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Reaching Everyone Programme of Research On Violence In diverse Domestic Environments

PROTOCOL - confidential

Feasibility of a randomised controlled trial of a group programme for men who are concerned about their behaviour in relationships with women: pilot study

- **This protocol is structured in concordance with HRA guidance and order of content**

Short title: Trial of a group programme intervention for men who are concerned about their behaviour

PROTOCOL VERSION NUMBER AND DATE

- Version 2.0
- Dated 09/02/2018

RESEARCH REFERENCE NUMBERS

IRAS Number:	178666
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ISRCTN Number / Clinical trials.gov Number:	ISRCTN71797549
SPONSORS Number:	UoB RRC 2630
FUNDERS Number:	NIHR RP-PG 0614-20012

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: DocuSigned by: A6FCBDDBFE914CD... Date: ...../...../.....

June 9, 2022

Name (please print): Adam Taylor

Position: Head of Research Governance

Chief Investigator:

Signature: Date: 21/10/21.

Name: (please print):

.....PROFESSOR GENE FEDER……..

Statistician:

Signature:

T. J. Peters 21 October 2021

Name: (please print):

.....PROFESSOR TIM PETERS.....

Position: Lead Statistician

.....

KEY TRIAL CONTACTS

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Funder(s)	National Institute for Health Research (NIHR) Ref: RP-PG-0614-20012
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Independent Programme/Trial Steering Committee (PSC):	**Dr Penny Bee (Independent Chair)** The School of Nursing, Midwifery and Social Work The University of Manchester Room 6.320, Jean McFarlane Building University Place Oxford Road Manchester, M13 9PL Penny.E.Bee@manchester.ac.uk Prof Rafael Perera-Salazar Professor of Medical Statistics Primary Health Care Oxford University rafael.perera@phc.ox.ac.uk Dr Amanda L. Robinson Reader in Criminology 1.01A. Glamorgan Building Cardiff University Cardiff, Wales, CF10 3AT robinsona@cardiff.ac.uk PPI Member representing female survivor group PPI Member representing male (ex)perpetrator group
Data Monitoring and Ethics Committee (DMEC)	**Chair: Prof. Judith McFarlane (Independent Chair)** Texas Woman's University Institute of Health Sciences-Houston Center 6700 Fannin St Houston, TX 77030 Prof. Toby Prevost Chair in Medical Statistics and Clinical Trials School of Public Health, Imperial College London a.prevost@imperial.ac.uk Dr. Alecia Nickless Trial Statistician Nuffield Department of Primary Care Health Sciences University of Oxford Radcliffe Primary Care Building Oxford, OX2 6GG alecia.nickless@phc.ox.ac.uk Dr Julie McGarry Faculty of Medicine & Health Sciences Queen's Medical Centre Nottingham, NG7 2UH julie.mcgarry@nottingham.ac.uk

TRIAL SUMMARY

Trial Title	Feasibility of a randomised controlled trial of a group programme for men who are concerned about their behaviour in relationships with women: pilot study	
Internal ref. no. (or short title)	Group programme for men who are concerned about their behaviour in relationships with women: a pilot trial	
Phase	pilot trial	
Trial Design	Individual randomisation	
Trial Participants	Men aged 21 and over and their female partners or ex-partners (aged 18 or over)	
Planned Sample Size	36 men plus their current or ex-partners (a total planned sample size of up to72)	
Treatment duration	The intervention programme is for 26 weeks	
Follow up duration	Up to 9 months	
Planned Trial Period	March 2017 – September 2018	
	Objectives	Outcome Measures
Primary	Sufficient men and partners recruited in order to meet progression criteria	Number of participants
Secondary	Sufficient men and partners retained and followed up in order to meet progression criteria	Number of participants

FUNDING AND SUPPORT IN KIND

FUNDER(S)	
NIHR **Ref: RP-PG-0614-20012** **Programme Manager: Emma Thompson**	**Financial** **Programme Grant for Applied Research**

ROLE OF STUDY SPONSOR AND FUNDER

The Sponsor (University of Bristol) oversee the regulatory and governance procedures are in place before, during and after the trial. The Sponsor ensures that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. This includes the safety and welfare of research staff (employees).

The Department of Health have prepared a contract between Bristol CCG (the grantholders) the University of Bristol (the provider) and other parties. The contract outlines the responsibilities of the funder.

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

- Programme Steering Committee

  The PSC will provide the overall supervision of the pilot trial, functioning as its TSC. It is completely independent of the investigators, their employing organisations, funders and sponsors. It will meet 2-3 times per year.

  Chair: Dr Bee

- Data Monitoring and Ethics Committee

  The DMEC will assess, at intervals, the progress of the pilot and safety data, and to recommend to the TSC and the sponsor whether to continue, modify, or stop a trial. It is completely independent of the investigators, their employing organisations, funders and sponsors. This committee will meet 2-3 times per year and be available in order to oversee any decisions regarding ethical considerations that occur throughout the trial.

  Chair: Prof Judith McFarlane

- Trial Management Group

  The Trial Management Group will meet 4 times a year to ensure all practical details of the trial are progressing and working well and that everyone within the trial understands them. This group will be formed by the following, in addition to other members of our Programme Advisory Group.

  Members: Prof Gene Feder (CI), Dr Mei-See Man (Programme manager), Dr Helen Cramer (workstream lead), Dr Karen Morgan (research fellow), Prof Tim Peters (statistician), Daisy Gaunt (Statistician), Dr Rebecca Kandiyali (economist), data manager, Neil Blacklock (Respect research director), representative from service provider, representatives from women and men PPI groups, respectively.

  Chair: Professor Feder

Protocol contributors

Dr Mei-See Man, Research Fellow and Programme Manager of the REPROVIDE Programme, of which this pilot trial from Workstream II is Study 7.

Role on Trial: To oversee and monitor that correct governance is in place prior to and during the trial and that trial related procedures are performed by all parties to acceptable standards of Good Clinical Practice.

Dr Helen Cramer, Research Fellow

Dr Karen Morgan, Research Fellow

Professor Tim Peters, Lead Statistician

Dr Rebecca Kandiyali, Lead Health Economist

Professor Gene Feder, Chief Investigator

Dr Birgit Whitman, Sponsor, University of Bristol

KEY WORDS:

Domestic violence and abuse (DVA)
Perpetrator and victim/survivor
Randomised controlled trial
Domestic violence perpetrator programme (DVPP)
Complex intervention
Mental health

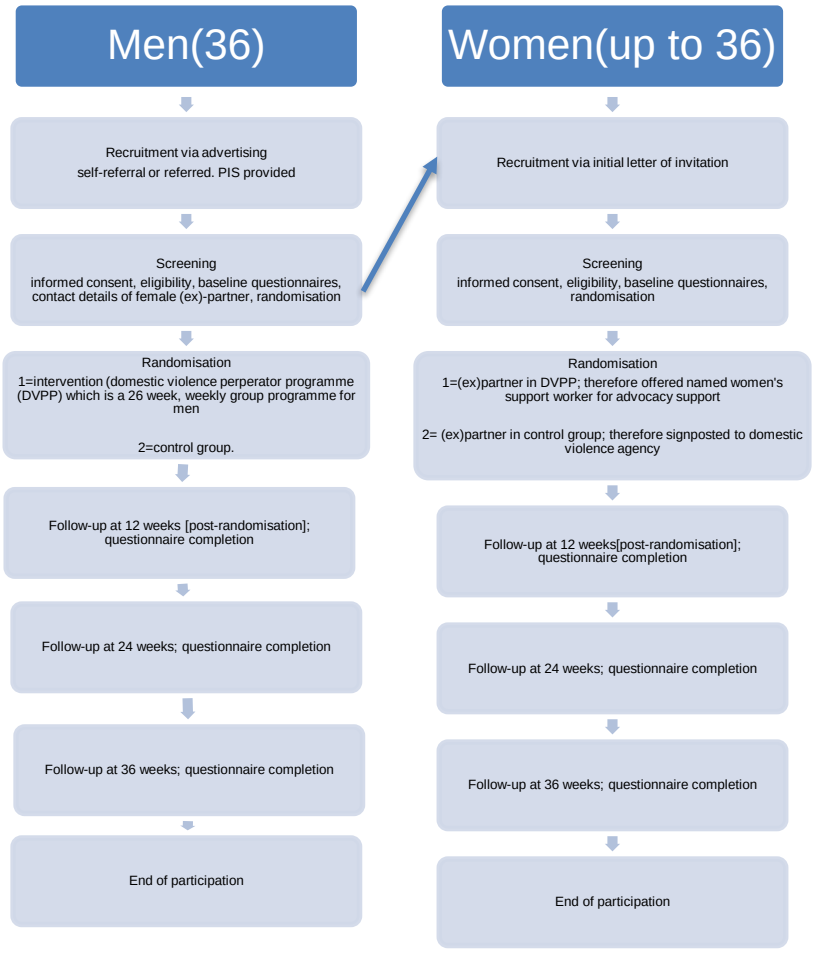
LIST of CONTENTS

LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
DMEC	Data Monitoring and Ethics Committee
DVA	Domestic violence and abuse
DVPP	Domestic violence perpetrator programme
GCP	Good Clinical Practice
ICF	Informed Consent Form
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
NHS R&D	National Health Service Research & Development
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
REPROVIDE	Reaching Everyone: Programme of Research on Violence in diverse Domestic Environments
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
TMG	Trial Management Group
TSC	Trial Steering Committee
TMF	Trial Master File

TRIAL FLOW CHART



- All participants will be contacted 2 weeks prior to follow-up due date to check informed consent and remind of participation.
- A selection of participants will be invited for interview during the study (see section 19 - qualitative interviews)

Feasibility of a randomised controlled trial of a group programme for men who are concerned about their behaviour in relationships with women: pilot study

1. BACKGROUND

Domestic violence and abuse (DVA), is defined as any incident or pattern of incidents of controlling coercive or threatening behaviour, violence or abuse between people aged 16 or over who are or have been intimate partners or family members, regardless of gender or sexuality. DVA poses a major public health and clinical challenge to the NHS[1,2] is associated with health problems in victims, perpetrators, and their children, including poor physical health, long-term illness or disability, and poor mental health, at an annual cost to the NHS of 1.8% of total budget with even greater societal costs[3]. The NHS (and health services internationally) have not responded adequately to this need[4]. There is growing recognition of its impact on women and children, but virtually no recognition by clinicians of men as victims or perpetrators and little research on effective interventions for men in healthcare settings. The evidence reviews in the NICE DVA guidelines[2] identify evidence gaps with regards to an integrated healthcare response and effective interventions targeted at perpetrators.

This pilot trial forms part of an NIHR Programme grant called Reaching Everyone: Programme of Research on Violence in Diverse Domestic Environments (REPROVIDE) and builds on previous work undertaken as part of the PROVIDE Programme (see http://www.bris.ac.uk/social-community-medicine/projects/provide/). We have undertaken an evidence synthesis to: i) identify the perpetrator group model with the greatest likelihood of effectiveness in reducing perpetration of DVA and increasing the safety of victims and their families; ii) identify components of other models that are likely to improve outcomes for survivors; iii) to refine our hypothesised causal pathway and logic model as well as inform our choice of outcome measures for the intervention trial.

Following a series of expert consultation and consensus meetings, we are now at the stage of taking the evidence of what works to adapt an existing domestic violence perpetrator programme (DVPP) and to pilot and test this as an intervention for men who perpetrate violence and abuse against their female partner(s) or ex-partner(s).

The rationale for this pilot trial is that, despite the ubiquity of perpetrator programmes in the UK, Europe and North America, there is still uncertainty about their effectiveness. There is a dearth of experimental studies both internationally[5] and outside of north America[6]. The health impact of DVA makes provision of effective perpetrator programmes to prevent further violence a legitimate part of healthcare services. With the move towards evidence-based commissioning of health services, we need to rigorously test programmes particularly with regards to safety and health outcomes for victims/survivors, but also for perpetrator behaviour. A major research recommendation of the NICE DVA guidelines is determining the effectiveness of perpetrator interventions in terms of victims' safety, across levels of risk, and including diverse and marginalised groups.

There will be a nested qualitative study within this pilot phase to explore processes of the intervention through observations/interviews to explore the intervention acceptability and adherence which will help to inform interpretation of the trial findings. This will also improve understanding of the needs of men (and their partners) who do not fulfil our trial inclusion criteria (e.g. in same sex relationships or unable to read English), but who may contact us in the recruitment process.

The overall objective of this pilot trial is to determine the acceptability and feasibility of the perpetrator programme intervention and trial design.

2. Rationale

Trials of DVPPs are challenging, from recruitment and retention of participants (perpetrators and their ex/partners) to adherence to the intervention. We will pilot an adapted DVPP intervention and the trial design, in particular assessing: the acceptability of the programme to perpetrators and victims/survivors of DVA, the feasibility of recruitment and follow up, and the completeness of outcome measure completion, with pre-specified criteria for proceeding to the full trial. This will be piloted in the greater Bristol area (including South Gloucester and North Somerset which has the infrastructure and referral pathways for a group programme (including the support for ex/partners from a domestic violence agency – Next Link) and that the agency delivering the programme (Splitz) is willing to adapt it to the intervention specification.
The programme length will be 26 weekly sessions over 26 weeks and the groups will be run on a rolling basis (i.e. as men finish the course, new men will join). A rolling programme improves the efficiency of the intervention and allows modelling of good behaviour by men who are nearing the end of the programme to men who have just joined it.

Eligible men will be allocated by a minimisation programme with a probabilistic component. Minimisation factors will be age, severity of previous violence and whether they are still with their partner. The allocation system will be constructed and, as necessary, monitored independently of the research team,

2.1 Assessment and management of risk

Conducting research in this population is not without risk to the participants, the researchers and the programme facilitators. The potential risks associated with this trial and more widely in our research group, have been considered and guidance has been produced to minimise/mitigate these risks. An extensive standard operating procedure (SOP) has been developed and is available as appendix 1. All research staff will be familiarised with this SOP prior to conducting any trial-related procedure.

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

Objectives:

(i) To recruit and randomise 36 male perpetrators. ***Two thirds*** of the men (24) will be randomised to a community-based perpetrator programme and ***one third*** **(12)** to the control normal care group.

(ii) To recruit female partners / ex-partners of the men who have been accepted onto the study.

(iii) To measure recruitment rate, adherence of participants, fidelity of intervention and retention, and improvement in safety or feelings of safety for partners and ex-partners

(iv) Identification of main cost drivers;

(v) To determine the acceptability of the intervention to perpetrators, and to their partners and ex-partners, the willingness for all participants to be randomised, the suitability of the primary outcome measure and the motivation for participation.

3.1 Primary objectives

The recruitment, randomisation and retention of 36 male perpetrators who will be randomised to either a 26 week weekly community-based perpetrator programme or control arm plus recruitment of their partners / ex-partners with up to a 9 month follow up in order to meet progression criteria.

3.2 Secondary objectives

1. Assess questionnaire completion
2. Develop fidelity framework for intervention
3. Identify and pilot the collection resource use data and the associated unit costs for cost effectiveness analysis
4. Determine acceptability of the intervention to perpetrators, associated victims/survivors and staff
5. Assess the willingness and risks faced by female partners and ex-partners to be involved in the pilot trial
6. Explore ways of improving retention in both the intervention and control arms for male and female participants
7. Assess the mechanisms of support and supervision needed for those involved in the delivery of the intervention

3.3 Exploratory endpoints/outcomes

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Trial: To assess recruitment and randomisation rate of men and their (ex) partners.	Number recruited and randomised in pilot trial	During 9 months
Trial: To assess retention of men and their (ex) partners.	Number retained during follow-up period.	During 9 months
Trial: To assess questionnaire completion	Completed data sets from PHQ-9, GAD-7, PTSD, EDQ5 and SF12 scale. Impact Toolkit questionnaire completion. ICECAP-A capability measure	3, 6 and 9 months post randomisation. At 9 months post randomisation only
Trial: To develop fidelity framework for intervention	A method to assess fidelity in the main trial	During 12 months

Trial: Identify and pilot the collection resource use data and the associated unit costs	Best method for collecting data on use of health and social care services and other related costs associated with the trial.	During 12 months
Intervention: To determine the acceptability of the intervention to perpetrators, associated victims/survivors and staff.	Qualitative interviews	Time points throughout the 18 month pilot trial.
Trial: Assess the willingness and risks faced by female partners and ex-partners to be involved in the pilot trial	Impact toolkit questionnaire; qualitative interviews; collection of adverse incidents/adverse events/serious adverse events	Time points throughout the 18 month pilot trial.
Trial: Explore ways of improving retention in both the intervention and control arms for male and female participants	Engagement with PPI groups; qualitative interviews	Time points throughout the 18 month pilot trial.
Intervention Assess the mechanisms of support and supervision needed for those involved in the delivery of the intervention	Qualitative interviews and feedback sessions.	Time points throughout the 18 month pilot trial

4 TRIAL DESIGN

This will be a pragmatic, parallel group individually randomised controlled pilot trial. We will be testing the feasibility and acceptability of the domestic violence perpetrator programme as well as the trial.

The domestic violence perpetrator programme (DVPP) will consist of a 26-week programme incorporating 22 weekly group sessions and 4 individual sessions. The sessions will be run by two experienced DVPP facilitators (one male and one female in order to model good gender role behaviours). The programme will start as a rolling programme, allowing new intakes of participants to join at specified intervals but after six months will become a closed programme, meaning that no new men will be able to join. This is to ensure that men will have completed the programme before the end of the pilot trial and to allow sufficient time for post-completion follow-up.

The weekly group sessions will incorporate most of the elements which exist in standard DVPPs. These include: goal identification and goal setting; recognising abuse; denial and minimisation; intents of violence; basic anger management; identifying urges to perpetrate abuse and cooling-down strategies; basic CBT; effects of DVA on partners and children; participant's own childhood experiences; impacts on children; active listening; conflict resolution; masculinity; beliefs and expectations; sexual respect; attachment styles; building empathy; loving relationships; emotional abuse; accountability.

Two pre-group individual sessions will assess suitability for the programme, will assess risk, and enable a needs assessment, and will begin relationship-building.

The remaining individual sessions will be tailored for participants' needs following the initial and ongoing assessment. Possible individual interventions might include deconstructing specific incidents of abuse; accountability letters or planning discussions with partner or children; relaxation or emotional regulation work.

New participants will only be able to join the group programme in specific weeks in order to minimise disruption to men already on the programme and to ensure that new men do not join in particularly challenging weeks (such as 'sexual respect). If there is a gap of more than two weeks between assessment and the next planned intake week, individual sessions will be scheduled in order to help the participants feel engaged with the programme and to reduce drop-out between assessment and programme start.

Unemployed or low-waged men will be able to claim reasonable travel expenses associated with the cost of participating in the research programme.

5 STUDY SETTING

This study will be community based.

Initial meetings with potential participants to check eligibility and seek consent will be arranged in a mutually convenient location for the researcher and participant. This is likely to be within a community wellbeing organisation, health or social care building, or university building. Care will be taken when recruiting men and women – see appendix 1. The intervention programme provider coordinator will organise a risk assessment in a similar location for men.

The group programme intervention will be run out of a central Bristol community setting. It is anticipated that this space will be rented on a weekly basis rather than being a permanent base for the duration of the trial.

Partners or ex-partners of male participants who consent to join the study will be contacted by a DVA advocate based in Next Link and will have contact with that advocate at Next Link or other safe settings

6 ELIGIBILITY CRITERIA

6.1 Inclusion criteria for male participants

- ≥ 21 years of age
- Use of abusive behaviour in current or previous relationships with women partner(s) or ex-partner(s) and concerned about that behaviour
- Ability to read and complete outcome questionnaires

Inclusion criteria for partners/ex-partners

- Female partners or ex-partners of men using violence/abuse in their relationships
- ≥18 years
- Ability to read and complete outcome questionnaires

NB the difference in minimum ages between men and women has been discussed and the expert opinion is that younger men who abuse (pre-21) often aren't so ready to change and the younger age group of men report having qualitatively different types of relationships with women e.g. including abuse and use of internet and social media and in this way the younger men can't and don't relate as well to all the other men of older ages in group setting. In addition, younger men are more likely to be groomed (in terms of potentially abusive and/or criminal behaviours) and that it could therefore be problematic having young men and older men together in the same group.

6.2 Exclusion criteria for male participants

- Men who do not have a female partner or ex-partner
- Court mandated referral to perpetrator programme
- Men who are high risk perpetrators of DVA as assessed by the intervention group co-ordinator
- Men who are deemed by the intervention group coordinator not willing to engage with the intervention.
- Participants who cannot understand the English language sufficiently well to give informed consent and to complete the questionnaires.
- Participants with a diagnosis of a mental illness that will prevent them from programme engagement, e.g. active psychosis,
- Participants with current unstable use/misuse of drugs or alcohol

6.3 Exclusion criteria for partners/ex-partners

- Participants who cannot understand English sufficiently well to give informed consent and to complete the questionnaires.
- Women who are deemed by the DVA support worker to be put at greater risk if they take part in the study.
- Women who are incapacitated by substance abuse or serious mental illness at time of seeking consent

7 TRIAL PROCEDURES

Recruitment strategy to identify suitable men who will self-refer or be referred – (See Consort Flowchart A below).

1. Initial telephone discussion about study with prospective participant and what to expect
2. If suitable, the PIS will be sent via email or mail
3. Followed up by a telephone call or email within 5 days.
4. If wish to continue, arrange joint meeting with the DVPP coordinator.
5. At meeting:
    a. Researcher explains the study and obtains informed consent from the participant to join the study.
    b. The DVPP coordinator assesses suitability to potentially join a perpetrator programme, collects contact details for potential participant, for his current /

ex-partners, and also for any mental health or substance abuse workers supporting the potential participant.

c. Researcher asks participant to complete male baseline questionnaires.
d. Participant is randomised and immediately informed of results.
e. If man is in intervention arm, what happens next will be explained and work with intervention coordinator to ensure arrangements are understood.
f. If man is in control arm what happens next will be explained.
g. Supply a timeline of when to expect reminder contact and questionnaires for 3, 6 and up to 9 months to all.

6. Follow up contact with current or ex-partner and explain study (See Consort Flowchart B below). Check when the last contact with her partner occurred and ask about frequency of contact. If agrees to take part, arrange to meet if safe and check study understanding, obtain consent.
7. At meeting with female partner/ex-partner:
    a. Complete female baseline questionnaires
    b. Inform current or ex-partner of male's allocation to randomisation arm and contact women's worker appropriate to trial arm (dedicated worker – intervention arm; generic women's worker control arm).
    c. Supply a timeline of when to expect reminder contact and questionnaires for 3, 6 and up to 9 months to all.

7.1 Recruitment

Anonymised information on all potential participants (men and women) contacted will be collected in line with CONSORT reporting guidance. This will include:

- age
- gender
- ethnicity
- the reason not eligible for trial participation, or if they are eligible but declined (see also qualitative protocol 7.9)

Participants will be recruited using a variety of methods from a range of sources. These will include:

RECRUITMENT FROM	METHOD OF RECRUITMENT
General practices	Referral/telephone call/email to research team
IRIS service	Referral/telephone call/email to research team
Children's services	Referral/telephone call/email to research team
National offender management services (NOMS)	Referral/telephone call/email to research team

Women's DVA services, including hospital IDVAs/AE departments	Referral/telephone call/email to research team
Social services	Referral/telephone call/email to research team
Police, including contact cards to hand-out	Referral/telephone call/email to research team
Self-referrals	Via social media campaign, public engagement events, local media notices.
Men's helpline (Respect service)	Referral/telephone call/email to research team
Women's Aid helpline	Referral/telephone call/email to research team
Via existing men's services	Referral/telephone call/email to research team
Advertisements in men's gyms	Self-referral telephone call/email to research team
Advertisements in football club locations	Self-referral telephone call/email to research team
Advertisements in men's toilets	Self-referral telephone call/email to research team

We will be extending our recruitment campaign across the Bristol, North Somerset and South Gloucestershire (BNSSG) region. A full-time research associate and part-time research fellows will be involved in the recruitment process.

Posters, leaflets, adverts etc will be used as part of the recruitment strategy. We will target areas with a high density of male attenders such as gyms, police and fire service, football clubs, cricket clubs. We will also use social media (Facebook, Twitter). We will arrange a press release via the University of Bristol.

Potential participants who do not attend arranged initial eligibility meetings as planned will be contacted two more times before contact ceases.

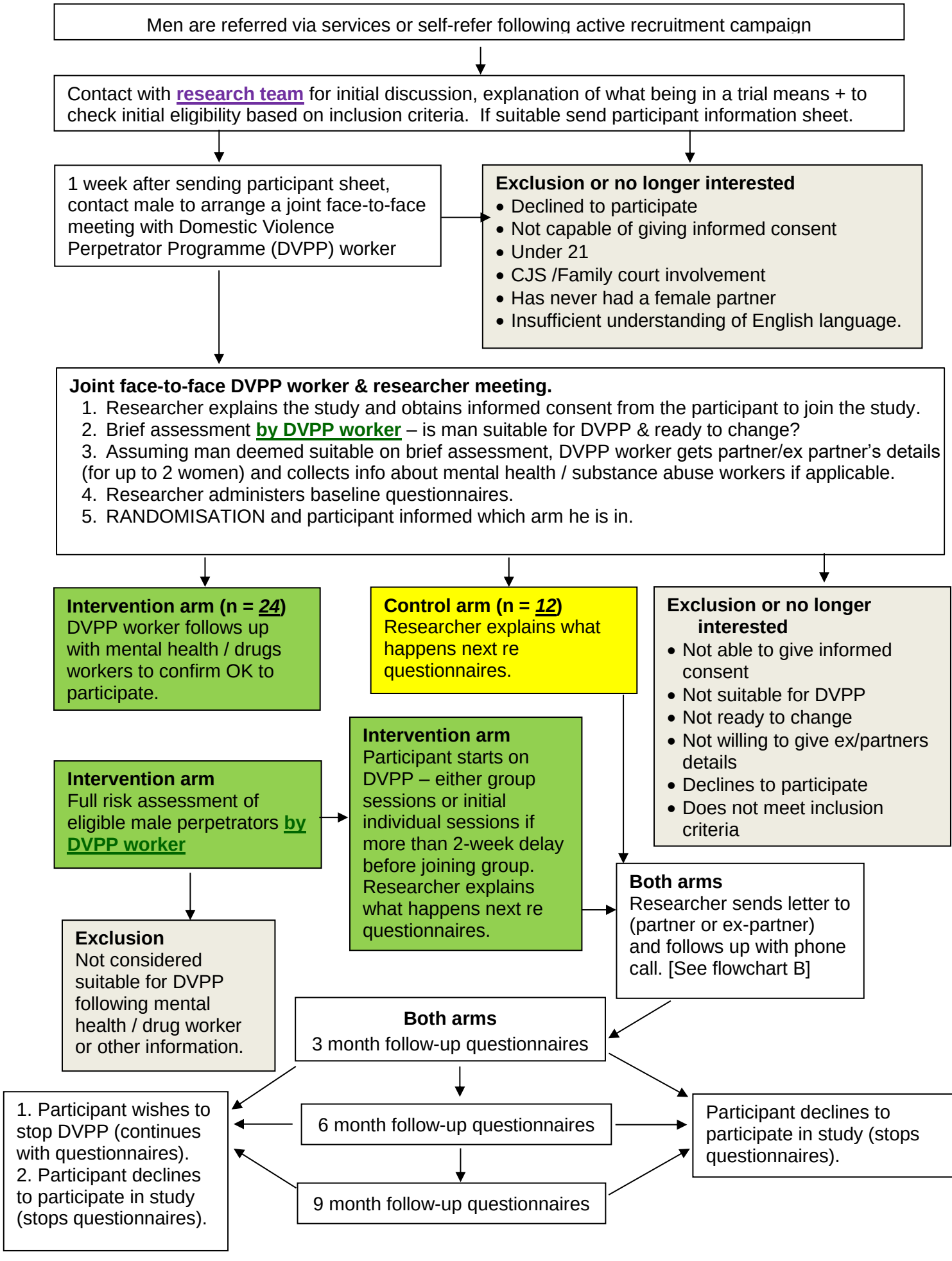
Men who meet the inclusion criteria and consent to participate, will undergo a full risk assessment if they are allocated to the intervention arm as indicated below (Consort Flowchart A).

Female current partners or ex-partners will be contacted by the research team initially by letter, to be followed up by either a phone call, email or further letter, using contact details provided by the male partner/ex-partner. At this point, women will be asked when the last contact with her partner was and what frequency of contact occurs. Women who meet the inclusion criteria and who agree to participate will be provided with dedicated support if the partner or ex-partner has been allocated to the intervention arm or will be signposted to relevant services if she declines to participate or if her partner or ex-partner has been allocated to the control arm.

CONSORT Flowchart: A

Trial of a group programme intervention for men who are concerned about their behaviour.

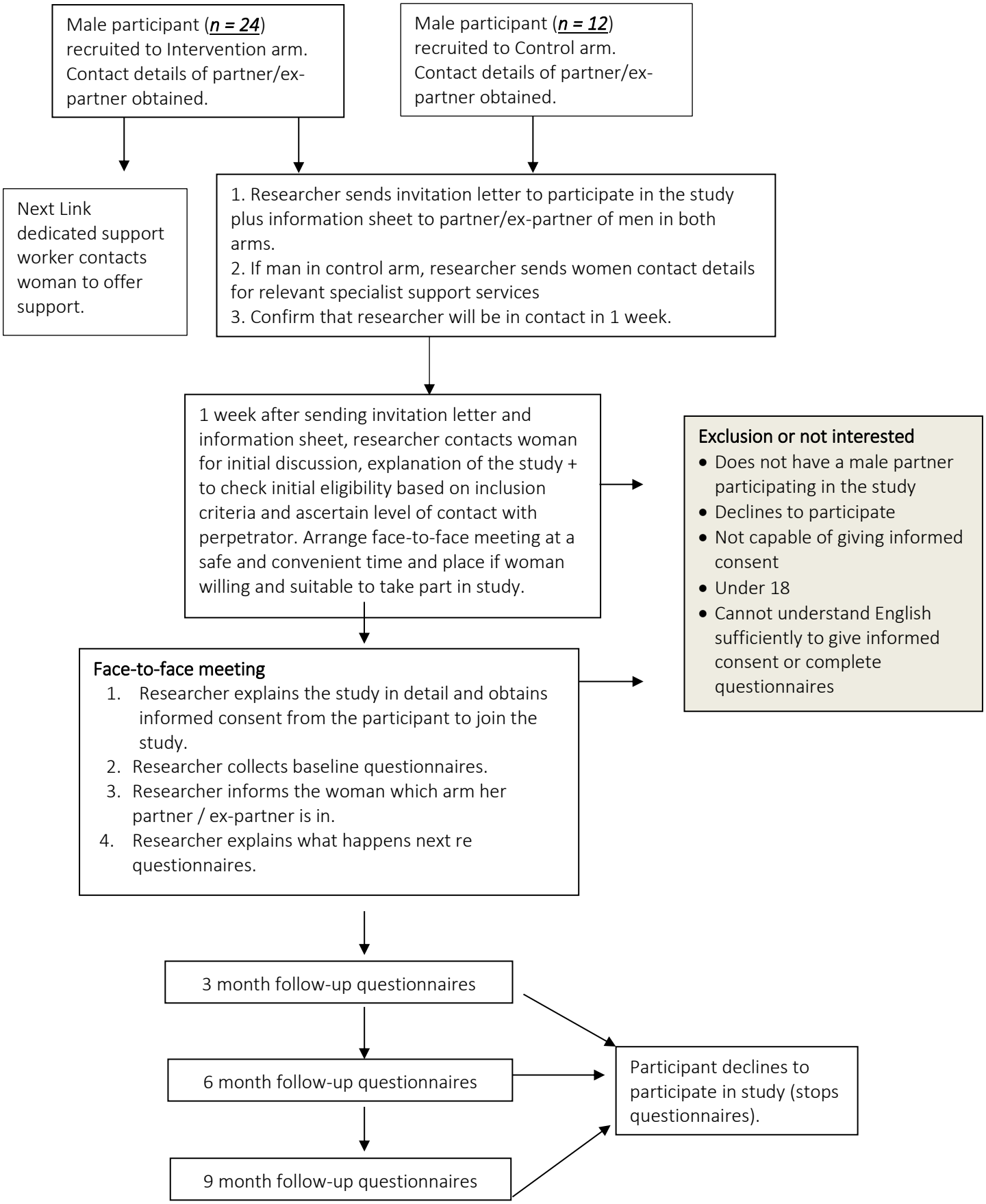
Recruitment Strategy: Men



CONSORT Flowchart: B

Trial of a group programme intervention for men who are concerned about their behaviour

Recruitment Strategy – Women Partners / ex-Partners



7.1.2 Screening and consent

The chief investigator (CI) retains overall responsibility for the informed consent of participants at their site and must ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

The research team will be responsible for the consent process and this will be duly checked and monitored by the Programme Manager.

Informed consent will be obtained prior to the participant undergoing the risk assessment and randomisation process. The right of a participant to decline participation without giving reasons will be respected. The participant will remain free to withdraw at any time from the trial without giving reasons. However, as part of the pilot trial, we aim to briefly carry out telephone interviews with participants who withdraw and who are happy to talk to us in order to understand whether this is due to the design of the DVPP, or for other reasons (see also Qualitative protocol section).

The CI and Programme Manager will take responsibility for ensuring that all vulnerable subjects are protected and participate voluntarily in an environment free from coercion or undue influence.

7.1.3 Assessment of capacity

Assessment of capacity to consent is important in all research and particularly in this study for the female current or ex-partners who may have experienced many years of control or coercion.

For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:

- understand the purpose and nature of the research
- understand what the research involves, its benefits (or lack of benefits), risks and burdens
- understand the alternatives to taking part
- be able to retain the information long enough to make an effective decision
- be able to make a free choice
- be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
- where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected.

A person is assumed to have the mental capacity to make a decision unless it is shown to be absent. Mental capacity is considered to be lacking if, in a specific circumstance, a person is unable to make a decision for him or herself because of impairment or a disturbance in the functioning of their mind or brain. In practice for participants with mental incapacity this means that they should not be included in clinical trials if the same results can be obtained using persons capable of giving consent and should only be included where there are grounds for expecting that their taking part will be of direct benefit to that participant, thereby outweighing the risks.

7.1.4 Involvement of Young People

Although the UK Government definition of DVA includes people over the age of 16, for the purposes of this trial, we will not be recruiting men under the age of 21 or female partners/ex-partners under the age of 18. However, we will be collecting parent-reported measures of child health and wellbeing using the Kidscreen-10[7,8] which we will ask mothers of children aged 8-18 to complete.

7.2 The randomisation scheme

Bristol Randomised Trials Collaboration will provide an automated randomisation procedure whereby participants will be randomly allocated, in a ***2:1*** ratio to the intervention and control arms respectively via a computer program accessed remotely by the recruiting researcher. A minimisation procedure will be used. This will assure similar distribution of selected participant factors between study arms. The first participant is truly randomly allocated; for each subsequent participant, the treatment allocation that minimises the imbalance on the selected factors (age group, severity of abuse, whether still with female partner) between groups at that time is selected, albeit still with a probabilistic element retained.

The allocation will be documented initially via a confirmatory email from the randomisation system to the recruiting researcher. This information will then be recorded on the trial database and an email sent to the intervention coordinator by the researcher. The female current or ex-partner will be notified of the man's allocation after her recruitment. If the female partner or ex-partner declines to take part in the study we will still inform her of the man's allocation as this may have safety implications for her and any children. For women who decline, we will send a list of contacts in case she changes her mind and seeks further support.

7.3 Baseline data

Quantitative measures

A previous trial of a psychological intervention in women presenting at a DVA service utilised some of these measures in the form of a questionnaire at baseline. We choose to use the same measures so that a cohort comparison can be usefully observed. Most of these measures are also appropriate for measuring outcomes for male perpetrators but we will also be seeking to confirm this during the pilot study through the qualitative work (see also Qualitative section).

Although it is likely that we will be using abuse measures as primary outcomes, pilot findings, particularly in relation to recruitment and retention of women participants will inform whether the abuse reported by men or women (or both) will be our primary outcome(s).

Measures to be completed from all male participants:

7.3.1 Physical / mental health status

- PHQ-9 – a brief measure of depressive symptoms[9,10].
- GAD-7 – a brief measure of anxiety symptoms[11,12]
- PCL-5 Post-Traumatic Stress Symptom [13]
- Short Form-12[14] – a measure of general health/QoL
- EQ-5D-5L[15] - a measure of health-related quality of life (http://www.euroqol.org/)
- NODS-CLiP[16] – a measure of adult pathological and problem gambling
- ICECAP-A[17] – ICEpop CAPability measure for Adults (at 9 months only)

7.3.2 Abuse measures

- Impact Monitoring Toolkit scale for men[18]

7.3.3 Current or past physical and/or mental health problems (self-reported), including treatment.

7.3.4 Substance abuse using AUDIT for alcohol use[19] and DUDIT for other substances[20].

7.3.5 Socio-demographic measures including age, number of children at home, ethnicity, income, occupation.

Measures to be collected from all female participants

7.3.6 Physical / mental health status:

- Short Form-12 (SF-12)
- PHQ-9
- GAD-7
- EQ-5D-5L - a measure of health-related quality of life (http://www.euroqol.org/)
- ICECAP-A – ICEpop CAPability measure for Adults (at 9 months only)

7.3.7 Health related Quality of Life measure for children (proxy measure) completed by parent:

- Kidscreen [7,8]

7.3.8 Abuse measures

- Impact Monitoring Toolkit scale for women

7.3.9 Current or past physical and/or mental health problems (self-reported), including treatment.

7.3.10 Substance abuse using AUDIT for alcohol use[19] and DUDIT for other substances[20].

7.3.11 Socio-demographic measures including age, number of children at home, ethnicity, income, occupation.

See Table 1 for measures and timelines during pilot trial.

Table 1

Questionnaires	Also known as:	Baseline	3 months	6 months	9 months
For male perpetrators and female victims					
Socio-demographic measures	Eg age, number of children at home, ethnicity, income, occupation.	✓			
Resources use questions	Use of health and social services, CSJ, medication use, housing, employment and benefits, use of children's services		✓	✓	✓
SF-12 (v2)		✓	✓	✓	✓
PHQ-9		✓	✓	✓	✓
GAD-7		✓	✓	✓	✓
EQ5D		✓	✓	✓	✓
PCL5	PTSD / Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5)	✓	✓	✓	✓
AUDIT	Alcohol Use Disorders Identification Test	✓			✓
DUDIT	Drug Use Disorders Identification Test	✓			✓
NODS-CLiP	Gambling screening questions	✓			✓
ICECAP-A	ICEpop CAPability measure for Adults				✓
Current or past physical &/or mental health problems	(self-reported), including treatment.	✓			
For male perpetrators only					
IMPACT (perpetrators/ clients)	IMPACT toolkit client TO (first contact) – INTERVENTION ARM	✓			
IMPACT (perpetrators/ clients)	IMPACT toolkit client TO (first contact) for CONTROL ARM MEN*	✓			
IMPACT (perpetrators/ clients)	IMPACT toolkit client T2 (client half way through intervention) INTERVENTION ARM**		✓	✓	

IMPACT (perpetrators/ clients)	IMPACT toolkit client T2 (client half way through intervention) CONTROL ARM *		✓	✓	
IMPACT (perpetrators/ clients)	IMPACT toolkit client T3 (end of intervention) INTERVENTION ARM				✓
IMPACT (perpetrators/ clients)	IMPACT toolkit client T3 (end of intervention) CONTROL ARM*				✓
Abuse when participant was a child		✓			
For female victims only					
IMPACT (victims/ artner)	IMPACT toolkit partner TO (first contact) – intervention	✓			
IMPACT (victims/ partner)	IMPACT toolkit partner TO (first contact) control arm*	✓			
IMPACT (victims partner)	IMPACT toolkit partner T2 - half way through intervention- intervention arm **		✓	✓	
IMPACT (victims/ partner)	IMPACT toolkit partner T2 - half way through intervention – control arm*		✓	✓	
IMPACT (victims/ partner)	IMPACT toolkit partner T3 (end of intervention) – intervention arm				✓
IMPACT (victims/ partner)	IMPACT toolkit partner T3 (end of intervention)- control arm*				✓
KIDSCREENS -10p	Parent version UK	✓	✓	✓	✓

* The IMPACT toolkit is designed for administering to clients (and victims) who are engaged either directly or indirectly in perpetrator programmes. For the control arm participants the text will need to be changed slightly so that it also makes sense to participants who are involved in a pilot trial which will ultimately be testing the efficacy of a perpetrator programme.
**IMPACT toolkit T1 (client and victim) may replace T2 at 3 months if there has been significant time lag between baseline questionnaire (T0) and start of the group for men in the intervention arm.

7.3.12 Process measures

- numbers of DVPP modules/sessions attended
- digital audio/visual recording of treatment sessions with independent evaluation of intervention fidelity
- additional 1:1 contact time for men in DVPP
- contact time for women in support service
- numbers of referrals or initial interest (self-referral) from different routes and proportion of referrals which result in successful recruitment

7.3.13 Police offender reports

7.4 Trial and follow-up assessments

Questionnaire measures will be repeated at 3, 6 and up to 9 months following randomisation (depending on time left between participant starting the study and the end of the study) and we will continue to try to collect these data even if the participant decides to just discontinue the intervention, unless they explicitly withdraw from intervention and trial. Consent will be checked prior to each data collection time-point. A reminder contact will be sent out to all participants 2-3 weeks before the next data point is due. We will try to accommodate participants' preferences for contact method (e.g. phone call, text, email, mail). Participants who withdraw from the trial or do not reply to three requests for questionnaire completion by whatever method however, will be defined as 'lost to follow up'.

Through in depth interviews with male perpetrators and brief interviews with intervention non-attenders as well as regular weekly updates between the research team and the intervention facilitators we will gain an understanding of retention issues and develop retention strategies for use in the full trial.

7.5 Economic analysis

The aim of the economic analysis will be to assess the feasibility of, and inform the design of, a full economic evaluation to establish the cost-effectiveness of the group programme. The intervention could have potentially wide-reaching effects across difference sectors of the economy so we will use the pilot study to identify the main cost drivers in order to make the full trial as efficient as possible. To this end, we will collect data on: participants' and their partners' use of health services; other public sectors such as social services, housing, and criminal justice; the voluntary sector; their own personal out-of-pocket expenditure; and time off work. These data will be collected using the questionnaire administered at 3, 6 and 9 months post-randomisation. Sources of the associated unit costs will be identified.

Data on resources required to provide the group programme will be collected as part of the trial process and we will pilot a method of valuing these.

We will analyse the data at the level of the individual patient. A key outcome will be the completeness of the questionnaire data therefore missing data will be scrutinised to establish whether this is systematic or random and this analysis will be used to inform changes to the questionnaire content and/or administration.

The full trial will compare mean cost per participant with key outcomes including quality adjusted life years formed from responses to the EQ-5D-5L and the SF-12. The pilot work will examine the

responses to these instruments at each time point and make recommendations regarding data collection for the main trial.

7.6 Nested qualitative study

The overall objective of the pilot study is to determine the acceptability and feasibility of the perpetrator programme intervention and trial design. In order to fulfil this objective and fully explore uncertainties and issues of feasibility we will take an ethnographic approach and collect qualitative data using a variety of different methods. Key issues of uncertainty to be examined would include: the acceptability of the intervention to perpetrators and victims/survivors of DVA; the feasibility of recruitment and follow up. The data will be collected at different time points during the pilot study to help inform and best support the understanding and improvement of the intervention. As a pilot trial, the risk of influencing responses to outcome measures is less problematic.

We will undertake qualitative data collection in 5 main areas:

7.6.1 Men's experiences of participation in the intervention or control arms

Interviews with men in the intervention arm

Semi-structured in-depth interviews will be conducted at different time points during and after the intervention with a purposive sample of men. Maximum variation sampling will seek to ensure that men from different age groups, socioeconomic status, ethnicity, different levels of attendance at the weekly groups and different levels of severity of abuse are selected. Interviews will focus on the acceptability and perceived effectiveness of the programme. Questions might include: views on the recruitment process; motivation for joining the study; aspects of the intervention they found most helpful and most challenging; if they felt that their behaviour had changed as a result of their participation; and views on the role of both facilitators and other participants in any perceived changes of behaviour. It is anticipated that the interviews would last approximately 1 hour and would be conducted either face-to-face or by phone. The interviews would mainly be carried out by experienced researchers.

Interviews with men in control arm

Semi-structured in-depth interviews will be conducted at different time points with a purposive sample of men. The maximum variation sampling will seek to ensure that men are selected from different age groups, ethnicity, socioeconomic status and different levels of severity of abuse. Interviews will focus on the recruitment process, randomisation, and motivation to join the study and study acceptability. Data from interviews with men in the control arm would also help to contribute to an understanding of usual care. Interviews would be conducted either face-to-face or by phone and would last between 30 minutes and 1 hour.

7.6. 2 Observation of process

Observations of a small sample of the recruitment, assessment and randomisation process will be carried out to both inform the interviews and to help identify problems that may hinder recruitment. All observational work will contribute to describing the key characteristics of the intervention, its context and initial understandings of the key ingredients of success in the event of a positive full trial at a later stage. Video recordings of the intervention will be watched as part of the qualitative and ethnographic work, as well as for assessment of intervention fidelity. Video recording of group perpetrator programmes outside of research is routinely carried out and so it will not be an additional burden. Watching the videos of the intervention group will help to support and inform the interviews with men in the intervention arm.

7.6.3 Female partners' and ex-partners' experience of participation in the intervention and control arms

Interviews with female partners and ex-partners in intervention and control arms

Semi structured in-depth interviews will be conducted with a purposive sample of female partners and ex partners. Participants will be selected using maximum variation sampling to ensure representation in different age groups, socioeconomic status, ethnicity, levels of abuse experienced and the extent to which they accepted specialist DVA support. Interviews will focus on the acceptability and perceived effectiveness of programme. Possible questions will include if, and in what ways, they feel the behaviour of their partners or ex-partners has changed, whether they feel more or less safe, aspects of the intervention they found useful, feedback on the appropriateness of the measures being used, and any effects they feel the intervention might be having on their everyday life, including the impact on any children. It is anticipated that the interviews would last between 30 minutes and 1 hour and would be conducted either face-to-face or carried out by phone. Suitable safe working protocols for both the female participant and researcher would be in place such as safe ways to contact the participant and a safe back up contact (see Safety protocol appendix 1).

7.6.4 Views of men and women who declined participation or were consented and then either did not engage with the intervention or dropped out of the study

We will seek the views of eligible men and women who at some stage in the recruitment process decide to decline participation and the views of participants who withdrew or did not attend the intervention. It is likely that participants who drop out of the study will be less willing to talk to the researchers but we would try to capture their views where they are willing to give consent to a final 'exit' interview. Possible questions would include reasons for dropping out and whether continuing participation (and engagement in the intervention) could be supported. Whereas we would seek the views of decliners during the recruitment process with some gentle, impromptu and informal follow up questions, participants who drop out of the intervention or from the study will be conducted by telephone. The brief questions will last less than 10 minutes unless the participant wants to give more significant feedback. We would attempt to contact the participants who drop out of the study up to three times.

7.6.5 Views of men who are excluded from the study because they do not fulfil inclusion criteria

As a separate sub-study, outside the context of the pilot trial, we plan to seek consent for in-depth semi structured interviews with a purposive sample of men not eligible for the study due to reasons such as sexual preference (i.e. no women partners or ex-partners), unstable drug or alcohol abuse, insufficient command of English or mental health issues which prohibit engagement in the study. The reason for doing these interviews is to make sure that we have some understanding of how the intervention might be adapted for more marginalised groups. Participants will be selected using maximum variation and interviews will focus on the criteria used for exclusion and possible ways to be more inclusive. It is anticipated that the interviews would last between 30 minutes and 1 hour and would be conducted either face-to-face (with an interpreter present if necessary) or carried out by phone.

We will use a safety protocol for all face-to-face interviews and a lone worker checking-in system (see Safety protocol appendix 1). As far as possible, a neutral, safe location will be used for interviews, with a responsible person nearby. (See Safety protocol, appendix 1)

7.6.6 Experience of intervention providers

Semi structured interviews will be carried out with all the intervention group facilitators, risk assessors (if different from facilitators), facilitators' supervisory managers, women's advocates and associated staff if appropriate. These interviews will be carried out at the end of the intervention and focus on the acceptability, strengths and weaknesses of the intervention, how the intervention compares with other interventions experienced, views on the suitability criteria and perceived effectiveness of programme. It is anticipated that the interviews would last approximately hour and would be conducted either face-to-face or by phone. Shorter telephone interviews will also be conducted at an earlier stage with a sample of professionals referring men into the pilot trial. These interviews will be conducted during the recruitment period to help ensure that any difficulties or obstacles to recruitment that we have the opportunity to address issues highlighted. Possible questions might include: the demographic and mental health profiles of men they work with; the perceived success of recruitment methods; who they think the intervention was most suitable for; and the referral process.

7.6.7 Observation of process

Observations from the facilitator training sessions, intervention group videos and ongoing weekly feedback from facilitators will be collected. These observations and weekly feedback will help inform the intervention provider interviews and provide data for understanding study retention (intervention arm) and fidelity to the programme manual. Researchers will also systematically note observations outside of the intervention, such as comments by participants when completing questionnaires. Observation guides will be developed and shared within the team to support the researchers in this recording process.

The sampling matrix below gives an idea of numbers of interviews planned but these may change depending on whether we feel adequate information is captured at an earlier stage or needs slightly more exploration (data saturation).

Sampling matrix

Participants	**Intervention**	**Control**
Male perpetrators	15	5
Female partners and ex partners	5	5
Excluded participants	Up to 10	
Participants who withdraw or drop out	We will informally seek the views of all participants who withdraw or drop out where possible.	
Staff associated with intervention	Up to 10	

7.7 Withdrawal criteria

- A participant will be withdrawn from the intervention trial if it becomes known that participation leads to an increase in danger to their partner or ex-partner or their children or the intervention facilitators. Similarly, if the danger extends to the research team, they will be withdrawn from the study. These decisions will be taken by the CI and programme manager in consultation with the DMEC and in collaboration with the DVPP facilitators. These decisions will be documented appropriately.
- The follow up of participants that have withdrawn from the intervention will continue so long as the participant still consents to be included.

7.8 End of trial

As this is a pilot trial, we will determine whether to progress to the full trial based on pre-specified criteria:

Criteria to move to full trial	Determined by
Recruitment of participants	Rate and source of recruitment and sufficient number in order to meet progression criteria
Retention of participants	Up to 9 months post randomisation in order to meet progression criteria

Criteria for progression to full trial:

- The recruitment of 36 men within 9 months and/or a steady state recruitment rate that is consistent with this aim.
- follow up of male participants of 0.6 (95% ci 0.4 to 0.8) at 1 year
- follow up of female participants of 0.5 (95% ci 0.4 to 0.7) at 1 year

8 Safety reporting

For this trial of a complex intervention, we will use the definitions assigned by Good Clinical Practice and more commonly used in trials of medication. We acknowledge that the risks in this population for AEs and SAEs is high, so will have protocols in place for recording and appropriately reporting.

8.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant in the trial, including occurrences which are not necessarily caused by or related to being part of the trial.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Please refer to the safety and ethical conduct SOP in appendix 1.

8.2 Process and responsibilities for reporting SAEs

All SAEs will be recorded on the relevant form of the CRF (see appendix) and reported to the PI and chair of the DMEC within 48 hours of receiving the report. The Programme Manager or Trial Manager is responsible for reporting to the PI and Chair of DMEC.

The PI and chair of the DMEC will consider whether the SAE is: not related to participation, possibly related to participation or definitely related to participation. Judgement will be made on whether to report the possibly related cases on to the Sponsor and ethics committee chair, but all cases of definitely related will be reported onwards.

A cumulative review of all safety information by the TSC/DMEC will be made on 6 monthly basis.

All SAEs will be followed up where appropriate by the researcher, the intervention coordinator or the women's worker. If it is felt that a child or adult are at significant risk, then the standard safeguarding procedure will be initiated, as outlined in the Safeguarding Flowchart, appendix 2.

All adverse event reporting will be in accordance with the UH Bristol 'Research Safety Reporting Policy' (http://www.uhbristol.nhs.uk/media/2518477/research_safety_reporting_sop_009_uhbristol_r_i_v8.0_19.10.15.pdf.

The statistician will remain blinded to group allocation relating to AE/SAE reporting.

8.3 Data Monitoring and Ethics Committee (DMEC):

In accordance with the Trial Terms of Reference for the DMEC, periodically reviewing overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis will be undertaken.

8.4 Programme Steering Committee (PSC):

In accordance with the Trial Terms of Reference, the DMEC will report its periodic review of safety data to the PSC.

8.5 Notification of deaths

All deaths will be reported to the sponsor irrespective of whether the death is related to participation in the trial. This information will be passed to the sponsor within 24 hours of receiving the notification by the Programme Manager in lieu of a trial manager.

9 STATISTICS AND DATA ANALYSIS

For the purposes of this pilot trial, data will be analysed and reported using descriptive statistics only as the pilot is not sufficiently powered for a comparison of outcomes between the groups. However, the findings from this pilot will inform the power calculation required for the full trial and a Statistical Analysis Plan will be produced once the findings from this pilot are reviewed and it is clear that progression to a full trial will happen. The SAP will be developed once the full trial primary and secondary outcomes are determined. Data on recruitment, randomisation and retention will be collected and recorded in line with CONSORT guidelines. All secondary outcome measures will be analysed and presented by trial arm for the baseline and 9 month time point to inform trial primary objectives.

9.1 Analysis of nested qualitative study

Interviews with participants will be audio-recorded and transcribed for analysis professionally. The audio aspect of the video data will be transcribed professionally (depending on budget availability) and supplemented with observational data by the researchers. For any informal observations about context for example, the researcher will summarise and write up their more detailed field notes for sharing. The interview and observation transcripts will be individually read and re-read, from which an initial coding framework will be developed. This framework will be added to and refined, with coded material regrouped as new data from subsequent interviews / video data is gathered. We will analyse the data sets thematically. We will triangulate the different data sources. Data analysis for the interviews and observational data will be broadly thematic. NVivo will aid data management, and enable comparisons/build relationships between the different parts of the data (e.g. interview data with perpetrators, partners /ex partners and providers, observation data and field notes). The codes will gradually be built into broader categories and themes. The data will be scrutinised for differences and similarities within themes across groups/interviewees, seeking disconfirming as well as confirming cases. One researcher will lead the analysis of each sub dataset e.g. of perpetrators or providers, but other team members will independently code a sub-sample of transcripts for inter-rater reliability. All team members will meet to discuss the preliminary coding framework and themes and to ensure that the emerging analysis is trustworthy and credible. An extract of the coding framework may also be considered at the PPI groups for discussion.

10 DATA HANDLING

10.1 Data collection tools and source document identification

Source Data and documents

Source data for this trial will be the confidential data collected by the DVPP coordinator during the risk assessment procedure for men and the women's worker needs assessment for the women. These documents will remain the property of the service provider, but will be made available to the research team to verify contact information given to the researcher. To this end, the source documents will be the information recorded by the service providers in their confidential files.

Since the research team will need to collect information on number of contacts made, then access to source data will be agreed at the outset of the trial.

Case report forms

A case report form (CRF) will be prepared for each participant to record all data required by the trial protocol. It will be a printed document, the contents of which will be entered onto the database for statistical analysis.

10.2 Data handling and record keeping

Administrative data including names, addresses and other personalised data will be stored in the University of Bristol (UOB) SQL Server Cluster and entered using an MS-Access frontend. We will not be using MS-Access to store data.

Clinical data are collected using the BRTC Redcap software. REDCap is a secure, web-based electronic data capture (EDC) system designed for the collection and management of research (as distinct from administrative) data. Although the REDCap system has been developed (and it is supported) by Vanderbilt University, SSCM has set up its own infrastructure to host the REDCap application so that all elements reside within UoB.

All clinical data is stored in a secured UoB server subject to standard UoB security procedures. The full database is backed up daily and any changes to the database are logged every 5 minutes. A disaster/recovery plan is in place so that the data could be restored to the latest 5 minute backup.

A combination of field type validation, data ranges, logic and thorough testing is used to ensure the quality of the data collected via REDCap. Clinical data are anonymised by Identification Code and all data collection are made by Identification Code.

REDCap user roles can be used in combination with filed validation as identifier to determine the data that can be viewed by different members of the team. This facility can be used to avoid unblinding the statistician if necessary.

Clinical data entry can be performed by accessing the REDCap application directly or via surveys. In order to access the application directly, users from the research team will be added to the system (following request from the Programme Manager) by the Data Manager. It is the Programme Manager's responsibility to add the user to a specific project and role.

Both Clinical and Administrative data are secured using robust security mechanisms. Both systems also have audit logs cataloguing individual changes with data/time, old value, new value and the identity of the user who made the change.

Both systems are managed by UOB Information Services and have backup facilities including dumps to tape and snapshots. Any data transfer is done either using UOB systems secured by the University's Active Directory system linked to each user's identity. Files transferred external to UOB will use encrypted files over the UOB secure file transfer facility (FLUFF).

10.3 Access to Data

Data can only be accessed by authorised accounts and authorisation can only be granted by specific people such as the CI, the Programme Manager, or the research team.

10.4 Archiving

- archiving will be authorised by the Sponsor following submission of the end of study report
- the questionnaire data will be archived
    - the location and duration of record retention for essential documents and the trial database will be recorded.
- all essential documents will be archived for a minimum of 5 years after completion of trial
- destruction of essential documents will require authorisation from the Sponsor

11 MONITORING, AUDIT & INSPECTION

- A Trial Monitoring Plan will be developed and agreed by the Trial Management Group (TMG) and TSC based on the trial risk assessment which may include on site monitoring.
- The University of Bristol has a Service Level Agreement with UHBristol whereby the NHS Trust monitors 10% of the University's Sponsored studies.

12 ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Research Ethics Committee (REC) review & reports

- before the start of the trial, approval will be sought from a REC for the trial protocol, informed consent forms and other relevant documents e.g. advertisements
- substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the study
- all correspondence with the REC will be retained in the Trial Master File/Investigator Site File
- an annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended
- it is the Chief Investigator's responsibility to produce the annual reports as required.
- the Chief Investigator will notify the REC of the end of the study
- if the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination
- within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC

12.2 Peer review

An outline of this pilot trial was included in the NIHR grant application that was approved for funding. This was extensively peer reviewed (10 independent reviewers and the PGfAR panel). This protocol was reviewed by members of the TSC prior to submission for Sponsor approval and REC submission.

12.3 Public and Patient Involvement (PPI)

We have active PPI groups informing our research. A group of female survivors (women who have experienced DVA) and a separate group of male ex-perpetrators (men who have been through a DVPP) have informed the design of the research and the intervention. Both groups have input into the recruitment material including the PIS and ICF process. Regular planned meetings will help inform issues around recruitment and retention of participants.

Our PPI groups will also be involved in the planning of the qualitative interview questions, the interpretation of the findings and either the planning for the full trial, or the dissemination of the pilot findings.

12.4 Protocol compliance

All changes to this protocol that may be required as part of the pilot trial will be documented and submitted for approval. No participant will knowingly be enrolled as a trial participant if they do not meet the eligibility criteria or restrictions specified in the trial protocol.

Any accidental deviations from the protocol will be adequately documented on the relevant forms and reported to the Chief Investigator.

12.5 Data protection and patient confidentiality

All investigators and trial site staff must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Personal information on research participants will be collected and kept secure by the creation of a coded, depersonalised database where the participant's identifying information is replaced by an unrelated sequence of characters. This will be securely maintained with the linking code in separate locations using encrypted digital files within password protected folders and storage media. Access to this data will be limited to the research team with responsibility for data entry and analysis.

Anonymised data will be made public via a data sharing initiative. Personal details will be kept for 5 years after participation. The custodian of this will be the CI at the University of Bristol.

12.6 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

The development of the domestic violence perpetrator programme involves a number of partners who are collaborators in this research. A memorandum of understanding will be prepared by the University of Bristol Research Commercialisation Manager intellectual property will be a standing item on the trial steering group.

12.7 Indemnity

This study will be sponsored by the University of Bristol. The University has Public Liability insurance to cover the liability of the University to research participants.

12.8 Amendments

All updates to this protocol and approvals thereof will be conducted and recorded in the appropriate way.

- amendments will be made once the decision at the TSC/DMEC or other programme advisory group has been documented.
- The programme manager or trial manager will decide whether the amendment is substantial or non-substantial
- substantive changes will be communicated to relevant stakeholders (e.g., REC, trial registries, R&D, regulatory agencies in accordance with the latest advice and guidance.
- the amendment history will be tracked to identify the most recent protocol version and this will be available as an appendix to this protocol and within the Trial Master File.
- Guidance on the categorisation of amendments can be found on the HRA website. http://www.hra.nhs.uk/resources/after-you-apply/amendments/

12.9 Post trial care

Participation in the DVPP intervention will be for approximately 26 weeks. Evidence suggests that following this, some men benefit from an informal follow-on group, which may need to be funded separately. The trial follows participants up for 3, 6 and 9 months post-randomisation. It is likely that after this time we would sign-post men and women to relevant ongoing support agencies if this were necessary.

12.10 Access to the final trial dataset

- The statistician, database manager and research fellows will have access to the full dataset but a master copy will be protected.

13 DISSEMINATION POLICY

For academic publications we will follow the Consort Guidelines and checklist prior to generating any publications for the trial to ensure they meet the standards required for submission to high quality peer reviewed journals etc. http://www.consort-statement.org/

- The University of Bristol owns the data arising from the trial
- On completion of the pilot trial, the data will be analysed and tabulated and a Final Study Report prepared. This will feed into the main trial protocol which will follow this pilot if the intervention and trial methods are acceptable.
- Any dissemination of this pilot trial (either academic or lay) will be done in discussion and agreement with the participating investigators
- The NIHR require that they have one month to review publications prior to submission.
- The NIHR require that funding needs to be acknowledged within all publications: Disclaimer/acknowledgement thus:

  "This report is independent research funded by the National Institute for Health Research (Programme Grants for Applied Research, REPROVIDE (Reaching Everyone Programme of Research On Violence in diverse Domestic Environments), RP-PG-0614-20012). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health."

- We will prepare and publish a quarterly newsletter that will be made available via our website. The audience for this will be aimed at our PPI group members, but trial participants will also be encouraged to access this if they want to know the outcome of the trial. For participants or PPI members who cannot access the internet, a paper copy in the post will be made available if it is safe to send to the given address.
- For the pilot trial we will not publish the protocol, but if a favourable outcome means that the full trial goes ahead, we would publish the trial protocol. The full study report, anonymised participant level dataset, and statistical code for generating the results will be made publicly available following the completion of the trial and programme, estimated to be in 2022/23.

13.1 Authorship eligibility guidelines and any intended use of professional writers

- The main author of the final report will be first author and all other contributors will be listed in alphabetical order. The last author will be the CI.
- All publications that arise from this trial will use the criteria for individually named authors or group authorship (The International Committee of Medical Journal Editors has defined authorship criteria for manuscripts submitted for publication) and this will be agreed in advance.

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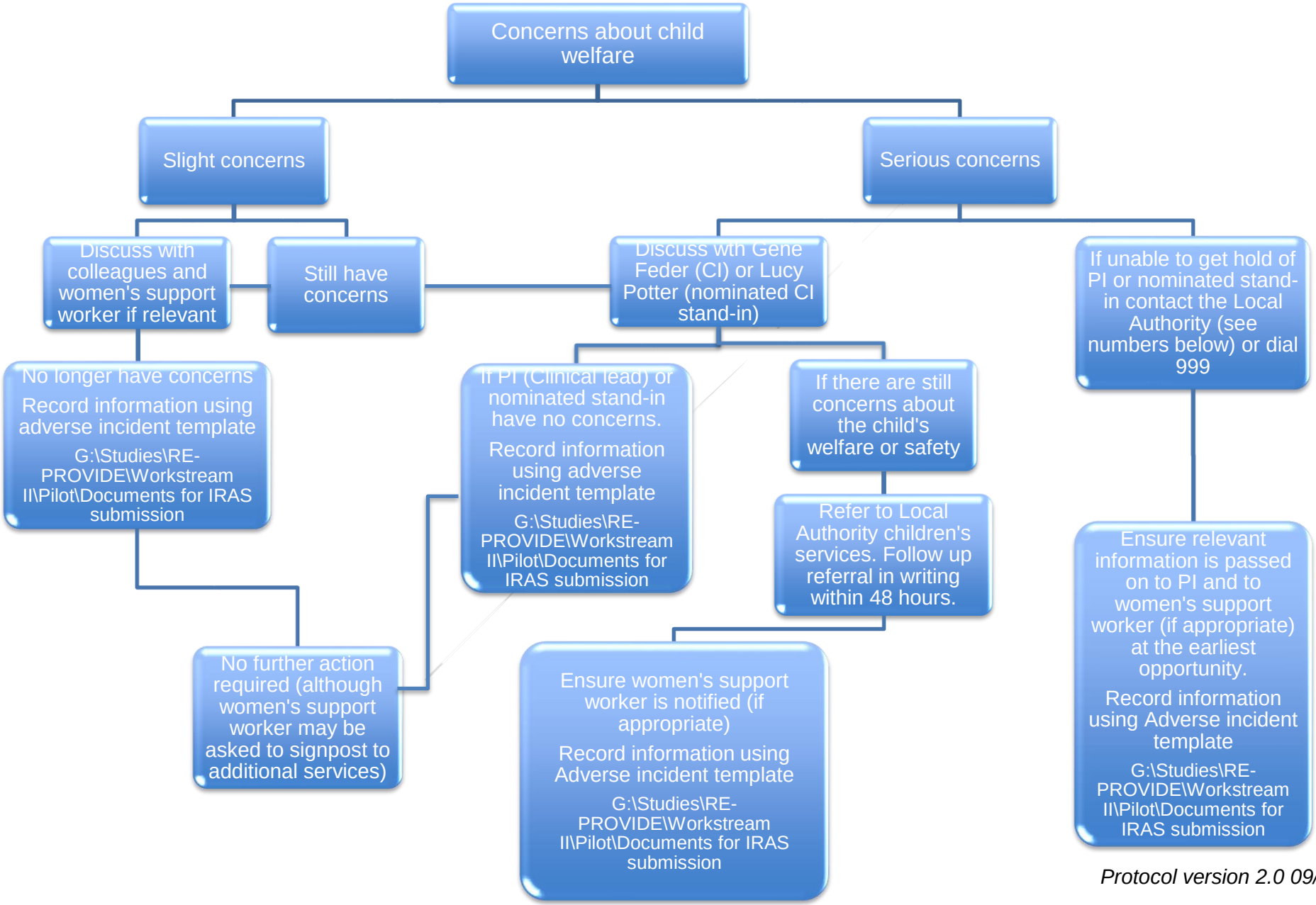
15. APPENDICIES

1. **Safe and ethical conduct protocol for Reprovide participants and researchers (attached separately)**
2. **Flowchart for Safeguarding reporting**
3. **Pilot Trial Master File Contents**
4. **Schedule of Procedures summary**
5. **Safety Reporting Flow Chart**
6. **Amendment History**

Appendix 2


Concerns about child welfare
Slight concerns
Serious concerns
Discuss with colleagues and women's support worker if relevant
Still have concerns
Discuss with Gene Feder (CI) or Lucy Potter (nominated CI stand-in)
If unable to get hold of PI or nominated stand-in contact the Local Authority (see numbers below) or dial 999
No longer have concerns
Record information using adverse incident template
G:\Studies\RE-PROVIDE\Workstream II\Pilot\Documents for IRAS submission
If PI (Clinical lead) or nominated stand-in have no concerns.
Record information using adverse incident template
G:\Studies\RE-PROVIDE\Workstream II\Pilot\Documents for IRAS submission
If there are still concerns about the child's welfare or safety
Refer to Local Authority children's services. Follow up referral in writing within 48 hours.
Ensure relevant information is passed on to PI and to women's support worker (if appropriate) at the earliest opportunity.
Record information using Adverse incident template
G:\Studies\RE-PROVIDE\Workstream II\Pilot\Documents for IRAS submission
No further action required (although women's support worker may be asked to signpost to additional services)
Ensure women's support worker is notified (if appropriate)
Record information using Adverse incident template
G:\Studies\RE-PROVIDE\Workstream II\Pilot\Documents for IRAS submission

Bristol	
First Response Team: 0117 903 6444.	Emergency Duty Team: 01454 615 165
Nth Somerset.	
Children's Services: 01275 888808.	Out of Hours: 01454 615165
Sth Gloucestershire	
Children's Services: 01454 866000.	Out of hours: 01454 615165

15.3 Appendix 3

Required documentation

REPROVIDE RCT Pilot Perpetrator Programme

Pilot Trial Master File Contents

Section	Details	Who	Completed by	Version number	Date & version of update	Comments
1	**Protocol:**					
2	**Patient Information:** - Participant information sheet - trial - Men - Women - Participant information sheet interviews - Men - Women - Professionals - Participant information sheet – subgroup interviews - all - Informed Consent form (ICF) - Men x 2 - Women x 2 - Professionals x 1 - Subgroup interviews x 1 - Recruitment Strategy - Advertisements for participants - Recruitment flyer for men	**Men** **Men** **Men**	**KM** **KM** **KM**	V5. V5 1.1	18.07.2017 18.07.2017 11.07.2017	
3	**Approvals / Regulatory:** - REC approval - ISRCTN registration - Other applicable approvals -					
4	**Agreements/ funding:** - Copy of any signed agreements between involved parties					

	- Sponsorship agreements / sponsorship letter, - Copy of financial information (funding application/ award letter/ R&D costings) - Insurance/ Indemnity certificates or statements - Petty cash -					
5	**Research Team – Staff and training** - Signed and dated CV of Investigators and research team as appropriate - Delegation log - Evidence of GCP training (if not stated in CV)					
6	**Consent forms:** - Signed participant consent forms					
7	**Data collection:** - Trial case record forms (CRFs) - Agreement with BRTC - Database instructions - Statistical analysis plan					
8	**Safety:** - Adverse Event reporting - Serious Adverse Event forms - Reporting pathway					
9	**Reports:** - Annual progress reports - Final Study Report (after completion of trial) -					
10	**General correspondence** - Trial Management Group (**TMG)** - Data Monitoring Ethics Committee (**DMEC)**					

	- REPROVIDE Advisory Group (**PAG)** - Miscellaneous correspondence -					
11.	**Standard Operating Procedures** - Safety and Ethical considerations - Data entry					

15.4 Appendix 4 – Schedule of Procedures

Procedures	
Informed consent	1
Eligibility assessment	1
Risk assessment	1
Randomisation: Intervention attend DVPP – men; support for women Control men (questionnaires only) Control women, support signposted	Up to 26 weekly visits of a DVPP. Reminder phone calls when questionnaire is being sent out.
Baseline questionnaires	In person
3 month questionnaires	Post or in person
6 month questionnaires	Post or in person
9 month questionnaires	Post or in person

15.5 Appendix 5 – Safety Reporting Flow Chart

SERIOUS ADVERSE EVENTS (SAE)

All SAEs should be reported and the relevant form completed by the researcher/facilitator. This should be sent to the Programme Manager who will notify the CI (Prof Feder) and Chair of DMEC within 48 hours.

The CI DMEC Chair will decide whether the SAE is:

1. Definitely related to intervention/participation?
   This will require a report to Sponsor and EC.

2. Possibly related to intervention/participation?
   This will require discussion and a decision
   Whether to report to Sponsor.

3. Not related to intervention/participation?
   This will need to be stored in the SAE spreadsheet.

All reported SAEs require full reporting and follow-up. This may require obtaining further information from the participant, facilitator of the DVPP or the women's worker.

ADVERSE EVENTS (AE)

Researcher should complete the relevant form and forward to the Programme Manager who will add to the AE spreadsheet.

All SAEs and AEs will be reviewed by the members of the PSC/DMEC.

Sponsor: Dr Birgit Whitman (birgit.whitman@bristol.ac.uk)
CI: Professor Gene Feder (gene.feder@bristol.ac.uk)
DMEC Chair: Prof Judith McFarlane (JMcFarlane@twu.edu)
Programme Manager: Dr Mei-See Man (mei-see.man@bristol.ac.uk)

15.6 Appendix 6 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.2	19.7.2017	KM	Addition of travel expenses for low waged men New male participant recruitment flyer Randomisation ratio change from 1:1 to 2:1 Addition of past abuse to inclusion criteria Information sheet for professionals
2	2.0		MM	

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee HRA.