are very similar in industrialised and non-industrialised countries (Campbell 2002). Most studies in the United States show that between 4%-8% of pregnant abused women are physically abused during pregnancy. This compares closely with 6%-8% during the past year in the United Kingdom, 6%-7% in Canada, at least 7% in South Africa, but is substantially lower than the 11%-21% in Sweden, and 13% in Nicaragua. The health risks for abused mothers and their unborn children are substantial. The most serious outcome is the death of the mother (Parsons 1999) or the foetus (McWilliams 1993; Jejeebhoy 1998). In well-designed studies, the outcome most associated with partner abuse is low birth weight, although there is also evidence for increased risk of miscarriage (Gazmararian 2000; Taft 2004) and foetal injury (Mezey 1997).

Psychosocial health of abused women

The most prevalent mental health sequelae of intimate partner abuse are depression and post-traumatic stress disorder (McCauley 1995; Ratner 1993; Golding 2002; Coid 2003). Women living in abusive relationships are three times more likely to be diagnosed depressed or psychotic (Stark 1996) and they often have feelings of low self-esteem and hopelessness (Kirkwood 1993). Among Australian women attending general practice who have been abused, depressed women are significantly more likely to have experienced combined physical, emotional and sexual abuse than are non-depressed abused women (Hegarty 2004). Living in a violent

relationship may exacerbate a predisposition to depression; however, a woman's first exposure to abuse can also be a causal factor for subsequent depression (Campbell 1999; Silva 1997). Abused women are nearly four times as likely to suffer from post-traumatic stress disorder compared with non-abused women, and this can be directly related to experiencing intimate partner abuse (Golding 2002; Silva 1997). There is also evidence from the United States, Scandinavia and Papua New Guinea that increased suicidal tendencies are associated with abuse (Counts 1987; Golding 2002). Other signs of emotional distress associated with intimate partner abuse are self-harm and para-suicide (Stark 1996; Heath 2003), anxiety, insomnia and social dysfunction (Ratner 1993). A Nicaraguan study found that 70% of cases of emotional distress in women were a direct consequence of abuse (Ellsberg 1999).

In industrialised countries a further mental health problem associated with partner violence is the abuse of alcohol and drugs (McCauley 1995; Ratner 1993; Golding 2002). Substance abuse and intimate partner abuse often co-occur. Women who have experienced physical or psychological violence are fifteen times more likely to abuse alcohol and nine times more likely to abuse drugs than are non-abused women (Stark 1996). There is also evidence that alcohol and drug abuse for some women is directly attributable to intimate partner abuse (Stark 1996; Golding 2002).

The impact of intimate partner abuse on health service usage

Women experiencing intimate partner abuse present to health services very frequently and require wide-ranging medical services (Campbell 2002; Davidson 2001). They are admitted to hospital more often than are non-abused women and are prescribed more medication (Koss 1991; Wisner 1999), particularly analgesia (Lo Fo Wong 2007). A Canadian study set in a hospital accident and emergency department found that abused women access medical care three times more often than non-abused women do (Ratner 1993). There is also evidence of a positive linear relationship between severity of abuse and the use of health-care services (Koss 1991).

It is difficult to calculate the societal economic impact of intimate partner abuse but the costs are high (Walby 2004b). In a study that compared health plans in the United States, a 92% increase in costs was associated with partner abuse, with much of this increased cost being attributable to providing mental health care provision (Wisner 1999). A recent Australian study estimated that in 2002-3 the costs to

the community were in the order of AUD8.1 billion with the main contributors being pain, suffering and premature mortality (Access 2004). Thus, in addition to the very serious individual health consequences associated with abuse, there are also wider economic implications for society.

Description of the intervention

Interventions to improve the health consequences for women who are experiencing or have previously experienced intimate partner abuse

Interventions may be primary, secondary or tertiary. In the context of intimate partner abuse, primary interventions are concerned with preventing the onset of abuse, secondary interventions aim to prevent further abuse, and tertiary interventions deal with the consequences of abuse once the abuse has ceased. The focus of this review is on secondary and tertiary intervention.

A range of such interventions has been evaluated. These may be classified as interventions aimed at directly helping abused women (such as the provision of advocacy or therapy), and those aimed at indirectly helping abused women by improving the response of the professionals with whom they come into contact (such as the introduction of screening protocols or the provisi on of education and training about intimate partner abuse). In order to have clear evidence about what professionals can do safely and effectively to decrease the impact of intimate partner abuse on women, all such interventions need to be evaluated. To this end, we have planned to conduct a suite of systematic reviews evaluating the effectiveness of interventions to improve the health consequences for women who are experiencing or have previously experienced intimate partner abuse. This review is the first of these and examines the effectiveness of individual advocacy interventions (see also Taft 2007).

Advocacy

In the context of domestic violence services, advocacy is a term that varies within and between countries, depending on institutional settings and historical developments of the role of advocates. (Feder 2006a). Advocates engage with individual clients who are being abused, aiming to empower them and linking them to the community services. In some health settings they may also have a role in bringing about system change, catalyzing increased recognition by

clinicians of women experiencing abuse. For the purposes of this review we define the core activity of advocacy as provision of legal, housing and financial advice and, facilitating access to and use of community resources such as refuges or shelters, emergency housing, and psychological interventions. Advocates can also provide ongoing support and informal counselling. The heterogeneity in models of advocacy will be explored in more depth in the review itself, based on the descriptions of interventions in the primary studies.

How the intervention might work

Most advocacy interventions are based around the concept of empowerment: talking through potential solutions with the woman (rather than being prescriptive and telling her what she ought to do), helping the woman to achieve the goals she has set, and helping her to understand and make sense of the situation and her responses to it (Campbell 1993).

The aims of advocacy programmes are multifaceted and may include helping abused women to access services, the reduction or cessation of abuse, and the improvement of abused women's physical or psychological health. Advocacy may be offered as a stand alone service, but may also be part of a multi-component, multi-agency intervention. At present, it is not known whether multi-component interventions are more effective than those comprising a single component.

Why it is important to do this review

We plan to examine in this systematic review that follows this protocol to examine the effectiveness of advocacy interventions with individual women who are still with their partners, as well as those who have left the abusive relationship. This is because it is known that women who leave violent relationships often continue to be abused, sometimes because the partner pursues them or they choose to return (Mullen 1999; Shalansky 1999), or because the woman enters another abusive relationship (Hegarty 1999; Summerfield 2003).

Objectives

To assess the effectiveness of advocacy interventions conducted within or outside of health care settings for women who are experiencing or have previously experienced intimate partner abuse.

Methods

Criteria for considering studies for this review

Types of studies

Controlled studies which allocate participants or clusters of participants by a random or a quasi-random method (such as alternate allocation, allocation by birth date, etc) to an advocacy intervention compared with usual care. For this review, we define "usual care" as that care typically provided at that setting *or* that care with minimal additions in the form of an information card or leaflet listing the addresses and telephone numbers of local support agencies.

Types of participants

Women aged 15 years and over identified as having experienced intimate partner abuse, recruited from any setting.

Eligible studies can recruit women in any settings, including health care or criminal justice facilities, refuges or domestic violence agencies. Typically, recruitment is via face-to-face contact with consecutive women in these settings.

Types of interventions

Any advocacy intervention compared to usual care. Studies will be included if the intervention incorporated facilitation of access to and use of community resources such as refuges or shelters, emergency housing, and psychological care, either with or without ongoing informal support or counselling for the woman.. We will include studies where advocacy is evaluated as an adjunct to another intervention, such as psychotherapy, but only where advocacy is the only difference between arms of the study.

Types of outcome measures

Primary outcomes

Incidence of abuse

Forms of abuse included:
(i) physical
(ii) sexual
(iii) emotional
(iv) financial

Abuse may be assessed using self-report measures (scales such as Index of Spouse Abuse, Women's Experience of Battering, Conflict

Tactics Scale, or a single question about continuing abuse) or from the recording of abuse in medical or police records.

Psychosocial health

(i) quality of life (measures such as SF-36)
(ii) depression (measures such as Center for Epidemiologic Studies Depression Scale)
(iii) anxiety (measures such as Spielberger's State-Trait Anxiety Inventory)

Secondary outcomes

Physical health

(i) deaths, all-cause and partner abuse-related (documented in medical/police records/regional and national databases)
(ii) physical injuries, such as fractures and bruises (self-reported or documented in medical and dental records)
(iii) any chronic health disorders, such as gynaecological problems, chronic pain and gastrointestinal disorders (self-reported or documented in medical and dental records)
(iv) any general measures of physical health (measures such as Daily Symptoms Questionnaire)
(v) pre-term birth (self-reported or documented in medical records)

Psychosocial health

(i) post-traumatic stress (measures such as Impact of Events scale)
(ii) self efficacy (measures such as Generalized Perceived Self-Efficacy Scale)
(iii) self-esteem (measures such as Rosenberg Self Esteem Scale)
(iv) perceived social support (measures such as Sarason's Social Support Questionnaire)
(v) alcohol or drug abuse (measures such as Addiction Severity Index, Alcohol and other Drug Abuse Scale)
(vi) attempted suicide(self-reported or documented in medical records)
(vii) self-harm (self-reported or documented in medical records)
(viii) impact on relationships (self-reported)

Socio-economic outcome measures

(i) income
(ii) housing
(iii) participation in education
(iv) participation in work

'Proxy' or intermediate outcome measures (including take-up of referrals to other agencies)

(i) the use of safety behaviours (e.g. use of coded telephone messages to a friend, keeping clothes at a friend's house, hiding emergency money)
(ii) the use of refuges/shelters
(iii) the use of counselling
(iv) calls to police
(v) police reports filed
(vi) protection orders sought
(vii) maintenance of family ties (i.e. children staying with mother)

We recognise that post-intervention changes in some of these proxy measures may be associated with both 'positive' and 'negative' health outcomes for abused women and require careful interpretation. For instance, increased refuge/shelter usage may reflect proactive behaviour on the behalf of abused women but it may also reflect an escalation of violence that has led to the women needing to seek safety. Where authors report any adverse outcomes from interventions, such events will be recorded and discussed in a narrative summary.

Timing of outcome assessment

We plan to document the duration of follow-up in all included studies. We do not know the optimum period of follow-up. Thus, while an intervention may have some immediate positive effects on the health of an abused woman (such as a reduction in physical violence), other outcomes may not be so readily apparent. For example, even after leaving an abusive relationship, a woman may be traumatised for many months afterwards and any positive mental health effects may not be evident for some time. For purposes of this review, we will define short-term follow-up as up to and including 12 months, medium-term follow-up as from 12 to 24 months, and long-term follow-up as more than two years.

Search methods for identification of studies

Searches will be undertaken of the international literature for peer-reviewed and non-peer reviewed studies. There will be no language or date restrictions applied to the search strategies used and a trials filter will not be applied as we want searches to be as inclusive as possible.

Electronic searches

The following electronic databases will be searched:

CENTRAL and DARE (Cochrane Library)

MEDLINE
EMBASE
CINAHL

ASSIA
Social Science Citation Index
IBSS
PsycINFO
British Nursing Index
metaRegister of Controlled Trials
Health Management Information Consortium
Midwives Information and Resource Index

The search strategy for MEDLINE is as follows:

1.(BATTERED ADJ WOMEN).TI,AB.
2.BATTERED-WOMEN.MJ. OR SPOUSE-ABUSE.MJ. OR DOMESTIC-VIOLENCE.MJ.
3.(ABUSE$3 NEAR WOM$3).TI,AB.
4.(ABUSE$ NEAR PARTNER$).TI,AB.
5.(ABUSE$ NEAR SPOUS$).TI,AB.
6.((WIFE OR WIVES) NEAR BATTER$).TI,AB.
7.((WIFE OR WIVES) NEAR ABUSE$).TI,AB.
8.(VIOLEN$ NEAR PARTNER$).TI,AB.
9.(VIOLEN$ NEAR SPOUS$).TI,AB.
10.(VIOLEN$ NEAR (DATE OR DATING)).TI,AB.
11.1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10
12.(CHILD ADJ ABUSE).TI,AB.
13.CHILD-ABUSE.MJ. OR CHILD-ABUSE-SEXUAL.MJ.
14.11 NOT (12 OR 13)
15.(WOM$3 OR FEMALE$3).TI,AB.
16.WOMEN.MJ. OR FEMALE.MJ.
17.(ADOLESCEN$ OR TEEN$).TI,AB.
18.ADOLESCENT.MJ.
19.15 OR 16 OR 17 OR 18
20.ADVOCACY.TI,AB.
21.PATIENT-ADVOCACY#.DE. OR CONSUMER-ADVOCACY#.DE.
22.COUNSEL$.TI,AB.
23.COUNSELING#.W..DE.
24.(SOCIAL ADJ WORK).TI,AB.
25.SOCIAL-WORK#.DE.
26.MENTOR$.TI,AB.
27.MENTORS#.W..DE.
28.(CRISIS ADJ INTERVENTION).TI,AB.

29.CRISIS-INTERVENTION#.DE.
30.(RISK ADJ ASSESSMENT).TI,AB.
31.RISK-ASSESSMENT#.DE.
32.(SOCIAL ADJ WELFARE).TI,AB.
33.SOCIAL-WELFARE#.DE.
34.(SOCIAL ADJ SUPPORT).TI,AB.
35.SOCIAL-SUPPORT#.DE.
36.(HELP ADJ SEEKING).TI,AB.
37.(INFORMATION ADJ GIVING).TI,AB.
38.(GIV$3 ADJ INFORMATION).TI,AB.
39.(ADVICE ADJ GIVING).TI,AB.
40.(GIV$3 ADJ ADVICE).TI,AB.
41.(PATIENT ADJ EDUCATION).TI,AB.
42.PATIENT-EDUCATION#.DE.
43.HEALTH-EDUCATION#.DE.
44.SAFETY.TI,AB.
45.SAFETY#.DE.
46.(WOMENS ADJ HEALTH).TI,AB.
47.WOMENS-HEALTH#.DE.
48.20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47
49.14 AND 19 AND 48

Terms will be modified as necessary for other databases, and all search strategies will be reported in the completed review.

We plan to search other electronic sources including the website of the World Health Organisation (http://www.who.int/topics/violence/en/) and the Violence Against Women Online Resources (http://www.vaw.umn.edu/) website.

Searching other resources

Handsearching

We will handsearch the following journals from 1980 onward : *American Journal of Public Health*, *Australian and New Zealand Journal of Public Health*, *Journal of Family Violence*, *Medical Journal of Australia*, *Violence and Victims*, and *Women's Health*.

Citation tracking

We will examine the reference lists of acquired papers, and tracked citations forwards and backwards.

Other search strategies

In order to check for possible omissions, we will contact the first or correspondence authors of all the primary studies included in the review and also relevant researchers and members of intimate partner abuse groups and related organisations around the world. Efforts will be made to make contacts in European countries where English is not the first language via the *Domus Medicus* organisation, and worldwide via the MRC Gender & Health Unit and the Department of Gender and Women's Health at WHO.

Data collection and analysis

Selection of studies

Abstracts of articles found will be reviewed independently by two review authors in pairs (JR and CR or JR and DD or JR and GF). Where possible, disagreements between the review authors will be resolved by discussion. When agreement cannot be reached during selections, a third adjudicator (either GF or an editor from the CDPLPG editorial base) will be consulted to help assess whether the study potentially fulfils inclusion criteria.

Full articles for abstracts selected will be retrieved and each of the articles assessed independently against the inclusion criteria by two of the review authors, in pairs. Any disagreements will be resolved as above.

Data extraction and management

Data from included studies will be extracted by one review author and entered onto electronic collection forms. Any missing information will be requested from the first or correspondence authors of papers. All extractions will be independently checked by a second author. This work will be done in review author pairs (JR, DD, and CR). Again, where possible any disagreements between the two review authors will be resolved by discussion and no adjudication by a third author will be required. Where necessary, the first authors of studies or the correspondence authors will be contacted to assist in resolving the disagreement. All relevant extracted data will be entered into RevMan 5.0.

We will record the following information in the Table 'Characteristics of Included Studies':

- Methods: randomisation method, intention to treat analysis, power calculation
- Participants: method of identification/recruitment of participants, setting, country, inclusion criteria, exclusion criteria, numbers

recruited, numbers dropped out, numbers analysed, age, ethnicity, socioeconomic status, educational background

- Interventions: brief descriptions of intervention (including frequency and duration of intervention events) and details of comparison (the '-usual care' provided)
- Outcomes: timing of assessments, outcomes assessed, scales used
- Notes: where necessary, further information to aid understanding of the study

Assessment of risk of bias in included studies

We will evaluate the validity of the trials by the following criteria: Methodological quality will be assessed independently by two review authors (JR and GF) according to the Cochrane Collaboration Handbook (Higgins 2008). Review authors will independently assess the risk of bias within each included study based on the following six domains with ratings of 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias):

Sequence generation

Description: the method used to generate the allocation sequence will be described in detail so as to assess whether it should have produced comparable groups; review authors' judgment: was the allocation concealment sequence adequately generated?

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Allocation concealment

Description: the method used to conceal allocation sequence will be described in sufficient detail to assess whether intervention schedules could have been foreseen in advance of, or during, recruitment; review authors' judgment: was allocation adequately concealed?

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Blinding

Description: any measures used to blind outcome assessors will be described so as to assess knowledge as to which intervention a given participant might have received; review authors' judgment: was knowledge of the allocated intervention adequately prevented during the study?

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Incomplete outcome data

Description: If studies do not report intention-to-treat analyses, attempts will be made to obtain missing data by contacting the study authors. Data on attrition and exclusions will be extracted and reported as well the numbers involved (compared with total randomized), reasons for attrition/exclusion where reported or obtained from investigators, and any re-inclusions in analyses performed by review authors; review authors' judgment: were incomplete data dealt with adequately by the reviewers? (See also 'Dealing with missing data', below).

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Selective outcome reporting

Description: attempts will be made to assess the possibility of selective outcome reporting by investigators; review authors' judgment: are reports of the study free of suggestion of selective outcome reporting?

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Other sources of bias

Was the study apparently free of other problems that could put it at a high risk of bias?

In addition to the categories above, we will assess the following for each included study:

Baseline measurement

Description: did investigators assess intervention and control groups at baseline to ensure comparability between groups; review authors' judgment: were groups comparable at baseline or were change scores provided to account for differences?

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Reliability of primary outcome measures

Description: information should be provided by the study investigators to confirm that the primary outcomes were measured

using reliable scales (e.g. Cronbach's alphas of ≥ 0.6 are reported); review authors' judgment: are the primary outcomes assessed using reliable measures?

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Protection against contamination

Description: the allocation process should protect against contamination, i.e. against the possibility that participants in the control group will receive all or part of an intervention (examples of possible contamination include the interventionist also providing "usual care" for control group participants, or participants in the intervention and control arms having the opportunity to communicate); review authors' judgment: were adequate steps taken by the study investigators to prevent contamination)?

Ratings: 'Yes' (low risk of bias); 'No' (high risk of bias) and 'Unclear' (uncertain risk of bias)

Measures of treatment effect

Binary outcomes

For binary outcomes, a standardised estimation of the Odds Ratio (OR) with a 95% confidence interval will be calculated.

Continuous outcomes

Continuous data will be analysed where means (or mean changes) and standard deviations are available in published reports or are obtainable from the authors of studies, or calculable. In those instances where means and standard deviations are not available and cannot be calculated, findings will be reported as by the study authors.

Where studies use different scales to measure similar outcomes, treatment effects for these outcomes will be standardised by dividing the mean difference in post-intervention scores or change from baseline scores for the intervention and control groups by the pooled standard deviation to create the Standardised Mean Difference (SMD) with 95% confidence intervals.

Unit of analysis issues

(a) Cluster-randomised trials

Where trials have used clustered randomisation, we anticipate that study investigators would have presented their results after appropriately controlling for clustering effects (robust standard errors or hierarchical linear models). If it is unclear whether a cluster-randomised trial has used appropriate controls for clustering, the study investigators will be contacted for further information. Where appropriate controls were not used, individual participant data will be requested and re-analysed using multilevel models which control for clustering. Following this, effect sizes and standard errors will be meta-analysed in RevMan5 using the generic inverse method (Higgins 2008)). If appropriate controls were not used and individual participant data is not available, author SE (responsible for statistical guidance in this review) will attempt to control for clustering. If there is insufficient information to control for clustering, outcome data will be entered into RevMan5 using individuals as the units of analysis, and then sensitivity analysis will be used to assess the potential biasing effects of inadequately controlled clustered trials (Donner 2001).

(b) Multi-arm trials

All eligible outcome measures for all trial arms will be included in this review.

Dealing with missing data

We will contact the original investigators to request any missing data and information on whether or not it can be assumed to be ‘missing at random’.

For dichotomous data, we will report missing data and dropouts for each included study and report the number of participants who are included in the final analysis as a proportion of all participants in each study. We will provide reasons for the missing data in the narrative summary and will assess the extent to which the results of the review could be altered by the missing data by, for example, a sensitivity analysis based on consideration of 'best-case' and 'worst-case' scenarios (Gamble 2005). Here, the 'best-case' scenario is that where all participants with missing outcomes in the experimental condition had good outcomes, and all those with missing outcomes in the control condition had poor outcomes; the 'worst-case' scenario is the converse (Higgins 2008, section 16.2.2).

For missing continuous data, we will provide a qualitative summary. The standard deviations of the outcome measures should be reported for each group in each trial. If these are not given, we will impute standard deviations using relevant data (for example, standard deviations or correlation coefficients) from other, similar

studies (Follman 1992) but only if, after seeking statistical advice, to do so is deemed practical and appropriate.

We will report separately all data from studies where more than 50% of participants in any group were lost to follow-up, and will exclude these from any meta-analyses.

Assessment of heterogeneity

We will assess the extent of between-trial differences and the consistency of results of any meta-analysis in three ways: by visual inspection of the forest plots, by performing the Chi squared test of heterogeneity (where a significance level less than 0.10 will be interpreted as evidence of heterogeneity), and by examining the I^2 statistic (Higgins 2008; section 9.5.2). The I^2 statistic describes approximately the proportion of variation in point estimates due to heterogeneity rather than sampling error. We will consider I^2 values less than 30% as indicating low heterogeneity, values in the range 31% to 69% as indicating moderate heterogeneity, and values greater than 70% as indicating high heterogeneity. We will attempt to identify any significant determinants of heterogeneity categorised at moderate or high.

Assessment of reporting biases

We plan to draw funnel plots to investigate any relationships between effect size and study precision, closely related to sample size (Egger 1997). For meaningful funnel plots, a large number of trials with a spread of sample sizes are required (Glasziou 2001; Hayashino 2005).

Data synthesis

Where comparable data are available we plan to perform meta-analyses. The decision whether to pool data in this way will be determined by the comparability of populations and interventions (clinical heterogeneity), of the duration of follow-up (methodological heterogeneity), and of the outcomes being used in the primary studies. Where we deem it inappropriate to combine the data in a meta-analysis, we will document reasons transparently and present effect sizes and 95% confidence intervals for individual outcomes in individual studies.

Subgroup analysis and investigation of heterogeneity

Should sufficient data be available we plan to perform subgroup analyses for the following: comparisons where advocacy is the sole active intervention and those where it is combined with other

interventions; and interventions set in health service settings versus non-health service settings. Theoretical justification for subgroup analyses:

(i) Domestic violence activists and service providers argue that the effectiveness of advocacy is enhanced by integration of advocacy services into a coordinated community response, including criminal justice agencies, refuges/shelters, welfare support, and health health services. (Feder 2006). This strategy, based on the 'Duluth' model, is a network of agreements, processes and applied principles created by the local shelter movement, criminal justice agencies, health care and human service programmes (Clapp 2000). The proposed sub-group analysis will test whether the (potential) effectiveness of advocacy is enhanced (or diminished) by other interventions in the context of a coordinated community response. It is theoretically plausible that even in the absence of a full community coordinated response, an additional intervention combined with advocacy will have a synergistic effect and therefore we will include studies that test a combined intervention, as long as the control group is also exposed to the additional intervention;

(ii) If domestic violence advocacy is an effective intervention overall, policy makers and service commissioners need to know if this effect is moderated by the setting in which it is delivered. For example, if a health care setting enhanced the effect, then this would be an appropriate context for commissioning advocacy

Sensitivity analysis

To assess the robustness of conclusions to quality of data and approaches to analysis, sensitivity analyses are planned to investigate the effects of study quality, differential drop-out, intention to treat, and duration of follow up.

Timeframe

Review authors intend to complete this work within a year and to update within three years.

Acknowledgements

We are grateful to the DPLPG editors and staff, particularly to our contact editor, Professor Geraldine Macdonald, and Review Group Coordinator, Jane Dennis, for their input.

SFI Campbell supports this review.

Contributions of authors

Jean Ramsay will write the protocol, search databases, select papers, extract data from papers, enter and analyse data, write the first draft of the review and edit text. Gene Feder will edit the protocol, select papers, extract data, analyse data and edit text of the review. Carol Rivas and Danielle Dunne will search databases, select papers, extract data from papers, contribute to assessment of results and edit the text of the review. Sandra Eldridge will provide statistical guidance and edit text of the review. Yvonne Carter, Leslie Davidson, Kelsey Hegarty Angela Taft and Alison Warburton will contribute to the writing and editing of the protocol, results, and final text of the review.

Declarations of interest

None known.

Published notes

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