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Reaching Everyone Programme of Research On Violence In diverse Domestic Environments

PROTOCOL - confidential

The effectiveness and cost-effectiveness of a group programme for men who are concerned about their abusive behaviour in relationships with women: A randomised controlled trial

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

PROTOCOL VERSION 5.0 AND 17.02.2021

RESEARCH REFERENCE NUMBERS:

IRAS Number:	261128
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SPONSORS Number:	UOB: 2019-1474
FUNDERS Number:	NIHR RP-PG 0614-20012

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TRIAL SUMMARY

Trial Title	The effectiveness and cost-effectiveness of a group programme for men who are concerned about their abusive behaviour in relationships with women: A randomised controlled trial	
Internal ref. no. (or short title)	Group programme for men who are concerned about their abusive behaviour in relationships with women	
Phase	Main study	
Trial Design	Individually randomised controlled trial	
Trial Participants	Men aged 21 and over and their female partners or ex-partners (aged 18 or over)	
Planned Sample Size	366 men plus their current or ex-partners (a total planned sample size of up to 732)	
Treatment duration	The intervention group programme is for 23 weeks (with additional individual sessions based on need and a monthly Relapse Prevention Group (RPG) for an additional 6 months following completion of the programme).	
Follow up duration	Up to 12 months	
Planned Trial Period	April 2019 – July 2021	
	Objectives	Outcome Measures
Primary	To investigate the effectiveness of the group programme intervention on reducing men's abusive behaviour against women	Men's self-reported measure of abusive behaviours (ABI) at 12 months
Secondary	To investigate the effectiveness and cost-effectiveness of the group programme intervention on men's abusive behaviour and wellbeing and on partners and ex-partners experience of abusive behaviours and wellbeing	Men's self-reported measures of abusive behaviours and wellbeing, police reports of incidents and partners/ex-partners' self-reported measures of the experience of abusive behaviours and wellbeing

FUNDING AND SUPPORT IN KIND

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

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 grant holders) the University of Bristol (the provider) and other parties. The contract outlines the responsibilities of the funder.

ROLES & RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITTEES

- Programme Steering Committee (PSC)

  The PSC will provide the overall supervision of the wider programme and this trial. It is completely independent of the investigators, their employing organisations, funders and sponsors. It will meet every 6 months.

  Chair: Dr Penny Bee

- Data Monitoring and Ethics Committee (DMEC)

  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 once every 6 months and be available in order to oversee any decisions regarding ethical considerations that occur throughout the trial.

  Chair: Prof Judith McFarlane

- Trial Management Group (TMG)

  The TMG will meet every 2-3 months 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 (Co-PI), Dr Karen Morgan (Co-PI), Prof Tim Peters (Statistician), Daisy Gaunt (Statistician), Dr Rebecca Kandiyali (Health Economist).

  Chair: Prof Gene Feder

Protocol contributors

Dr Mei-See Man, Research Fellow and Programme Manager of the REPROVIDE Programme, of which this trial from Workstream II is Study8

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.

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Dr Karen Morgan, Research Fellow and PI

Professor Tim Peters, Lead Statistician

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Sponsor, University of Bristol

KEY WORDS:

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

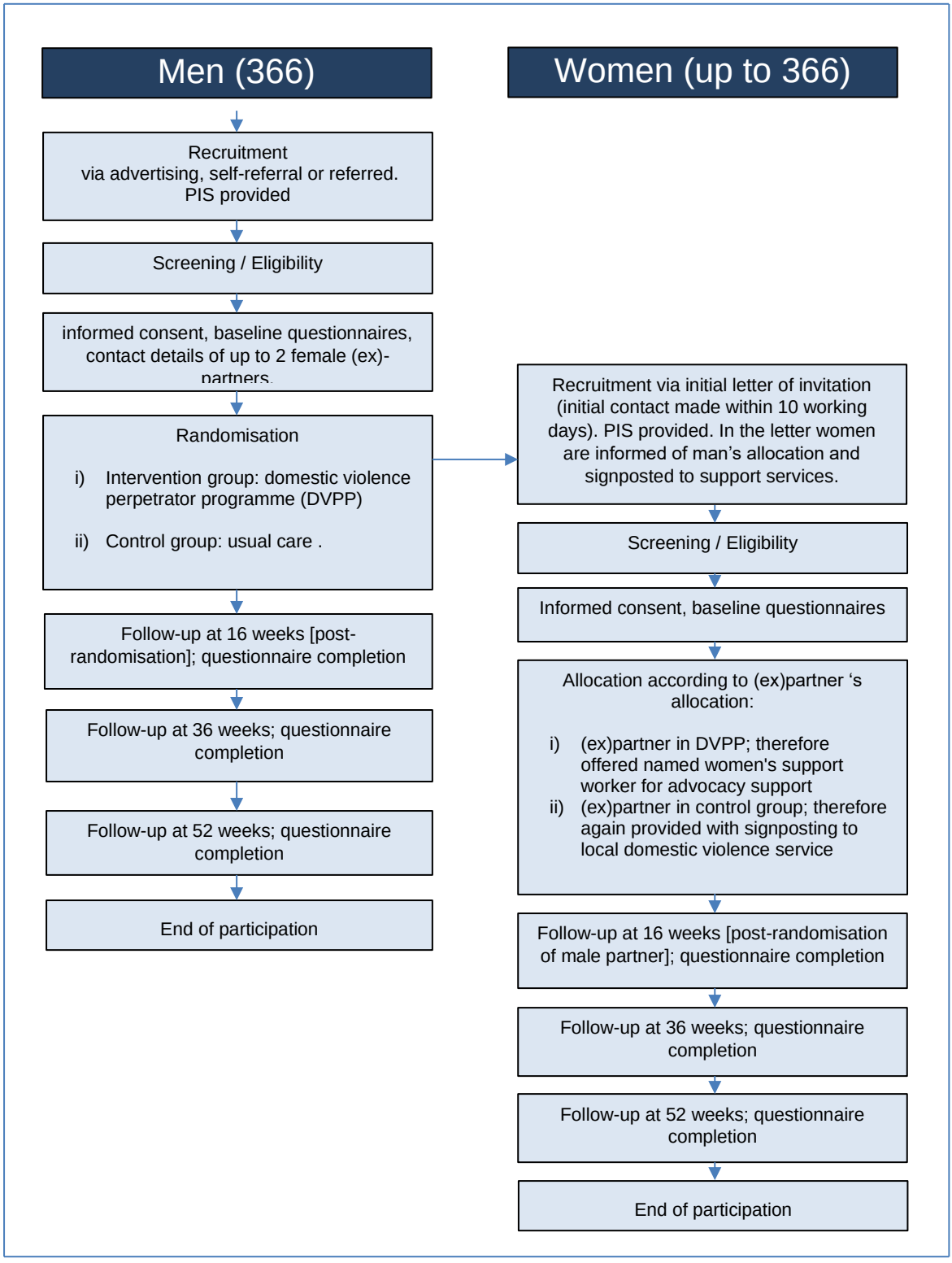
LIST of CONTENTS

LIST OF ABBREVIATIONS

ABI	Abusive Behaviours Inventory
ABI-R	Abusive Behaviours Inventory- Revised
AdminDB	Administration Database
AE	Adverse Event
APR	Annual Progress Report
AQ-10	Autism spectrum Quotient
AUDIT-C	Alcohol Use Disorders Identification Test-C
BAME	Black, Asian and Minority Ethnic
BANES	Bath and North East Somerset (CCG)
BNSSG	Bristol, North Somerset and South Gloucestershire (CCG)
CBT	Cognitive Behavioural Therapy
CCG	Clinical Commissioning Group
CHU-9D	Child Health Utility
CI	Chief Investigator
CONSORT	CONsolidating Standards of Reporting Trials
CPQ-SF	Communication Patterns Questionnaire – Short form
CRF	Case Report Form
DMEC	Data Monitoring and Ethics Committee
DSA	Data Sharing Agreement
DUDIT	Drug Use Disorders Identification Test
DV(A)	Domestic Violence (and Abuse)
DVPP	Domestic Violence Perpetrator Programme
EQ-5D	EuroQuol – 5D
GAD-7	Generalised Anxiety Disorder assessment - 7 item
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HRA	Health Research Authority
ICECAP-A	ICEpop CAPability measure - A
ICC	Intra Cluster Correlation
ICF	Informed Consent form
ISF	Investigator Site File
IDVA	Independent Domestic Violence Advisor
IPVRAS	Adapted Intimate Partner Violence Responsibility Attribution Scale
IQR	InterQuartile Range
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
PAS	Propensity for Abusiveness Scale
PC-PTSD-5	Primary Care Post Traumatic Stress Disorder screen - 5 item
PGfAR	Programme Grant for Applied Research
PHQ-9	Patient Health Questionnaire – 9 item
PI	Principal Investigator

PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PSC	Programme Steering Committee
PSS	Public Sector and Societal (perspectives)
QALY	Quality Adjusted Life Years
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
REPROVIDE	Reaching Everyone: Programme of Research on Violence in Diverse Domestic Environments
REDCap	Research Electronic Data Capture
RPG	Relapse Prevention Group
SAE	Serious Adverse Event
SD	Standard Deviation
SDV	Source Data Verification
SF-12	Short Form health survey – 12 item
SOP	Standard Operating Procedure
SSI	Site Specific Information
TMG	Trial Management Group
TSC	Trial Steering Committee
TMF	Trial Master File
UHBristol	University Hospitals Bristol NHS Foundation Trust
UoB	University of Bristol

TRIAL FLOW CHART



The effectiveness and cost-effectiveness of a group programme for men who are concerned about their abusive behaviour in relationships with women: A randomised controlled trial

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 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.bristol.ac.uk/population-health-sciences/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 trial.

We have also undertaken pilot work in which we found it was feasible to recruit and retain sufficient men who are concerned about their abusive behaviour and their (ex)partners to take part in a group intervention as part of an RCT. Similarly, our questionnaire completion rates reached our target of >60% retention at the end of the study period for both men and women enrolled into the pilot study. We have further developed a fidelity framework for the

intervention and have determined through the use of qualitative interviews that the intervention was acceptable to perpetrators, (ex)partners and staff.

Following a series of expert consultation and consensus meetings, and in line with our successful pilot work, we are now at the stage of testing this domestic violence perpetrator programme (DVPP) intervention for men who are concerned about their abusive behaviour in their relationships with women.

2. RATIONALE

The rationale for this 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.

The overall objective of this RCT is to determine the effectiveness of the perpetrator programme intervention.

The programme length will be 23 weekly sessions over 23 weeks with additional individual sessions based on need, and a monthly Relapse Prevention Group (RPG) for an additional 6 months following completion of the programme. The groups will be run on a rolling basis (i.e. new men will join the group at appropriate intervals). 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. The partners of men randomised to attend the DVPP will be offered a named women's support worker for advocacy and support. The number, frequency and length of sessions with the women's support worker, if taken up, will vary depending on need for each woman.

Eligible men will be randomised by a minimisation programme with a probabilistic component. Minimisation will be by whether or not they are still with their partner

(categories). The allocation system will be constructed and, as necessary, monitored independently of the research team.

There will also be a process evaluation including a nested qualitative study within the main trial (including, where possible, interviews with those who do not meet our criteria). This will explore processes of the intervention through observations/interviews to examine intervention acceptability, adherence and fidelity which will help to inform interpretation of the trial findings. This will also improve understanding of the needs of men (and their partners) and help to explain where the intervention may have worked for some and not others. This will be especially informative in examining/exploring the intervention's acceptability and effectiveness amongst men (and their partners) who identify as Black, Asian or Minority Ethnic (BAME), and perpetrators from the gay, bisexual, transgender and intersex communities. Interviews would provide specific insights into the challenges and barriers they may encounter and 'what works' for these groups.

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. A safety protocol has been developed and is available as a separate document (see SAFE and ETHICAL CONDUCT PROTOCOL FOR REPROVIDE PARTICIPANTS AND RESEARCHERS). All research staff will be familiarised with this protocol prior to conducting any trial-related procedure.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objectives

To investigate the effectiveness of the group programme intervention on reducing men's abusive behaviour against women. This will be achieved by the recruitment and (as far as possible) retention of 366 male perpetrators who will be randomised to either a 23-week weekly community-based perpetrator programme or usual care control arm plus, wherever possible, recruitment of their partners/ex-partners with a 12 month follow up.

3.2 Secondary objectives

1. Assess the effect of the perpetrator intervention on measures of DVA, health and wellbeing of the male participant, plus reports of police incidents.
2. Assess the effect of the intervention on measures of experience of DVA, health and wellbeing of female partners and ex-partners
3. To compare the costs and consequences of the intervention from NHS and public and societal perspectives (PSS)
4. Determine acceptability of the intervention to perpetrators, victims/survivors and professionals working with perpetrators and with victims/survivors
5. Through mixed methods process evaluation, to explore the extent to which the intervention was implemented, fidelity to the intervention, how and why the intervention was or was not beneficial.

3.3 Outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
To investigate the effectiveness of the group programme intervention on reducing men's abusive behaviour against women.	Primary outcome: Abusive Behaviours Inventory-revised (ABI).	**Baseline, 12 months:** ABI;
To assess the effect of the perpetrator intervention on measures of DVA, health and wellbeing on the male participants, plus reports of police incidents	ABI; IMPACT toolkit questions; criminal justice questions; PHQ-9; mental health questions; Generalised Anxiety Disorder assessment (GAD7); Primary Care-Post Traumatic Stress Disorder 5 (PC-PTSD-5); Propensity for Abusiveness Scale (PAS); Adapted communications patterns questionnaire- short form (CPQ-SF); adapted Intimate Partner violence Responsibility Attribution Scale (IPVRAS); Alcohol Use Disorders Identification test-C (AUDITC); Drug Use Disorders Identification Test (DUDIT); childhood experiences questionnaire; Reflective Functioning Questionnaire (RFQ)	**Baseline only:** mental health questions; childhood experiences questionnaire; **Baseline and 12 months only:** criminal justice questions; AUDITC; DUDIT; RFQ **Baseline, 4, 8 and 12 months:** ABI; IMPACT toolkit;; PHQ-9; GAD7; PC-PTSD-5; PAS; Adapted CPQ-SF; adapted-IPVRAS;
To assess the effect of the intervention on measures of experience of DVA, health and wellbeing of female partners and ex-partners	IMPACT toolkit; ABI-R; criminal justice questions; PHQ-9; mental health questions; GAD7; PC-PTSD-5; AUDITC; DUDIT; childhood experiences questionnaire;	**Baseline only:** mental health questions; childhood experiences questionnaire; **Baseline and 12 months only:** AUDITC; DUDIT; **Baseline, 4, 8 and 12 months:** IMPACT toolkit; ABI-R; PHQ-9; GAD7; PC-PTSD-5;
To determine the cost effectiveness of the intervention to the individual and society	Resource use questionnaire; police data; ICECAP-A; EQ-5D; SF-12, CHU-9D	**Baseline, 4, 8 and 12 months:** Resource use questionnaire; ICECAP-A; EQ-5D; SF-12, CHU-9D **12 months only:**

		Police data

4 TRIAL DESIGN

This will be a pragmatic, parallel group individually randomised controlled trial. We will be investigating the effectiveness and acceptability of the DVPP (including an RPG) and integrated women's support worker service as the trial intervention. We will use a mixed methods process evaluation to inform acceptability and barriers to implementation and an economic analysis of cost effectiveness.

4.1 Intervention

The DVPP will consist of a 23-week programme incorporating additional individual sessions based on need, and a monthly RPG for an additional 6 months following completion of the programme, and will be run by RESPECT accredited teams.

The group sessions will be delivered by two experienced DVPP facilitators (one male and one female where possible 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 eighteen months it 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 trial and to allow sufficient time for post-completion follow-up.

The weekly group sessions will incorporate most of the elements that 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; and accountability

The 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. The delivery team will refer and signpost men to specialist services as part of their normal DVPP conduct.

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.

All those invited to take part in the study, regardless of income or employment status, will be able to claim reasonable travel expenses associated with the cost of participating in the research programme.

4.2 Women's intervention

Women partners or ex-partners of men who are allocated to the intervention arm will be contacted by a designated women's safety worker as part of the intervention. It is the woman's decision whether she engages with the women's safety worker. Women can engage with the women's safety worker and decline to take part in the research, or they can take part in the research and decline the women's safety worker supporter, or they can accept or decline both.

Women's safety workers offer support to women who may want to remain at home, or who feel unsafe at home and need to go to a safehouse, or who want to stay at home and are not ready or do not wish to leave their abusive partner. Practical and emotional support is given to help victims to keep safe and also help with any court proceedings, connecting into the community and planning for the future.

4.3 Usual care control arm description (both men and women)

Men who are allocated to the usual care control arm will not receive any intervention or referrals from the research team; however, they are free to access any other services available to them as part of their usual care. The research team may signpost to other appropriate services (e.g. mental health services) if it is felt to be appropriate and/or necessary.

All women regardless of their partners' allocation will be signposted to women's support services.

4.4 Relapse prevention group (RPG)

Men who are allocated to the intervention arm will be able to access the RPG upon completing the DVPP. The RPG will meet monthly and will be run by the local service provider team (facilitator or DVPP coordinator). These meetings will be less structured than

the DVPP programme, with an emphasis on ‘checking in’ on how the participants are managing their behaviours.

5 STUDY SETTING

This study will be community based.

Initial meetings will be arranged in a mutually convenient location for the researcher, DVPP coordinator and potential participant. This will be within a community wellbeing organisation, health or social care building, or university building. Care will be taken when recruiting men and women.

The group programme intervention will be run out of community settings at four sites; three in south west England i) Bristol, North Somerset and South Gloucestershire (based in Bristol), ii) Somerset (based in Taunton), iii) Wiltshire and Bath (based in Trowbridge) and the fourth in south Wales iv) Blaenau Gwent (based in Blaina). This space will be rented on a weekly basis (if necessary) with the DVPP coordinator being based on site for the duration of the trial. If the women’s safety worker is not provided ‘in house’ but by another organisation, this worker will be co-located with the programme coordinator for at least one day per week to support good information sharing.

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 complete outcome questionnaires with or without assistance of the researcher
- Need to be able to understand and participate in an English-speaking group setting
- Must have contact with an abused partner or ex-partner within the last twelve months at the time of recruitment or, anticipate having contact with an abused partner or ex-partner within the next twelve months

6.2 Inclusion criteria for partners/ex-partners

- Female partners or ex-partners of men using violence/abuse in their relationships
- ≥18 years
- Ability to complete outcome questionnaires with or without assistance of the researcher

The difference in minimum ages between men and women has been discussed and the expert opinion is that younger men who abuse (pre-21) are often not so ready to change and the younger age group of men report having qualitatively different types of relationships with women. For example, younger men can use the internet and social media to be abusive much more and in this way 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 it could therefore be problematic having very young men and older men together in the same group.

6.3 Exclusion criteria for male participants

- Court mandated referral to perpetrator programme
- Men who are deemed too high risk as assessed by a DVPP coordinator or by the research team
- Men who are deemed by the DVPP coordinator as not willing to engage with the intervention.
- Men with known previous violence or aggression towards professionals
- Participants who cannot understand the English language sufficiently well to give informed consent and to complete the questionnaires (with or without assistance) or to participate in a group setting.
- Participants unable to consent to and engage with a group programme (this will include, but is not limited to, persons with a serious mental health difficulty, serious learning disability or unstable substance misuse difficulties.
- Men who have private court cases ongoing regarding child custody/access
- Men who have ongoing criminal justice investigations for a DVA incident towards a partner or ex-partner (i.e. waiting to hear if will be going to court or waiting for a court date).
- Men who are unwilling or unable to provide partner/ex-partner details to enable the research team to contact them. Men who fall outside the catchment areas (for the purposes of collecting data on police records).
- With the exception of attending a group programme of any length while in prison, men who have already participated in a group perpetrator programme which was longer than 6 weekly sessions or 4 days, within the last 12 months.

6.4 Exclusion criteria for partners/ex-partners

- Participants who cannot understand English sufficiently well to give informed consent and to complete the questionnaires (with or without assistance).
- Women who are deemed (by the women's safety worker, DVPP coordinator or research team) to be put at greater risk if they take part in the study.

7 TRIAL PROCEDURES

7.1 Referrals

Anonymised information on all potential participants (men and women) contacted will be collected in line with the Consolidated Standards Of Reporting Trials (CONSORT)[7] reporting guidance. This will include:

- age
- gender
- ethnicity
- sexuality
- the reason not eligible for trial participation, or if they are eligible but declined (see also nested qualitative study, section 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
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,	Referral/telephone call/email to research team
Self-referrals	Via RESPECT helpline, GP, leaflets.
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

Recruitment will be from across the Bristol, North Somerset and South Gloucestershire (BNSSG) region, Bath and North East Somerset (BANES), Wiltshire, Somerset and south Wales. Experienced researchers will be involved in the recruitment process.

Posters, leaflets, adverts etc will be used as part of the recruitment strategy to GPs, pharmacies and other local community settings. In addition, we will use targeted advertising using digital media platforms eg. Facebook. This will be part of a focused strategy outlining an enhanced e-recruitment campaign that will take the form of advertisements online (e.g. Google Ad Words, Facebook, and Twitter). The advertisements will contain information about the study, and direct interested individuals to our contact details and/or website, through which they can access more detailed information about the study and register their interest in participating. The recruitment strategy will outline when and where best to post information, reaching out to both potential recruits (ie Facebook) and for professional services referring potential recruits (ie Twitter). The strategy will include what influencers we contact and what audiences we will tailor targeted advertisements to. People will have control over adverts and can close/block them if they so wish to. We have carefully considered the risks around using each digital media route and will monitor this on an ongoing basis, seeking advice from ethics, RESPECT and our PPI groups as appropriate, and the many studies which are increasingly using this approach, see for example Boxall J L, Using Social Media as a Recruitment Tool for Clinical Trials, August 2020.

Potential participants who do not attend (i.e. did not call to re-arrange or cancel) two arranged initial eligibility and assessment meetings as planned will not be contacted further.

Men can be referred to the study by services (e.g. social services), can be signposted to the study (e.g. by their GP or RESPECT men's perpetrator helpline) or they can self-refer into the study (e.g. if they pick up a REPROVIDE leaflet or find study details through internet searching; see Consort flowchart A).

7.2 Recruitment

Once a man has self-referred or been referred to the research team, he will undergo the following:

1. Prospective participant has an initial telephone discussion with a researcher about study, eligibility screened.
2. If eligible, the Participant Information Sheet (PIS) will be sent via email or post.

3. Followed up by the researcher with a telephone call or email within 5 days and study explained with any questions from the participant answered.
4. If the participant wishes to continue, a joint recruitment meeting is arranged with the researcher and DVPP coordinator.
5. At the recruitment meeting:
    a. Researcher checks ID, assess understanding of the study and checks eligibility whilst the DVPP coordinator assesses suitability to potentially join a perpetrator programme. (If the participant is unsure about proceeding, or if the researcher or the DVPP coordinator suspect lack of understanding, or motivation, or have any other concerns about proceeding, the meeting should be stopped at this stage. The participant may be offered the opportunity to make a second appointment if more time is needed and if both the researcher and the DVPP coordinator feel this is appropriate).
    b. If the researcher, DVPP coordinator, and participant are happy to proceed, the researcher obtains informed consent from the participant to join the study. Both the DVPP coordinator and the researcher obtain contact details for the participants current and/or ex-partners, as well as GP contact details. The DVPP coordinator collects further information regarding mental health and substance misuse and any other agencies the participant is currently working with.
    c. Researcher asks participant to complete male baseline questionnaire.
    d. The participant is randomised and immediately informed of results.
    e. If participant is allocated to the intervention arm, the next steps are explained to him, and the DVPP coordinator arranges a full assessment meeting (which includes a full risk assessment).
    f. If participant is allocated to the control arm the next steps are explained to him. The participant is given a timeline of when to expect reminder contact and questionnaires for 4, 8 and 12 months to all.

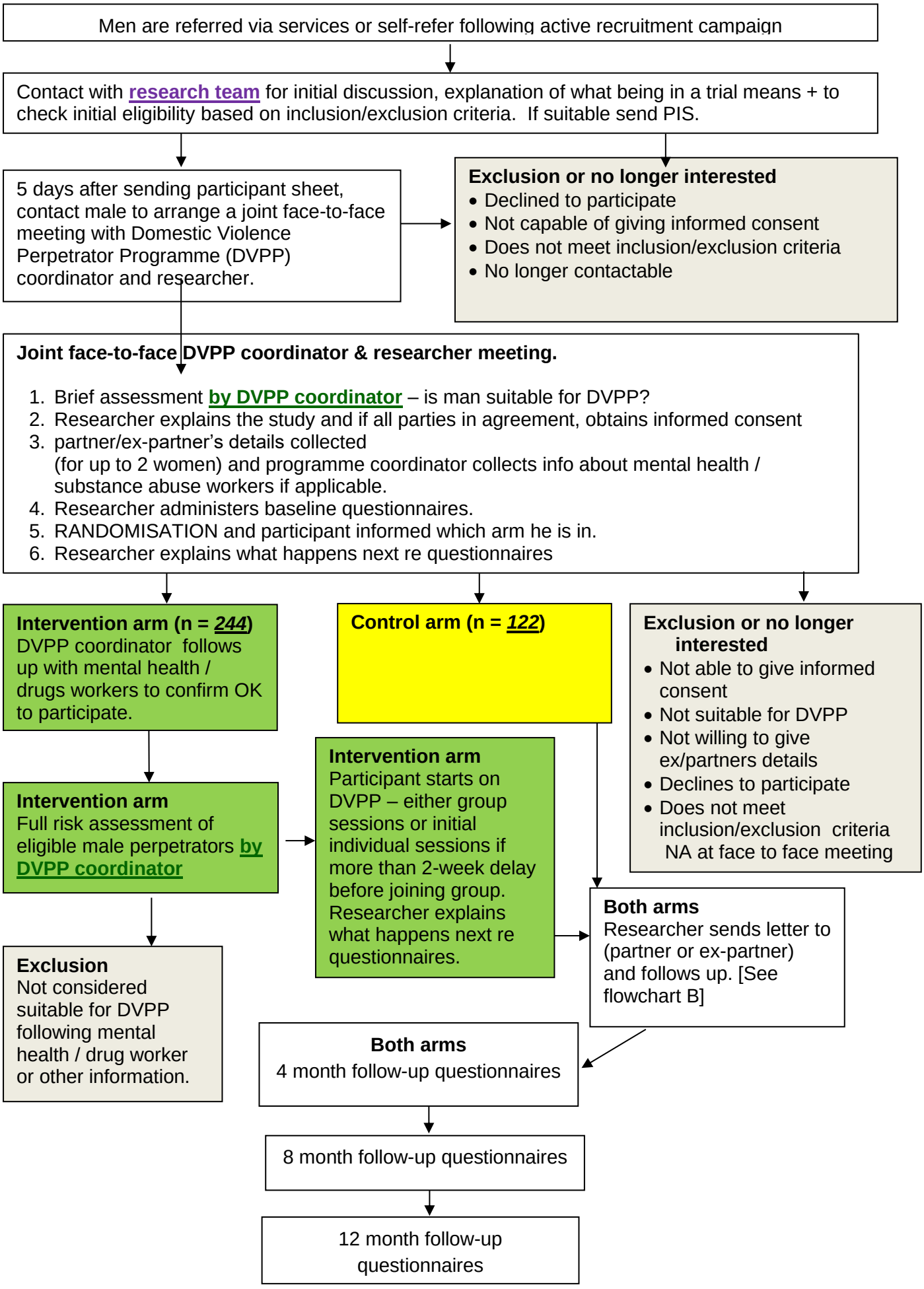
6. For men allocated to the intervention, the DVPP coordinator informs the appropriate Women's Support Worker of the (ex)partner's contact details.
7. Initial contact with current or ex-partner will be by letter, email, and/or by telephone to explain study, and inform current or ex-partner of male's allocation to intervention or control group. Women with ex-partners in the intervention group will be told that the women's safety worker will be in touch. Control (ex)partners will be signposted to appropriate local domestic violence services (See Consort Flowchart B below). All

women will be signposted to services regardless of if they wish to take part in the research or not.

8. If (ex)partner agrees to take part in the research, a meeting will be arranged to meet at a mutually convenient and safe location, to discuss the study in more detail. For (ex)partners unable to meet in person, informed consent may be taken through discussion over the phone, and in writing by email.
9. At meeting with female partner/ex-partner:
    a. The researcher explains the study again and obtains informed consent from the participant to join the study.
    b. If the participant is unsure about proceeding, or the researcher is unsure about proceeding for any reason, the meeting should be stopped before obtaining informed consent. The participant may be offered the opportunity to make a second appointment if the researcher feels this is appropriate and/or more time is needed by either party.
    c. If the researcher and the female participant are happy to proceed, the researcher obtains informed consent from the participant to join the study.
    d. Once consent has been received, collect supplementary information and complete female baseline questionnaire. For (ex-)partners unable to meet in person, supplementary information may be obtained over the phone or by email, and the baseline questionnaire may be completed by the researcher over the phone, or a link provided for the participant to complete online.
    e. Supply a timeline of when to expect reminder contact and questionnaires for 4, 8 and 12 months to all.

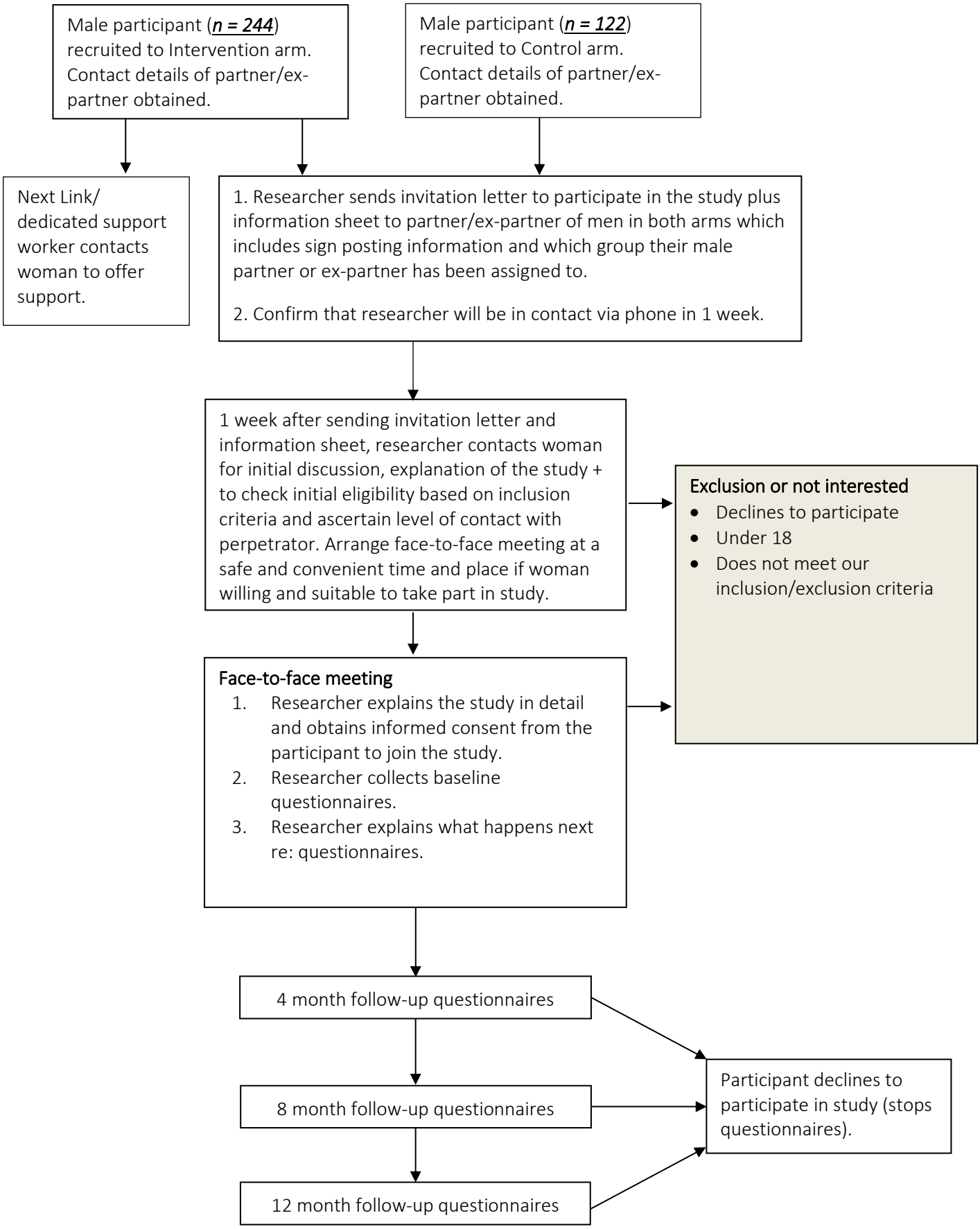
CONSORT Flowchart: A

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



7.2.1 Screening and consent

The Chief Investigator (CI) retains overall responsibility for the informed consent of participants 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 full 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, we will aim to briefly carry out telephone interviews with participants who withdraw and who are happy to talk to us (see also Qualitative section).

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

7.2.2 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 and/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.

7.2.3 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 CHU-9D[8,9] which we will ask mothers of children aged 8-18 to complete.

7.3 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. Randomisation will be stratified by site (Bristol, Somerset, Wiltshire, South Wales) and minimised by relationship status. This will assure similar distribution of selected participant factors between study arms. The first participant is independently randomly allocated; for each subsequent participant, the treatment allocation that minimises the imbalance on the selected factors (relationship status) between arms at that time is selected, albeit with a probabilistic element retained.

The allocation will be confirmed via an email from the randomisation system to the research team. This information will then be recorded on the trial database although not revealed to certain researchers (statisticians and health economists) blinded to allocation.

7.4 Quantitative Outcome data

Most of the questionnaires have been piloted and deemed appropriate for measuring outcomes for perpetrators of domestic abuse and victim/survivors.

7.4.1 Primary outcome

The **primary outcome** will be abuse reported by men based on the Abusive Behaviour Inventory (ABI)[10] measure of abuse at 12 months post randomisation.

7.4.2 Baseline measure only

The following measures will be collected at the baseline timepoint only.

- Socio-demographic measures including age, ethnicity, sexuality, religion, education, employment, income, housing, number of children at home,
- Current or past physical disability or mental health problems (self-reported), including treatment.
- Autism spectrum Quotient-10 (AQ-10)[11]
- Adverse Childhood experiences (adapted from PROVIDE survey and juvenile victimisation questionnaire[12])
- IMPACT monitoring Toolkit – Client or partner T0[13,14]

7.4.3 Secondary outcome measures

Measures to be completed from all male participants:

7.4.3.1 Physical/mental health status

- Patient Health Questionnaire-9 (PHQ-9) – a brief measure of depressive symptoms[15,16].
- Generalised Anxiety Disorder assessment (GAD-7) – a brief measure of anxiety symptoms[17,18]
- Primary Care-Post Traumatic Stress Disorder scale -5 (PC-PTSD-5) – 5-item scale to assess Post-Traumatic Stress Symptoms [19]
- Euroquol-5 Dimensions (EQ-5D-5L)[20] - a measure of health-related quality of life (http://www.euroqol.org/)
- Short Form health questionnaire-12 (SF-12)[21] – at baseline and 12 month timepoints only
- ICEpop CAPability measure for Adults (ICECAP-A)[22] –measure of capabilities for adults

7.4.3.2 Abuse, attitudes and behavioural measures

- Impact Monitoring Toolkit scale [13,14] – Impact on your partner question, section 3. children and section 4. relationship status of client T2 questions only
- Abusive Behaviour Inventory (ABI)[10]
- Adapted Communications patterns – short form (CPQ-SF)[23]

- Propensity for Abusiveness Scale (PAS)[24]
- Adapted Intimate Partner Violence Responsibility Attribution Scale (IPVRAS)[25]
- Reflective Functioning Questionnaire (RFQ)[28]

7.4.3.4 Substance abuse measures

- Alcohol Use Disorders Identification Test-C (AUDIT-C) – measure for alcohol use[26]
- Drug Use Disorders Identification Test (DUDIT) measure for other substances[27].

7.4.3.5 Resource use including use of health services, social and community services, voluntary sector services and legal services.

7.4.3.6 Criminal Justice measures

- self-reported police call-outs, police orders, arrests, cautions and probation contact.
- Police reports directly from police records – see police data

Measures to be collected from all female participants

7.4.3.7 Physical/mental health status:

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

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

- CHU-9D[8,9]

7.4.3.9 Abuse measures

- ABI-R
- Impact Monitoring Toolkit scale for partners - Impact on you question, section 3. children and section 4. relationship status of client T3 questions only

7.4.3.10 Substance abuse measures

- Alcohol Use Disorders Identification Test-C (AUDIT-C) – measure for alcohol use[26]
- Drug Use Disorders Identification Test (DUDIT) measure for other substances[27].

7.4.3.11 Resource use including use of health services, social and community services, voluntary sector services and legal services.

See Table 1 for measures and timelines during the trial.

Table 1

Questionnaires	Also known as:	Baseline	4 months	8 months	12 months
For male perpetrators and female victims					
Socio-demographic measures	e.g. age, number of children at home, ethnicity, income, occupation, sexuality.	✓			
Resources use questions	Use of health and social services, CSJ, medication use, housing, employment and benefits, use of children's services	✓	✓	✓	✓
IMPACT	IMPACT toolkit	✓			
IMPACT	Selected questions from the IMPACT toolkit		✓	✓	✓
EQ-5D-5L	Euroquol	✓	✓	✓	✓
SF-12	Short Form health questionnaire-12	✓			✓
PHQ-9	Patient Health Questionnaire -9	✓	✓	✓	✓
GAD-7	Generalised Anxiety Disorder assessment -7	✓	✓	✓	✓
PC-PTSD	Primary Care PTSD / Post-traumatic Stress Disorder scale	✓	✓	✓	✓
AUDIT-C	Alcohol Use Disorders Identification Test-C	✓			✓
DUDIT	Drug Use Disorders Identification Test	✓			✓
Childhood experiences questionnaire	Abuse when participant was a child	✓			
RFQ	Reflective Functioning Questionnaire	✓			✓
ICECAP-A	ICEpop CAPability measure for Adults	✓	✓	✓	✓
Current or past physical &/or mental health problems	(self-reported), including treatment.	✓			
Your children	Information about number of children and type and nature of contact – self report	✓	✓	✓	✓
Your relationship	Relationship status, type and nature of contact and hopes for the future	✓	✓	✓	✓
For male participants only					
ABI	Abusive behaviour inventory	✓	✓	✓	✓
AQ-10		✓			
IPVRAS- adapted		✓	✓	✓	✓

Propensity for abusiveness		✓	✓	✓	✓
Communications patterns - adapted		✓	✓	✓	✓
For female participants only					
ABI-R	Revised Abusive behaviour inventory	✓	✓	✓	✓
CHU-9D	Proxy version	✓	✓	✓	✓

7.5 Follow-up assessments

The research team will endeavour to maintain contact with participants every 6-8 weeks via text message, email or phone call in order to keep men engaged in the trial.

Questionnaire measures will be repeated at 4, 8 and up to 12 months following randomisation and we will continue to collect these data even if the participant decides to 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, post). Participants will be contacted up-to seven times through different means (calls, text, email) to complete follow-up questionnaires.

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 challenges and barriers to retention and acceptability.

7.6 Police Data

The key value of the police data is that it gives us an 'external' source of data on which to evaluate changes in the incidents of abuse in the 2 trial arms. The police data also gives us crucial information about men in the control arm and intervention men who dropped out of the DVPP group, especially where they also withdrew from the research (especially since many of them went on to reoffend in the pilot study) and we have little other data on them.

The police data will be collected in two stages:

Stage 1: Negotiating access to police files

The initial set-up process will involve: (a) finding an appropriate strategic police lead to agree to the project, (b) draft and obtain sign-off on a Data Sharing Agreement (DSA) from both the

police and the University contracts team, and (c) securing police 'Core Vetting' and access to the force's data records system for the named members of the research team.

Stage 2: Data collection, coding and analysis.

For each man, we will identify domestic violence incidents (in which he was the perpetrator) in the 12 months prior to recruitment, and the 12 months since recruitment. A list of variables will be coded from each incident record, including: who were the victim and perpetrator; what was the risk assessment; were referrals made to DV services, safeguarding, other services (e.g. mental and physical health, drug/alcohol, housing); was it recorded as a crime (i.e. "crimed") and what was the offence; were arrests and charges made; was there a trial; was there a conviction; was there a sentence. In addition, some metrics will be taken of the length of the case to make cost estimates about police involvement.

7.7 Economic data

For each man, we will collect resource use, and outcomes data. The resource questions focus on service use across a range of health, public (including use of criminal justice) and third-sector services as well as out-of-pocket costs relating to the intervention or domestic violence. Outcomes will be assessed by the administration of three preference-based measures: EQ-5D, SF-12, and ICECAP-A. We will also collect resource use relating to women and any cohabiting children where women are identified and consented. We will use the proxy (parent) completed version of the CHU-9D where self-report by child is not possible. Resource and outcomes measurement for children will be limited to an index child (where mothers have more than one child it will be the child who has the first birthday in the year and is aged 5 or over).

7.8 Process Evaluation

7.8.1 Context of each service

National and local context will be recorded throughout the study period. This will include matters such as any funding granted or cut to DV services, as well as any other context-related issues such as high profile DV cases.

7.8.2 Process Measures for each service

- 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
- Proportion of referrals or self-referrals which are converted into recruited participants. Including numbers of referrals or initial interest (self-referral) from different routes and proportion of referrals which result in recruitment

7.8.3 Programme Integrity

For each service we will be measuring the wider programme integrity. This will cover things such as whether staff received timely and appropriate supervision, whether the service is working within a multi-agency framework and whether the general principles/ethos of the programme is delivered.

7.8.4 Fidelity to the model

More specifically, we will measure fidelity including looking at: whether the session adhered to delivery style/stance and principles/ethos; if the session objectives (or core components) were achieved; how often over a 6-10 week period did the intervention allow both appropriate flexibility and deviation; and adherence to the model as needed.

7.9 Nested qualitative study

Qualitative research within trials can help to answer questions regarding the 'what, how and why' relating to the impact (or lack of impact) of the intervention. For example, qualitative research can help to provide insight into how the trial was conducted, examine how the intervention was implemented, understand the effect of context on intervention delivery, explore the 'active ingredients' of an intervention, explore the acceptability of the intervention to a range of participants, understand the impact of the trial on researchers and participants, and ultimately to explain how and why certain results were or were not achieved. We will collect qualitative data using a variety of different methods including interviews, focus groups and observation.

We will undertake qualitative data collection across all four trial sites and in three main areas: 1) experiences of male participants and potential participants; 2) experiences of female participants; 3) experiences of service providers and referrers.

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

7.9.1.1 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. Interviewing participants at different stages of the intervention will help us to capture the acceptability of the intervention at different stages, and to capture any changes in understanding, motivation, feelings of safety (for the women) and effectiveness across the duration (and beyond) of the intervention. Maximum variation sampling will seek to ensure that men from different age groups, socioeconomic status, ethnicity, sexuality, 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 will be carried out by experienced researchers.

7.9.1.2 Interviews with men in control arm

Semi-structured in-depth interviews will be conducted at various time points (early and later in the programme) with a purposive sample of men. The maximum variation sampling will seek to ensure that men are selected from different age groups, ethnicity, sexuality, 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.

7.9.2 Qualitative observation of process

Observations and brief fieldwork notes 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. Full observational notes on the assessment and recruitment of a small sample of male and female participants will also be collected. All observational work will contribute to describing the key characteristics of the intervention, its context and initial understandings of the key ingredients of. Researcher observations and 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.

Observations from the facilitator training sessions, intervention group videos, observation field notes from the groups 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.

Video recorded sessions will be further analysed in another sub-study that has recently been funded by NIHR; *Processes of change in a group intervention for domestic violence perpetrators: a secondary qualitative analysis* (RfPB PB-PG-1217-20027).

A more in-depth examination of the working alliance between participants and facilitators in the intervention groups will be conducted as part of a sub-study led by Jonathan Fowler and funded by the Home Office entitled: An exploration of the working alliance in domestic abuse perpetrator programmes. This sub-study will include observations of groups, the administration to facilitators and participants of the Working Alliance Inventory, assessments of facilitators motivational interviewing skills and focus groups. See Appendix 4 for more details.

7.9.3 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).

7.9.4 Views of men and women who declined participation or were consented and then either did not engage with the intervention or withdrew from 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 withdraw from 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 withdrawal 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 withdraw from the study up to three times.

7.9.5 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 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 Safe and ethical conduct protocol for Reprovide participants and researchers)

7.9.6 Experience of intervention providers

Semi structured interviews will be carried out with all the intervention group facilitators, DVPP coordinators, facilitators' supervisory managers, women's advocates and associated staff, across all four trial sites. These interviews will be carried out at the end of the intervention and focus on the acceptability, active ingredients of the intervention, how the intervention compares with other interventions experienced, barriers towards implementation 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. 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.

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).

7.9.7 Sampling matrix

Participants	**Intervention**	**Control**
Male perpetrators	12	12
Female partners and ex-partners	8	8
Excluded participants	Up to 16	
Participants who withdraw or drop out	We will informally seek the views of all participants who withdraw (from the trial) and/or drop out of the intervention where possible.	
Staff associated with intervention	Up to 12	

7.10 Withdrawals and exclusions

- Prior to randomisation, should an eligible person choose to not participate, this is counted as a **decline**. Reasons for decline should be collected if possible.
- Following randomisation, a participant can be **excluded** from the intervention and/or research 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/researchers (or anyone else). These decisions will be taken by the CI and Programme Manager and

research team in consultation with the DMEC and in collaboration with the DVPP coordinator/facilitators. These decisions will be documented as withdrawn from the trial (intervention and questionnaires) and will be classed as **excluded** by facilitators and/or researchers.

- Participants can choose to withdraw from the intervention but may still be followed up by completing questionnaires so long as the participant still consents to be included. This will be classed as a **withdrawal from intervention only ('drop out')**.
- Participants may also choose to be a **full withdrawal** from the trial (i.e. from both intervention and follow up questionnaires). Withdrawn participants will be informed that the research team may still use their data up until the point that they chose to withdraw.

8 SAFETY REPORTING

For this trial of a complex intervention, we will use the definitions assigned by GCP 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 monitoring, 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)	An SAE 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 separate document: *safe and ethical procedures for participants and researchers.*

8.2 Process and responsibilities for reporting SAEs

All AE reporting will be in accordance with the University Hospitals Bristol NHS Foundation Trust (UH Bristol) 'Research Safety Reporting Policy':

http://www.uhbristol.nhs.uk/media/3094119/sop_009_research_safety_reporting_uhbristol_v9.2_22.12.17.pdf

All SAEs will be followed up where appropriate by the researcher, the DVPP 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.

As soon as possible and within 24 hours of becoming aware of the event, a researcher must complete the Initial SAE report form (see Safe and ethical procedures document). To complete this form an attempt should be made to gather all the relevant information requested on the form, however, the form should be sent to the Programme Manager within 24 hours of becoming aware of the SAE regardless of how limited the information is. If the Programme Manager is absent then these forms will need to be forwarded to the sponsor and UH Bristol by the researcher within 24 hours.

If necessary to gather further relevant information, once this relevant information has been gathered a more complete SAE form should be sent to the CI (Prof Gene Feder or clinical cover; copying in the Programme Manager) – so they conduct a clinical review of the SAE. The Programme Manager will then forward to the sponsor and UH Bristol. This follow up form with further relevant information along with the clinical review should be sent to the sponsor and UH Bristol within 5 days. Further follow-up SAE report forms should be completed, until the SAE is resolved or a decision of no further follow up action has been taken.

All the relevant SAE forms must be signed off by the CI (or appropriate delegated clinical personnel in the CI's absence). The chair of the DMEC will also receive copies of all SAE reports. The Programme Manager is responsible for reporting to the CI and Chair of DMEC.

The CI will assess the SAE for intensity, causality and expectedness (see section 8.6 below). The DMEC chair may make recommendations and advise on whether to report the possibly related cases on to the research ethics committee chair, but all cases of definitely related will be reported onwards.

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

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.

8.6 Assessment of serious/adverse events

All AEs and SAEs need to be assessed in terms of intensity, expectedness, causality

8.6.1 Intensity assessment

The assessment of intensity is based on clinical judgement using the following definitions:

- **Mild** – An event that is easily tolerated by the patient causing minimal discomfort and not interfering with everyday activities

- **Moderate** – An event that is sufficiently discomforting to interfere with normal everyday activities
- **Severe** – An event that prevents normal everyday activities

8.6.2 Expectedness

The level of expectedness can be either:

- **Expected** – Reaction could be predicted/is foreseeable
- **Unexpected** – Reaction was unanticipated

8.6.3 Causality

The relationship between the intervention and the occurrence of the event will be assessed, taking into account the participants medical history, current therapy and other risk factors. The relationship will be categorised as follows:

- **Not related** - Temporal relationship of the onset of the event, relative to the intervention is not reasonable, or another cause can by itself explain the occurrence of the event.
- **Unlikely** – Temporal relationship of the onset of the event, relative to the intervention, is likely to have another cause which by itself can explain the occurrence of the event.
- **Possible related*** – Temporal relationship of the onset of the event, relative to the intervention, is reasonable but the event could have been due to another, equally likely cause.
- **Probably related*** – Temporal relationship of the onset of the event, relative to the intervention, is reasonable and the event is more than likely explained by the intervention than any other cause.
- **Definitely related*** – Temporal relationship of the onset of the event, relative to the intervention, is reasonable and there is no other cause to explain the event.

*Where an event is classed as possibly, probably or definitely related, the event is an **adverse reaction**.

9 DATA ANALYSIS

9.1 Power calculation for sample size

Due to the design of this study (including that each intervention group has a rolling intake of participants), the power calculation for the primary outcome of comparing the mean participant ABI between the two treatment groups was calculated both with and without taking account of the potential clustering within the intervention group.

In all power calculations, it was assumed that a 2:1 allocation ratio (intervention:control) would be used, a total of 219 participants would be available for analysis and a two-sided significance level of 5% applied. The sample size was inflated to account for 40% attrition giving 366 participants recruited in total (244 intervention and 122 control).

The sample size unadjusted for clustering was calculated using the *power* command in Stata 15.1, with an effect size of 0.4SD. This would give 79% power.

The sample size accounting for clustering was calculated using the *clsampsi* command in Stata 15.1. The cluster sizes for the intervention treatment groups were 9.125 participants for each (16 groups in total) and there was no clustering assumed in the control group. A range of intervention intra-cluster correlations (ICCs) were considered (0.025 to 0.05), due to the uncertain (and at this stage unavoidably unknown) effect of clustering within this rolling-intake group structure. Notwithstanding this uncertainty, with an (arguably conservative) intra-cluster correlation of 0.05 the above sample size would yield a power of 73% to detect an effect size of 0.4SD, and a power of 80% to detect a 0.435SD effect size. For an ICC of 0.025, there will be 76% power to detect an effect size of 0.4SD and 80% power to detect an effect size of 0.42SD. We therefore believe that our sample size will have between 73% and 80% power to estimate an effect size of between 0.4 to 0.435, for a range of plausible ICCs (0.025 to 0.05).

9.2 Statistical analysis

Simple descriptive statistics will be used to describe all outcomes measures in both treatment groups. For continuous measures we will describe the mean (SD) for normally distributed variables and the median and interquartile range (IQR) if skewed.

The full analysis set will be all participants providing outcome data, in the treatment group to which they were randomly allocated.

The primary outcome of ABI will be analysed at the individual participant level using a multi-level linear regression model, which will appropriately model the correlation between rolling-intake of participants in the intervention groups and hence account for the clustered nature of these participants' outcomes, as well as the control groups without clustering. This model will be adjusted for the minimisation and stratification variables used in the randomisation scheme as covariates and the baseline ABI outcome.

Similar regression models to that used in the primary outcome analysis will be used for the analysis of secondary outcomes, for instance employing linear or logistic regression models as appropriate given the nature of the outcome. These will be adjusted for the minimisation and stratification variables used in the randomisation scheme as covariates and the relevant baseline outcome. Sensitivity analyses will inform the interpretation of the primary outcome analysis by using appropriate imputation or model-based methods for missing primary outcome data. Additional sensitivity analyses will be performed on primary and secondary outcomes by adjusting for any baseline variables which differ by an amount that appears potentially substantial.

A more detailed statistical analysis plan will be produced and published before the onset of the analyses.

9.3 Embedded Economic Evaluation

The economic analysis will employ a cost-consequences framework such that costs are reported alongside primary and secondary outcomes. In addition, we will report QALYs for both men, their partners and the index child. Costs and effects may be expressed in a single summary measure if it is appropriate to do so, for instance in terms of cost per QALY or life year at full capability. The approaches to missing data, sampling uncertainty, correlation of costs and effects, and adjustment for minimization and stratification variables will be specified in the health economic analysis plan, which will also be produced and published before the relevant analyses are undertaken. Presentation of results will allow for multi-sectoral costs and benefits, to include NHS&PSS, public sector, and societal perspectives.

9.4 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 qualitative data analysis software (QSR International) 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 (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 Patient and Public Involvement (PPI) groups for discussion.

10 DATA HANDLING

10.1 Data collection tools and source document identification

10.1.1 Source Data and documents

Source data for this trial will be self-reported participant questionnaires (either paper or electronic formats) from male and female participants, audio recordings from interviews/focus groups, case notes, the confidential data collected by the DVPP coordinator during the risk assessment procedure, intervention group video recordings, session notes by the facilitators, the women's worker needs assessment, women's worker contact log for the female participants, and the women's worker relevant case notes. The intervention documents will remain the property of the service provider, but will be shared with the research team to verify contact information given to the researcher. Data on police incidents involving male participants will also be collected. Since the research team will need to collect information on number of contacts made, then access to attendance data will also be collected.

10.1.2 Case report forms

A case report form (CRF) will be prepared for each participant to record all administration data required such as name, address, date of birth etc. It will be a printed document, the contents of which will be entered into an online administration database (AdminDB). All paper CRFs will be kept securely and separately from paper questionnaire data in line with GDPR and the Data Protection Act (2018).

10.2 Data handling and record keeping

Administrative data including names, addresses, contact details and other personalised data will be stored on a bespoke management database (AdminDB), designed and managed by

the BRTC and held in the University of Bristol (UoB) SQL Server Cluster. All participants will be allocated a unique numerical ID number which will be used to provide anonymity and track their data. Since ID numbers will be accessible from this system, researchers will have unique logins and access will be restricted and controlled by the Programme Manager.

Questionnaire outcome data are collected using the BRTC Research Electronic Data Capture (REDcap)[29] 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, Bristol Medical School has set up its own infrastructure to host the REDCap application so that all elements reside within UoB.

All questionnaire data are 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. Outcome data are anonymised by use of the ID number and no personal details will be held on the outcome database.

REDCap user roles can be used in combination with field 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 researchers if necessary.

Outcome 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 outcome (REDCap) and Administrative (AdminDB) 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

All personal information and research 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.

It is the intention of the research team to share underpinning research data in order to maximise, reuse and evidence findings as this is a requirement by the funder and publishing bodies.

Therefore, upon publication, anonymised research data may be shared with bona fide researchers after registration and approval by the University of Bristol's Data Access Committee and will be subject to legally binding agreement (DSA) on confidentiality and data use.

10.4 Data Storage

Where possible, personal identifiable details will be removed from hard-copy documents and replaced with the participant's unique trial identification number. During the study, all hard copy documents containing patient identifiable data (e.g. consent forms and CRFs) will be stored separately from research data (e.g. questionnaires) in (as a minimum) locked filing cabinets within alarmed, access restricted University buildings of each of the research centres. Only local research teams will have access to these locked cabinets.

Electronic data will only be accessible via a password protected database held on a secure server.

10.5 End of study Archiving

- archiving will be authorised by the Sponsor following submission of the end of study report
- where paper questionnaires have been completed, the data will be scanned and stored in the Research Data Storage Facility, a secure long-term data storage repository held at the University of Bristol.
    - 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

- Research procedures and progress will be constantly monitored by the Trial Management Group (TMG)
- A Trial Monitoring Plan will be developed and agreed by the TMG) and PSC based on the trial risk assessment which may include on site monitoring.
- The members, roles and responsibilities (including oversight and monitoring) of the TMG, PSC and DMEC are listed on page 7.
- 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) & Health Research Authority (HRA) review

- Approval will be sought from a REC and HRA for the trial, including study protocol, informed consent forms (ICF) 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 including such amendments
- Non-substantial/minor amendments require review by HRA only
- All correspondence with the REC and HRA 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 CI's responsibility to produce the annual reports as required.
- The CI will notify the REC of the end of the study
- If the study is ended prematurely, the CI will notify the REC, including the reasons for the premature termination
- Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the REC

12.2 Peer review

An outline of the 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 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 PSC/DMEC or other programme advisory group has been documented.
- The Sponsor or Programme Manager will decide whether the amendment is substantial (requiring full review and favourable ethical opinion from the REC) or non-substantial (requiring notification to the HRA but not full review).

Guidance on the categorisation of amendments can be found on the HRA website.
http://www.hra.nhs.uk/resources/after-you-apply/amendments/

- Amendments to the protocol will be submitted to the REC and HRA for approval. The sponsor will also be notified at this point.
- Substantive changes will be communicated to relevant stakeholders (e.g., REC, HRA, trial registry, 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.

Only once the amendment has been approved by the REC and HRA (or acknowledged in the case of a non-substantial amendment) can the amended protocol be implemented.

12.4 Protocol compliance and deviations

All changes to this protocol that may be required as part of the trial will be documented and submitted for approval via an amendment as above. Researchers should not implement any deviation from the protocol without the agreement of the CI and with REC approval, except where necessary to eliminate an immediate hazard to the trial participant. 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, including the nature and reasons for deviation, on a file note to be obtained in the Trial Master File and reported to the CI, Data Monitoring and Trial Steering Committee.

12.5 Data protection and patient confidentiality

All investigators and trial site staff must comply with the requirements of the General Data Protection Regulation and Data Protection Act 2018 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

The development of the DVPP 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. This is detailed in the certificate of insurance.

12.8 Access to the final trial dataset

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

12.9 Trial registration

This study isregistered on the Current controlled trials registry. ISRCTN15804282

13 PATIENT AND PUBLIC INVOLVEMENT (PPI)

We have two active PPI groups informing this 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. PPI groups have been consulted on the questionnaire content and formatting, recruitment strategies etc. Similarly, both groups have input into the recruitment material including the PIS and ICF process. Continued regular meetings will help inform any issues arising throughout the research period.

Our PPI groups will also be involved in the planning of the qualitative interview questions, the interpretation of the findings and planning and dissemination of the study findings.

14 KNOWLEDGE MOBILISATION AND DISSEMINATION POLICY

A separate knowledge mobilisation strategy and dissemination plan will be drafted in order to identify and target various stakeholders and audience groups to engage and disseminate information to.

The academic members of the research team have expertise in the presentation of evidence to a wide range of audiences at national and international level. They will work with experts on the Programme executive committee, steering committee and scientific advisory groups, complimented by commissioners, service users from third party sectors and charities to ensure that the research is disseminated widely and to the appropriate audiences.

14.1 Dissemination to academics

All researchers are encouraged to publish research from this programme of work. A publication plan will be drafted as part of a wider dissemination and knowledge mobilisation strategy. This publication plan will be mostly academic research papers comprising an initial list of key papers with tentative titles or key areas, target journals, lead and key co-authors and a potential timeline. This list will evolve over time and will be reviewed regularly to assess progress.

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
- 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."

- For the pilot trial we did not publish the protocol, but if a favourable outcome means that the full trial goes ahead, we would publish the full 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.

Credit and order of authorship will follow authorship eligibility guidelines

- The main author(s) of the final report will be first author and unless there are other individuals who have made especially substantial contributions then 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.

14.2 Dissemination to participants

- We will prepare and publish regular newsletters 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.
- We will take advice from our PPI representatives to engage their support in disseminating findings. This may involve the use of media (local radio and newspapers) and social media.

14.3 Dissemination to third sector organisations

- One of our partners is RESPECT who run regular national conferences on practice and research on DVA. We aim to publicise the ongoing research and findings at their meetings.
- We will also utilise our contacts with collaborating organisations e.g. Nextlink, Splitz and Barnado's, to disseminate study information and findings using their organisation's communication channels, e.g. their organisational newsletters, websites and networks.
- Finally we aim to run an end of study conference event where the results and implications of the study can be communicated to all stakeholders including interested third party organisations and commissioners.

14.4 Dissemination to Commissioners and Policy Makers

Commissioners and policy makers will be invited to the conference event as described above. Some members of the research team have participated in government select committees and in commenting on the latest government DV Bill consultation document. We will continue to contribute to inform policy and other relevant consultations.

A guide for commissioners or policy briefing will be produced with the help of Policy Bristol and our partners.

15 END OF STUDY

Investigators and/or the TSC have the right at any time to terminate the study for clinical or administrative reasons.

The investigators, with the advice of the DMC will establish a set of criteria for stopping the study prematurely.

The end of the study will be reported to the REC within 90 days, or 15 days if the study is stopped early. The investigators will inform participants and ensure that the appropriate follow-up is arranged for all involved.

A draft final report and a final summary report is required by the funder within 14 days after the completion date of the programme or date of termination.

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17 APPENDICIES

Appendix 1 Flowchart for Safeguarding reporting*

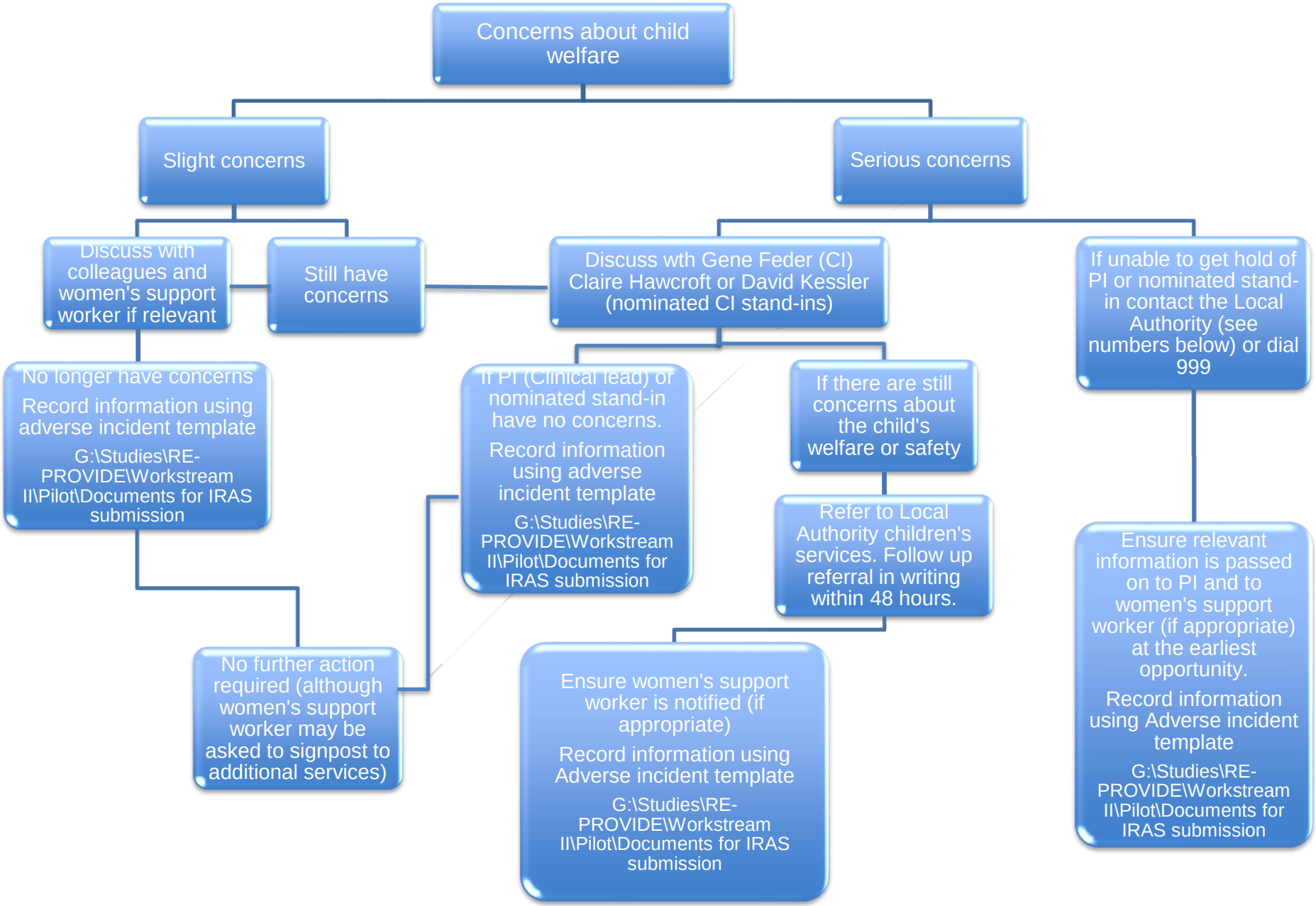
Appendix 2 Safety Reporting Flow Chart (SAEs)

Appendix 3 Response to COVID-19 Pandemic

Appendix 4 Amendment History

***Safe and ethical procedures for participants and researchers submitted as a separate document**

Appendix 1


Concerns about child welfare
Slight concerns
Serious concerns
Discuss with colleagues and women's support worker if relevant
Still have concerns
Discuss wth Gene Feder (CI) Claire Hawcroft or David Kessler (nominated CI stand-ins)
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.
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
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

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

Appendix 2 – Safety Reporting Flow Chart

SERIOUS ADVERSE EVENTS (SAE)

***Also see 'SAFE AND ETHICAL PROCEDURES FOR PARTICIPANTS AND RESEARCHERS' document**

All SAEs should be reported and the initial SAE form completed by the researcher/facilitator. This should be sent to the Programme Manager who will notify the CI (Prof Feder), Chair of DMEC, sponsor (incl UHBristol) within 24 hours.

The CI (with advice from the DMEC Chair) will assess the SAE for :

- intensity,
- expectedness
- causality to the intervention.
- what further action is required

1. Definitely related to intervention/participation?
   This will require a report to REC.

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

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. A follow-up SAE form must then be completed within 5 days of becoming aware of the event.

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: research-governance@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)

Appendix 3 - RESPONSE TO COVID-19 PANDEMIC

3.1 COVID-19 background

In December 2019, China alerted the World Health Organisation to a number of cases of a type of flu in Wuhan, Hubei province. Despite efforts to contain the virus, by 30th January it was declared a Public Health Emergency of International Concern and on the 11th March COVID-19 was characterised as a pandemic by the WHO. As a result of this and once the virus had reached a critical point within the UK, a range of mitigation measures have been advised by the NHS, the DHSC and NIHR, and by the UK government. These measures include 'social distancing' which involves: avoiding contact with anyone displaying symptoms of COVID-19; avoiding non-essential public transport; working from home where possible; and avoiding large gatherings (including family gatherings) and small public spaces such as pubs and restaurants. On 23rd of March, this was tightened further into a formal lock-down, with all non-essential business closed, further isolating people in their homes.

3.2 Implications of COVID-19 for the REPROVIDE Trial of a group programme intervention for men who are concerned about their abusive behaviour

The implications for the REPROVIDE randomised controlled trial and for potential participants are profound. Early indications from China are that the incidence of DVA increased when self-isolation was imposed and services are concerned that a similar increase will happen in the UK as a result of families having to self-isolate, compounded by increasing uncertainty over jobs and financial security for familiesi. In this context, the victim support and signposting services to partners and ex partners, and the identification and monitoring of abusive men that are provided within the context of the REPROVIDE study are vitally important services to continue. This we plan to do in a number of ways.

3.3 Participants already recruited to REPROVIDE

For those already recruited, we will:

a. Send an initial update to all participants (by post or email, as preferred) confirming their continued participation in the trial. Updates are in the current protocol;
b. For those in the intervention arm, inform them that the weekly DAPP groups have been suspended for men. However, the regular contact from the DAPP coordinator will continue. While regular contact is as per protocol, the suspension of groups is a change to the protocol in response to COVID-19;
c. Send a monthly check-in text with reminders of who to contact when needed, as per protocol;

d. Inform all participants that they are still in the trial and 4-, 8-, and 12-month questionnaires will still be sent out but that there may be a short delay in when they receive these questionnaires.
e. Monitor the 'holding' sessions that coordinators are conducting with male participants while groups are on temporarily suspension due to COVID-19
f. In the update to female partners and ex-partners (intervention and control arms) we will include a list of local and national domestic abuse services. For intervention ex/partners we will confirm that they will continue to be offered telephone support from the women's safety worker. This is as per protocol.
g. Initial contact with female partners and ex-partners is now a little earlier in the process, before men are randomised. This is to explain the study to the ex/partners and ensure that they do not feel their or their children's safety might be compromised if the man is recruited to the study, and in particular to ensure that she understands about the randomisation element as getting the control group can sometime be a disappointment to men.

Four month 'pause' to follow-up questionnaires

Initially, continuing to follow-up participants who have already been recruited, we were able to measure both men's self-reports of abusive behaviour, their mental health through the crisis and also reports of abusive behaviours from recruited ex/partners through the 4-month questionnaire.

However, as the vast majority of the participants have yet to start their intervention, and those that have started have not been able to participate in groups, a decision has been made following discussions with the trial statisticians to 'pause' the follow up questionnaires. The 'pause' will be for the period of COVID-19 lockdown that corresponds with the suspension of the intervention groups and the 'pause' will end once the groups recommence. All groups stopped the week of 16th March 2020. It seems likely that groups will resume/start up from the 3rd week in July. The pause period is therefore likely to be around 16-18 weeks (some flexibility was already built in to take into account a waiting period for enough numbers to form a group). Steps required include:

- Stopping secure research electronic data capture software from automatically inviting participants to complete follow up questionnaires;
- Sending a text burst to all participants to advise them of the pause and ensure they understand that the overall study period may now be longer than 12 months. For participants unable to receive a text burst, a letter will be sent out. They are invited to contact us if they have any concerns or questions;

- Some participants (n= 19 – both male and female) have completed 4-month follow-ups already, so they will experience a longer gap between 4- and 8-month questionnaires;
- Those who have already been asked to complete a 4-month questionnaire but the study has not yet received it, will continue to receive reminders for it.

Men and their ex/partners will continue to be monitored through the 'holding' contact provided by our intervention partners via weekly or bi-weekly telephone calls. Any safeguarding concerns and serious/adverse events will be reported as normal. Research team members will continue to check all returned postal questionnaires, reviewing these for safeguarding concerns.

As this is only for participants already recruited, there are no changes required to the participant facing documentation. As above, all participants will be contacted to ensure they are informed of the delays.

3.4 Intervention arm: Weekly group domestic abuse perpetrator programme and support to linked partners and ex-partners via the women's safety worker

As a result of the advice (and subsequent government order) to impose social distancing, the decision has been made to suspend all our group perpetrator programmes in all four sites with effect from 17th March 2020 and until further notice. Delivery partners will, however, maintain regular contact through weekly or two-weekly phone-calls or texts (or similar contact by another method) with male participants in the intervention arm. This has been termed 'holding' and for intervention men will be in the form of advice and support. An agreement has been reached with our partners on what 'holding' constitutes and this will be reviewed regularly. The DAPP coordinator will react appropriately to crisis situations and carry out safeguarding activities as and when the men share this information. Tools such as 'Time Out' will be used where appropriate, such as to de-escalate tensions, but the DAPP coordinators will not seek to proactively guide men to unpick their abusive patterns as they would in an individually delivered behaviour change programme. The ex/partners of the intervention men will still be able to contact their women's safety worker as usual.

The research team have developed templates for recording all male and female contacts and will collect this data from delivery partners on a regular basis to ensure accurate descriptions of the intervention alterations needed during COVID-19. A buddying system will be in place for the women's safety workers in two of the sites in case of illness during the COVID-19 period with the other two sites having more extensive backup cover for victim support within their own organisations. The research team and all delivery partners will continue to engage in regular

(virtual) meetings to troubleshoot concerns, to monitor how the one-to-one 'holding' contact for men progresses and to increase the consistency in this contact between sites.

Introduction of a hybrid approach to group delivery model during lockdown from February 2021

During the repeated COVID-19 lockdowns up to the end of 2020, as above groups were largely continued with one all-site pause being put into effect March–July 2020, with groups resuming in late July. However, the January+ 2021 lockdown saw a high infection rate and some partners felt it was not safe to continue face-to-face but rather than put in another pause to groups, suggested a modified approach could be used for a short period: a hybrid delivery model in which carefully chosen topics could still be delivered on-line, either in a full group situation or a mix of group and 1:1 methods (e.g. by telephone), depending on individual circumstances and taking into consideration their and their family's safety. This would be a short-term measure during the current or future lockdowns if the agency delivering REPROVIDE wants to use this in place of face-to-face group sessions.

We propose to select 1-2 core objectives for each session which the sites would then deliver to the participants, counting as a session from the manual. The hybrid delivery model may vary between sites and with the shared 1-2 core objectives in place, the sites may deliver the sessions according to their own preferences, constraints and understanding of what would work best for the men in their groups. For example, the hybrid model may consist of a 1-hour online group presentation, followed by a 30 minute 1:1 'check in' over the telephone with each man, conducted in the following days. Alternatively, the online group delivery model may be more participatory plus 1:1 check-ins, or, if the technical challenges to online groups seem too great, the delivery of the core objectives for each session could be delivered with each man over the telephone in a 1:1 session. The groups would revert back to face-to-face meetings as soon as feasible, recognising that this may take place at different time points in the different REPROVIDE sites, depending on local infection rates.

The reasons for this approach are:

- The rising incidence of Covid-19 infection, and possibly vaccine-resistant new variants, which increase the risk to staff and participants (and their families) in face-to-face group meetings, even with strict precautions.
- A concern that the groups would lose momentum in another full pause with the risk of increased dropouts from the intervention and the trial.

- A concern that another pause in the group programme may have significant cost implications which could not be met.

In adopting this hybrid model, we are considering:

a. Whether this should be only for men already on a group, rather than newly recruited men. Initially we will take this approach, but if lockdown goes on for longer, we will review using this delivery mode for all men until face-to-face groups resume;

b. Assessment of whether the online group model works for all men or whether less literate men/less technologically literate men need the sessions to be covered on a 1-1 online/ telephone basis. The intervention partners will make this decision at an individual level;

c. The length of online presentations, and have referred our partners to the new Respect online resource: https://hubble-live-assets.s3.amazonaws.com/respect/redactor2_assets/files/676/Online_Guidance_For_Domestic_Abuse_Service_Providers_January_2021.pdf;

d. What the safety implication are for these new formats e.g. avoiding delivering particular topics such as sexual respect online, and the potential presence of family members during the meetings;

e. Recording the on-line groups for monitoring purposes is being considered, as groups are already recorded. We will continue to collect data on one-to-one delivery elements as done in the previous pause.

Initial joint agreement was reached across all the sites for this hybrid proposal. This decision was backed up by the recent Respect guidance, affirming that switching to online work can still be in line with Respect standards, with certain safety protocols in place.

3.5 Continued (virtual) recruitment to the trial

We will continue to accept referrals in to the study as set out in S.7.1 and the research team will go through the recruitment process as outlined in S.7.2.1 – S.7.2.4 above, and will inform potential participants that we remain open to recruitment. In the light of COVID-19 restrictions, an addition to the above referral and recruitment procedure is that the research team will contact the ex/partner at this point, prior to proceeding to recruitment of the man, in order to get the ex/partner's views on how safe she and her family would feel if he was involved in the study, and particularly if he was assigned the control group. It will be particularly important to check this if a couple are in isolation in the same household. As long as the ex/partner is satisfied his involvement in the study will not increase the level of risk to her and her family, then recruitment will proceed. For as long as face to face meetings cannot take place due to

Government restrictions, assessments will take place virtually, using either Skype, WhatsApp or telephone.

Consent from the participant will be taken verbally over the phone/Skype/WhatsApp with the researcher talking him through each item on the consent form, initialling each item and signing the form on the participants' behalf. This verbal consent process will be audio recorded where possible. Informed consent going forward may also include (non-audio recorded) verbal consent followed by an email confirming their agreement to be part of the study. Informed consent may also involve the researcher going through the consent process verbally over the phone/Skype/WhatsApp with the DAPP coordinator witnessing the signing, then securely storing the written consent as well as photographing the consent form and sending to the researcher. A copy of the consent form with the method of consent agreement stated will be posted or emailed to the participant for his records. Although these options for informed consent are not as rigorous and are more open to bias compared with 'normal' trial proceedings, we feel that the ethical imperative to continue to identify and recruit abusive men and their ex/partners into the study reasonably balances these potential dangers.

3.6 Exclusion criteria for male participants: expansion of criteria for men who have ongoing criminal justice investigations

- Court mandated referral to perpetrator programme
- Men who are deemed too high risk as assessed by a DVPP coordinator or by the research team
- Men who are deemed by the DVPP coordinator as not willing to engage with the intervention.
- Men with known previous violence or aggression towards professionals
- Participants who cannot understand the English language sufficiently well to give informed consent and to complete the questionnaires (with or without assistance) or to participate in a group setting.
- Participants unable to consent to and engage with a group programme (this will include, but is not limited to, persons with a serious mental health difficulty, serious learning disability or unstable substance misuse difficulties.
- Men who have private court cases ongoing regarding child custody/access
- Men who have ongoing criminal justice investigations for a DVA incident towards a partner or ex-partner (i.e. waiting to hear if will be going to court or waiting for a court date). *Temporary exception to the exclusion criteria for men who have ongoing criminal justice investigations. Men who have ongoing criminal justice investigations for a DVA incident towards a partner or ex-partner (i.e. waiting to*

hear if will be going to court or waiting for a court date) to be included as long as there is a clear safety plan in place, all risks have been assessed and evaluated, and with the safety of the victim and undue influence on the court process remaining as paramount.

- Men who are unwilling or unable to provide partner/ex-partner details to enable the research team to contact them. Men who fall outside the catchment areas (for the purposes of collecting data on police records).

Use of e-Consent

The secure electronic clinical data collection software in use is REDCap, supported by the University of Bristol's (UoB) Trials Centre (BTC). UoB has recently approved the use of e-Consent within this system, and we propose to use this during lockdown. We may continue to use this system where needed, post-lockdown, as it is highly suited to our participant base, being simple to use for tablet and telephone consent as well as via a computer consent form.

There are many security features built into the system:

- The participant is expected to supply their name as well as their signature, using an obligatory signature box;
- eConsent questions are answered with a simple Yes/No option and all fields are compulsory with no exceptions;
- Each question will provide a specification to state whether a negative response excludes them from the trial with an exclusion message displayed. This ensures that the outcome of responding with a negative is made clear;
- The system sends the participant a completed PDF copy of their form once submitted;
- Forms are locked to prevent modification and can only be changed by authorised BTC Data Managers. All modifications require an official request and are logged.

At the beginning of any contact call, some additional risk management questions will be asked to ensure that, at the present time, the participant is in an environment which is both safe and private. Some basic questions on current circumstances may be added. The answers to these will not be recorded, as these are to ensure that the conversation following will be secure.

The participant will be asked to compete the baseline questionnaire either by a link to completing it immediately online, or by going through the questions with the researcher. If a participant is allocated to the intervention arm, the next steps are explained to him, and the DVPP coordinator will arrange a full assessment meeting (which includes a full risk

assessment) which will take place over the phone/Skype/WhatsApp or similar. The DVPP coordinator will then remain in contact with the participant on a regular basis until the group programme is able to re-start. If a participant is allocated to the control arm the next steps are explained to him. All participants will be given a timeline of when to expect reminder contact and questionnaires for 4, 8 and 12 months. Recruitment of ex/partners will be carried out as outlined in section 3.3 above and will take place over the phone or online via Skype/WhatsApp/GoToMeeting/Bluejeans or similar or by email.

3.7 COVID-19 specific qualitative work enhanced and expanded

The nested qualitative study already set out in section7.9 will be expanded to include questions in the topic guides relating to the impact of the pandemic on the male and female participants. In particular, questions will added to assess whether and how abusive behaviour may have increased (or decreased) as a result of self-isolation. With regards to sampling, because the recruited numbers of participants are still fairly small, we will invite a sample of men and women recruited to date to be involved (subject to the Trial Safety Protocols and a sampling framework).

Male and female participants in both the intervention and control arms will be asked to take part in a semi-structured telephone interview, provided it is safe for them to do so and they can be sure that the interview can take place without risk of being overheard. For male participants in the intervention arm, questions might include views on the recruitment process, motivation for joining the study, how those men who have started the intervention have found it so far and how they are dealing with the suspension of groups, how useful the “keeping-in-touch” calls from the programme coordinators are in this interim period, and how they are dealing with the impact of self-isolation. For men in the control arm, interviews will focus on the recruitment process, randomisation, and motivation to join the study as well as how they are dealing with the impact of self-isolation. Recruited ex/partners will be asked if they feel their male ex/partner’s behaviour has changed and how, whether they feel more or less safe and if the pandemic has had an impact on this, and whether they are sure they know where to get support if needed.

If the participant agrees, interviews will be recorded. Consent will be acquired at the beginning of the interview and if verbal, stored together with the rest of the interview. However, all recorded interviews will be marked as “Closed” when submitted for data sharing, with only anonymised transcripts being available for future data sharing purposes.

[1] Women's Aid (2020) 'The impact of COVID-19 on women and children experiencing domestic abuse, and the life-saving services that support them'. Available at https://www.womensaid.org.uk/the-impact-of-covid-19-on-women-and-children-experiencing-domestic-abuse-and-the-life-saving-services-that-support-them/

Appendix 4 – Additional Sub-study: An exploration of the working alliance in domestic abuse perpetrator programmes

This Appendix outlines the inclusion of an additional sub-study to REPROVIDE that explores the relationship between members of the intervention group, who are participating in a 23-week weekly behaviour change course, and the facilitators of those groups. The study consists of:

1) Quantitative data collection

Using the Working Alliance Inventory (WAI), a widely used and strongly validated instrument that explores how the relationship (the working alliance) between therapists/facilitators and clients/group-participants is experienced, data will be collected from 36 members of the intervention group, and from 16 group facilitators.
b. Examine both client and facilitator factors that may be influencing the strength of the working or therapeutic alliance. Potential factors include:

a) Whether the strength of the working alliance is linked to the reflective functioning of clients using data about client's reflective functioning already being collected as part of the trial.
b) Whether strength of the working alliance is linked to the motivational interviewing (MI) skills of the group facilitators, or other facilitator factors through:
    i) The Video Assessment of Simulated Encounters Revised version (VASE-R). VASE-R is a reliable and strongly validated instrument that assesses staff MI skills by requiring them to write responses to questions about three short video segments of actors playing clients with low or ambivalent motivation to make changes.
    ii) Other facilitator factors that may impact on the working alliance collected via a short questionnaire (e.g., gender, attitude towards a person's ability to change, length of training etc.).

2) Qualitative data collection

a) Group sessions will be observed for indications of the strength of the working alliance and factors that may be influencing this. Observations of the group sessions are already undertaken as part of the trial. This study adds one additional observation of each group session.
b) An anonymised summary of the findings from the above will be used as a starting point for focus groups with staff working within the intervention programme and/or a small group of ex-clients of similar programmes.

This relationship sub-theme emerged during the pilot study and has continued to be a theme of discussions with facilitators and PPI groups. Discussions have highlighted the perception of the centrality of the relationship (working alliance) between participants and facilitators in achieving outcomes. Strong associations between the strength of the working alliance for successful behaviour-change have previously been found with other client groups (Horvath et al., 2011 for a meta-analysis of 14,000 of these studies). Group participant factors and facilitator factors that could influence this association have also been suggested. The reflective functioning (capacity to understand behaviour in the light of underlying mental states and intentions) of participants has been suggested as a key characteristic of participants that will impact on the formation of strong working alliances. Poor reflective functioning was not measured in our feasibility study but is now being measured as part of the trial. The association between the working alliance and reflective functioning has not been explored previously within this type of intervention.

Building working alliances is a key skill of domestic violence perpetrator programme (DVPP) facilitators, and motivational interviewing (MI) has been highlighted in previous studies as a method for doing this. MI is a directive, client-centred intervention that focuses on building a relationship from which shared goals and tasks can be agreed between therapist and client. MI is at the heart of UK offender behaviour change programmes, and a recent survey of UK DVA perpetrator programmes showed 81% included MI as part of their interventions. The accrediting organisation for DVA perpetrator programmes in the UK, Respect, state in their standards that “motivational interviewing is a basic skill for those working with perpetrators of (DVA)”.

Given the evidence that MI skills are key in building a working alliance between facilitators and perpetrators, others facilitator factors may be equally - or more - important (eg. gender, attitude towards a person’s ability to change, length of training etc.) and this study will explore these factors further.

Justification for proposed amendment and its significance for the study

Although the working alliance between facilitators and participants was understood to be one factor in the theory of change for the intervention we now think it may be a strong predictor of behaviour change. A recent meta-analysis covering more than 14,000 treatments found a consistent reliable effect 7.5 times stronger than the impact of the choice of therapy model. There is also evidence that poor reflective functioning is predictive of challenges in forming a strong working alliance and a focus on the interactions in the working alliance and on strengthening this, is central to treatments that aim to improve reflective functioning. There is

also evidence that a range of facilitator factors, including their MI skills, influence the building of working alliances.

A greater understanding of the factors that influence the building of working alliances could have significant implications for the further development of DVPP models in future, and for interpreting some of the findings of the trial.

Aims and objectives

REPROVIDE DVPP RCT is testing the effectiveness of DVPPs. It is important to know if sub-groups of Intimate Partner Violence (IPV) perpetrators can be identified for whom the intervention is more, or less, successful. As a part of this, understanding the importance of the working alliance in achieving outcomes could be key. More specifically, the aim of the proposed sub-study is to explore the relationship between initial reflective functioning, improvements in reflective functioning and the strength of the working alliance between DVPP group session participants and facilitators, and how these factors impact on domestic violence. While the group participant's assessment of the working alliance has been found to have the strongest predictive power for outcomes, it has been questioned whether this is true for this DV client group (Santirso et al., 2018). The working alliance will therefore be assessed by both group participants and facilitators.

The main *research questions* are focused on building working alliances:

1) What client and facilitator factors impact on the building of working alliances in DVPP group sessions?
2) Are there indications that client reflective functioning is one of these factors?
3) Are there indications that facilitator motivational interviewing skills is one of these factors?
4) What other factors may impact on the building of working alliances in DVPP group sessions?
5) What are the implications of this for how these programmes are provided?
6) What are the possibilities for exploring these questions further?

Methodology

WAI data will be collected from facilitators and participants from the weekly eight different locations where the group sessions are run. Data will be collected prior to the start of the group session, followed immediately by observation of that group session. The actual completion of the WAI will take less than 10 minutes for group members, and less than 15 minutes for facilitators. VASE-R data from facilitators will be collected during a subsequent visit, or through an online version of the tool, which are available to address any potential barriers to face-to-face administration. The facilitator questionnaire will be collected at the

same time as the VASE-R. Administration of both instruments together takes about 40 minutes of facilitator time. The focus groups will be offered face-to-face and/or online. When focus groups are face-to-face, attendees will be offered travel expenses, and any other reasonable expenses. They will take 60-90 minutes.

In appreciation of the time spent completing forms for this sub study, participants and facilitators will receive a small thank you in the form of book or shopping tokens:

- WAI (£10); VASE-R (£10); attendance of focus groups (£10).

References

Horvath, A. O., Del Re, A. C., Flückiger, C., & Symonds, D. 2011. Alliance in individual psychotherapy. *Psychotherapy, 48,* 9–16

Santirso, F. A., Martín-Fernández, M., Lila, M., Gracia, E., & Terreros, E. (2018). Validation of the Working Alliance Inventory–Observer Short Version with male intimate partner violence offenders. *International Journal of Clinical and Health Psychology*, *18*(2), 152–161. https://doi.org/10.1016/j.ijchp.2018.02.003

Appendix 5 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
	2.0	20/05/2019	MSM	Pg 21 – on suggestion from REC, indicated that all those taking part in the study will be able to claim reasonable travel expenses. Pg 22 – eligibility criteria extended to contact with an abused partner within 12 months or anticipated contact within next 12 months Pg 34 – PHQ-9 and GAD-7 scales added to questionnaire and timepoints table 1.
1	3.0		MSM	Front page – Version no, date and ISRCTN number Pg 19 – adding RFQ and SF-12 to the outcomes table Pg 32-4 - amended the title of section 7.4.3.2 to include attitudes and behavioural measures so allow inclusion of the Reflective Functioning Questionnaire to outcomes list and Table 1. Pg 38/9 – Inclusion and use of observations of intervention group sessions Pg 54 – Inclusion of the ISRCTN number Pg 58 – Inclusion of the reference for the RFQ.
2	3.1	30/03/2020	MC	Front Page - Version no, date Pg 3 onwards - Version no. in footnote Pg 3 – Updated Programme Manager details Pg 6 – Updated NIHR Programme Manager name Pg 9 – Updated index Pg 60 – Updated Appendix List Pgs 64-67 - Inclusion of new section: “Response to COVID-19” which outlines the changes required to referral, recruitment and follow up of

				male participants and their ex/partners during the COVID-19 period.
3	4.0	08/04/2020	MC	Front Page - Version no, date Pg 3 onwards - Version no. in footnote Pg 4 – Updated REPROVIDE PM name Pg 6 – Updated NIHR PM name Pg 9 – Updated index Pg 24 – One addition to the Exclusion criteria for male participants Pgs 33-36 – Updated use of ABI questionnaire for men and ABI-R questionnaire for women, in text and in table Pg 58 – Update Reference No.10 Pg 61 – updated nominated stand-ins for Gene Feder for Safeguarding concerns Pg 69 – Updated amendment history
4	3.2 (Version 4 above was approved *after* Vs. 3.2.and 3.3, hence the odd numbering. See Filenote under Vs. 4.1 below.	30/06/2020	MC	Front Page - Version no, date Pg 3 onwards - Version no. in footnote Pg 65 – Three additional points under "Participants already recruited to REPROVIDE" Pg 65 – Inclusion of paragraph describing the "Four month pause to follow-up questionnaires" Pg 67 – Inclusion of "Use of e-Consent" Pg 69 – Recording of consent for qualitative interviews
5	3.3	05/11/2020	MC	Pg 1 Version no, date Pg 3 onwards - Version no. in footnote Pg 3 Trial Administrator added

				Pg 26 Trial procedures: Recruitment methodology, addition of digital media strategy information.
6	3.3	05/11/2020	MC	Pg 68 Appendix 3 Response to COVID-19 Pandemic, Exclusion criteria for male participants updated. Approved by sponsor as COVID-related.
N.B.	4.1 Back to a full and amalgamated version with both Oxford B and UoBristol RED approvals: now Version 4.1, see Filenote:  FILENOTE re background to Vs 4.1.	20/08/2020	MC	As approvals for these two Protocols were out of sync due to the COVID-19 lockdown period, Protocols Vs.3.3 and Vs.4.0 have been amalgamated into Protocol v. 4.1. The sponsor UoBristol's Governance team judgement was that we create a new Version 4.1 with all approved changes included, see Filenote under Vs. No.
7	4.1	08/02/2021	MC	Pg 1 Version no, date Pg.13 Correction, adding *ABI* into Glossary Pg. 20: Correction to wording to make clear ABI questionnaire is for men and ABI-R questionnaire is for women Pg. 67 Adding additional information on hybrid approach to group delivery model Pg.69 Correction, updated numbering
8	5.0	17/02/2021	MC	Front Page: Version No., date Pg 3 onwards: Version No. in footnote Pg 9: Updated index Pg. 40: Updated section: Qualitative observation of process (details in Appendix 4) Pg. 73: Addition of Appendix 4 - An exploration of the working alliance… Pg. 77: Appendix No. updated

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.