FULL TITLE: A UK MULTI-CENTRE CLUSTER RANDOMISED CONTROL TRIAL, WITH INTERNAL PILOT, OF THE ADVANCE-DIGITALLY SUPPORTED PERPETRATOR INTERVENTION COMPARED TO COMMUNITY JUSTICE OFFENDER MANAGEMENT (1:1), TO REDUCE INTIMATE PARTNER VIOLENCE (IPV), FOR MEN CONVICTED OF IPV WHO MISUSE SUBSTANCES (ADVANCE-D TRIAL).

Short Title: ADVANCE-D Programme for men convicted of domestic abuse serving a community sentence/ ADVANCE-D

Trial Identifiers

ISRCTN:	ISRCTN95692133		
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Study Synopsis

TITLE OF CLINICAL TRIAL:	A UK multi-centre cluster randomised control trial, with internal pilot, of the ADVANCE-Digitally supported perpetrator intervention compared to community justice offender management (1:1), to reduce intimate partner violence (IPV), for men convicted of IPV who misuse substances (ADVANCE-D trial).
Protocol Short Title/ Acronym:	ADVANCE-D Programme for men convicted of domestic abuse serving a community sentence
Funding	NIHR Public Health Programme [NIHR154546]

Study Phase:	Cluster randomised controlled trial with internal Pilot
Sponsor Name(s):	King's College London
Chief Investigator(s):	Gail Gilchrist
Medical Condition or Disease Under Investigation:	Intimate partner violence, substance use
Purpose of Clinical Trial:	To compare short (4 months), medium (12 months) and long-term (24 months) outcomes of ADVANCE-D with usual CJOM for men who misuse substances convicted of IPV (serving a community sentence or on license post imprisonment) who are subject to probation/JSW supervision and unsuitable for existing probation-based perpetrator interventions.
Primary Objective:	To conduct a multicentre superiority cluster randomised controlled trial (cRCT) with internal pilot, to assess whether ADVANCE-D with CJOM is superior to only CJOM in reducing IPV perpetration in the past 4 months at 12-months post-baseline, measured using the (Adapted) Abusive Behavior Inventory, compared to usual CJOM for men who misuse substances subject to probation/JSW supervision.
Secondary Objective(s):	• To assess whether ADVANCE-D with CJOM is superior to only CJOM at 4 and 12-months in reducing IPV victimisation, experienced by partners measured using the (Adapted) Revised Abusive Behavior Inventory (ABI-R). • To assess whether ADVANCE-D with CJOM is superior to only CJOM at 4 and 12-months in improving other IPV outcomes: (Adapted) Revised Controlling Behaviors Scale (CBS-R), technology facilitated abuse, stalking/harassment, locked in, using children against partner, feeling of safety (women only), (Adapted) Intimate Partner Violence Responsibility Attribution Scale (IPVRAS) (men only); well-being: Patient Health Questionnaire (PHQ-9), Generalised Anxiety Disorder symptoms (GAD-7), Primary Care PTSD Screen for DSM-5 (PC-PTSD-5), Propensity for Abusiveness Scale (PAS) [anger subscale] (men only); self-control: Brief Self-Control Scale (BSCS) (men only); substance use: Treatment Outcomes Profile (partial), Alcohol Use Disorder Identification Test (AUDIT), Drug Use Disorder Identification Test (DUDIT); quality of life: EQ-5D-5L for participants and their current or ex-partners. • To conduct a nested process evaluation to explore the implementation, mechanisms of impact, and contextual factors of delivering ADVANCE-D with participants and practitioners. • To assess whether ADVANCE-D with CJOM is superior to only CJOM at 4 and 12-months in improving children's well-being as reported by men and their (ex)-partners. • To compare costs and outcomes of ADVANCE-D with CJOM over and above usual CJOM using cost-consequences analysis at 4 and 12-months. • To link participants to routine databases and electronic records to compare health, social services, and criminal justice outcomes at 24-months between men offered ADVANCE-D with CJOM or usual CJOM and their (ex)-partners.

Trial Design:	Superiority cluster randomised controlled trial with internal pilot
Sample Size:	450 men (and their current or ex-partners) from 32 Probation Delivery Units (PDU)/ Justice Social Work Offices (JSW)
Summary of Eligibility Criteria:	Inclusion criteria for participants (men): 1. Adult (18+) men serving a community sentence or post imprisonment on license for IPV towards a female current or ex-partner. 2. Drugs or alcohol linked to criminogenic need recorded on OASys (England) or LS/CMI (Scotland). 3. Male participants must have a named current or ex-partner (index victim) whose contact details can be provided by Probation/Justice Social Work or by the male participant. 4. Able to communicate in and understand English for the purpose of research interviews. Exclusion criteria for participants (men): 1. Suitable for or attending an existing probation-based perpetrator intervention. 2. Man involved with the private family law court. 3. Where no contact details are available for the index victim, men will not be eligible to participate in the trial. 4. History of sex offences against children. 5. Answers 'strongly disagree' to all 8 items on the eHealth Literacy Scale (eHEALS). 6. Substance use impairs ability to take part in the trial (based on practitioner assessment of frequency/amount of substance use, impact of substance use on daily activities/functioning, and health, social, legal or financial problems as a result of substance use) assessed using the substance use screen (England) or SARA V3 (Scotland). Inclusion criteria for current or ex-partners (women): 1. Adult (18+) women who have a current or ex-partner participating in the trial that was sentenced for IPV towards them. 2. Lives in the UK. 3. Able to communicate in and understand English for the purpose of research interviews. Exclusion criteria for current or ex-partners (women): 1. Current order preventing her from contacting current or ex male partner recruited to the trial. 2. Other safety concerns that may put the male or female partner at risk. These will be considered on a case-by-case basis by Probation/Justice Social Work/the clinical lead e.g. where both participants share a mobile phone number, there are concerns about indirect contact between partners, the female participant has a court case pending for IPV or there are child protection concerns.

Intervention (Description, frequency, details of delivery)	ADVANCE-D is a 33-session (14-week) programme (+ refresher session one month-post programme) that is remotely delivered including: an individual goal-setting session; a welcome to group preparation session; 6 group sessions; 12 self-directed website sessions with a digital coach (avatar) to recap and practise skills learned in the group each followed by an individual coaching session with a facilitator (12 weekly coaching sessions in total). A refresher session takes place 4 weeks after the end of the programme.
Comparator Intervention:	Usual community justice offender management (CJOM) is the comparator intervention. Usual CJOM will vary but will include a supervising officer to manage risk and enforce the order/license. Existing group probation-based perpetrator programmes will not be used as a comparator in England.
Maximum Duration of Treatment of a Participant:	14 weeks (+ refresher 4 weeks after the end of the programme)
Version and Date of Final Protocol:	V10. 10.03.2026

Revision History

Protocol version	Description of changes from previous revision	Effective Date
Protocol Version 1.0	New Protocol	01.03.2024
Protocol Version 2.0	Updates requested by NIHR: 1. Digital literacy assessed using eHEALS instead of BBC scale.	28.03.2024
Protocol Version 3.0	Updates requested by sponsor: 1. Updated sponsor details 2. Eligibility criteria for staff added 3. Only related and unexpected SAEs need to be reported to the REC and to the sponsor	07.05.2024

Protocol version	Description of changes from previous revision	Effective Date
Protocol Version 4.0	Updates requested by ethics committee and KCTU: 1. Adapted measures should be specified as such in all cases (including for primary outcome) 2. Typo in primary objective 2.1.1 '*is superior in reducing IPV perpetration in the past 4 at 12-months'* corrected 3. Number of clusters randomised in internal pilot etc. made consistent across protocol 4. Corrections to randomisation section 5. AUDIT and DUDIT collected for both men and (ex)-partners at baseline and 12 months 6. Questions on children's well-being now also asked of men 7. EQ-5D-3L replaced by EQ-5D-5L 8. Corrections to text regarding screening process/instruments e.g. version of SARA used in England vs. Scotland 9. Updated eligibility criteria to state that participants must be able to respond to research interviews in English o Modified substance use inclusion criterion for males o Added inclusion and exclusion criteria for PDU/ JSWT o Confirmation that only 1 female will be registered in MACRO per male (the victim of the IPV crime) o Corrections to flow diagram to include JSWT and to make substance use eligibility clearer 10. Cut off score now included for eHEALS (ineligible if answers 'strongly disagree' to all 8 items) 11. Version number and date are incorrect in study synopsis and headers on each page. Signatures also out of date. 12. Adverse Events/incidents revised 13. Added follow-up window of +/- 4 weeks	25.06.2024

Protocol version	Description of changes from previous revision	Effective Date
Protocol Version 5.0	1. Changes made to 3.8 Safety data and 3.9 for clarity and to ensure all relevant events are captured 2. Changed SAE reporting time from 48 hours to 24 hours as requested by RGO 3. 3.4.4 added more detail regarding consent 4. Table 5 updated to include all measures being collected 5. 3.8.1 now updated to "*Following the baseline interview*, researchers will record any adverse events disclosed by participants and/or their (ex)-partners" 6. Inclusion/Exclusion criteria – two items have been deleted from inclusion criteria as they were already included in reverse in exclusion criteria. Reworded and moved eHEALS and substance use criteria from inclusion to exclusion criteria to ease comprehension as they required a negative response. Details of the ADVANCE-D languages moved to 3.4.8. Summary eligibility criteria updated to include all criteria. Updated SARA V3 exclusion criteria to include "*substance use functional impairment based on* the SARA V3 in Scotland" and added a new flowchart for this 7. 3.10 updated with correct reimbursement amounts for partners 8. Added new secondary outcome measure: (Adapted) Intimate Partner Violence Responsibility Attribution Scale (IPVRAS) (men only) 9. 5.1 and 5.3 updated randomisation section for clarity and removed duplicated information from 3.6.1 10. 3.7.8 listed all explanatory variables being collected 11. 5.4 blinding table updated with more information for clinical lead and health economist 12. Removed victimisation questions for men and perpetration questions for women 13. Corrected typos and updated blurry images	17.07.2024

Protocol version	Description of changes from previous revision	Effective Date
Protocol Version 6.0	1. Changed the substance use exclusion criteria text from "Alcohol and/or drug use 'daily' or 'almost daily' in the substance use screen (England) or substance use functional impairment based on the SARA V3 (Scotland)" to "Substance use impairs ability to take part in the trial (based on practitioner assessment of frequency/amount of substance use, impact of substance use on daily activities/functioning, and health, social, legal or financial problems as a result of substance use) assessed using the substance use screen (England) or SARA V3 (Scotland)." 2. Updated text before Table 2 and Figures 1, 2 and 3 in line with the above.	22.10.2024
Protocol Version 7.0	Updated section 3.1 regarding exceptional cases for male recruitment.	12.05.2025
Protocol Version 8.0	Updated section 3.2.1 Inclusion Criteria (Men) Updated section 3.2.2 Exclusion Criteria (Men) Updated section 3.2.4 Exclusion Criteria (Women) Updated section 3.3 regarding Informed Consent Process for Men and Women Updated section 3.4.4 in line with updates to 3.3 above Updated section 3.4.11 in line with updates to 3.3 above	24.09.2025
Protocol Version 9.0	Updated section 3.9 Measures to Promote Participant Retention Updated section 11 Oversight and Monitoring	10.12.2025
Protocol Version 10.0	Updated section 3.1 Study Setting and Recruitment Updated 3.4 Participant Timeline Updated 3.7.9 Record Linkage Updated 3.7.10 Process Evaluation Updated sectiion 10.3 Sample Size Calculation Updated section 10.4 Statistical Methods for Primary and Secondary Outcomes Updated section 10.6 Internal Pilot Updated section 10.7 Methods for Additional Analysis	10.03.2026

Disclaimer

The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Declaration of interest

Principal investigators and study sites have no financial and other competing interests to declare.

Glossary of terms

ABI	Abusive Behavior Inventory	**ITT**	Intention to Treat
ABI-R	Abusive Behavior Inventory - Revised	**KCTU**	King's Clinical Trials Unit
AE	Adverse Event	**KHP-CTO**	King's Health Partners Clinical Trials Office
CA	Competent Authority	**MHRA**	Medicines and Healthcare products Regulatory Agency
CI/PI	Chief/Principal Investigator	**MTA**	Material Transfer Agreement
Co-I/Co-app	Co Investigator/Applicant	**NDTMS**	Naitonal Drug Treatment and Monitoring System
CPO	Community Payback Order	**NIHR**	National Institute for Health Research
cRCT	Cluster Randomised Controlled Trial	**NEIP**	National Effectiveness Intervention Panel
CTU	Clinical Trials Unit	**NRC**	HMPPS National Research Committee
DCR	Data Clarification Request	**PDU**	Probation Delivery Unit
CI	Chief Investigator	**PI**	Principal Investigator (at site)
CJOM	Community Justice Offender Management	**PIN**	Participant Identification Number
CONSORT	Consolidated Standards of Reporting Trials	**PIS**	Participant Information Sheet
cRCT	Cluster Randomised Controlled Trial	**PP**	Probation Practitioner
CRF	Case Report Form	**PPI**	Patient and Public Involvement
CSV	Comma-Separated Values	**R&D**	Research and Development
CTIMP	Clinical Trial of Investigational Medicinal Product	**RA**	Regulatory Agency
CTU	Clinical Trials Unit	**RAR**	Rehabilitation Activity Requirement
DMC	Data Monitoring Committee	**RCT**	Randomised Controlled Trial
DPIA	Data Protection Impact Assessment	**REC**	Research Ethics Committee
DSUR	Development Safety Update Report	**RN**	Research Nurse
eCRF	Electronic Case Report Form	**SAE**	Serious Adverse Event/ Serious Adverse Reaction
EDC	Electronic Data Capture	**SAP**	Statistical Analysis Plan
eSMS	Emergency Scientific and Medical Services	**SDV**	Source Data Verification
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database	**SmPC**	Summary of Product Characteristics
GP	General Practitioner	**SS**	Senior Statistician
GCP	Good Clinical Practice	**SDW**	Source Data Worksheets
HMPPS	His Majesty's Prison and Probation Service	**SUSAR**	Suspected Unexpected Serious Adverse Reaction
ID	Identifier	**TM**	Trial Manager
IPV	Intimate Partner Violence	**TMG**	Trial Management Group
IRAS	Integrated Research Application System	**TS**	Trial Statistician
ISS	Integrated Support Service	**TSC**	Trial Steering Committee
JSW	Justice Social Worker	**UK**	United Kingdom
JSWT	Justice Social Work Team		

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1. INTRODUCTION

1.1 BACKGROUND AND RATIONALE

Around 1 in 3 women experience intimate partner violence (IPV), defined as any behaviour by an (ex)-intimate partner causing physical, sexual or psychological harm, including aggression, sexual coercion, psychological abuse, financial abuse and controlling behaviours[1] resulting in poor mental, physical and sexual health.[2,3] Having a male partner who misuses alcohol and/or drugs (substances) increases the risk of experiencing IPV and of domestic homicide.[4,5] Delivering effective targeted behaviour change interventions to male IPV perpetrators who misuse substances will reduce the harm to their female (ex)-partners. However, the Domestic Abuse Commissioner for England and Wales has recently highlighted the lack of access to perpetrator programmes,[6] with less than 1% of perpetrators receiving specialist behaviour change interventions.[7]

While no single factor explains why some men are more likely to perpetrate IPV, substance misuse, especially dependence, is a consistent risk factor.[8,9] Rates of IPV perpetration for men who misuse substances are up to 4 times higher than for men who do not.[10,11] We found that around 6 in 10 men in substance misuse treatment in England had ever perpetrated any IPV and 4 in 10 had done so in the past year, with 1 in 10 reporting perpetrating severe IPV in the past year.[11,12] Substance dependent men are 7 times more likely to be arrested for IPV,[13] and to abuse multiple victims.[14] Despite this elevated prevalence, men in substance misuse treatment are rarely referred to perpetrator programmes.[15-17] Few men in our study had ever received support for their abusive behaviour.[18] Moreover, men with substance misuse problems make up at least 50% of men in community and court mandated perpetrator interventions.[19,20] They are among the most high-risk and highly resistant groups of IPV offenders.[21,22] Recidivism for court-mandated IPV offenders who misuse substances is around 20-30%.[23] They are also more likely to drop out of court-mandated perpetrator programmes,[20,22] suggesting that integrating substance misuse treatment to IPV interventions can prevent reoffending in this group.[21]

Gap in the delivery of perpetrator interventions in probation that are responsive to substance misuse and the additional risks it presents

Delivering effective and targeted perpetrator interventions to male IPV offenders receiving community justice offender management (CJOM) who misuse substances could reduce both IPV and substance misuse, and improve the wellbeing of offenders, survivors, and children. There were 42,574 IPV convictions in 2020/21 in England and Wales.[24] While about 40% of them had substance misuse problems, only a small minority received accredited IPV group work programmes.[25] Probation acknowledge that substance misuse contributes to non-completion of court-mandated structured programmes.[26] There are no published evaluations of accredited IPV probation programmes[26] and no available services targeting the complex needs of court-mandated IPV perpetrators who misuse substances. Our support letters confirm that men subject to probation supervision (England and Wales) or justice social work (JSW; Scotland) who misuse substances are unsuitable for existing probation-based perpetrator interventions due to their substance misuse.

The Domestic Abuse Act 2021 (England and Wales)[27] requires an expansion of probation perpetrator programmes as the provision of Domestic Abuse Prevention Orders (DAPOs) will allow judges to compel perpetrators to attend behaviour change, substance misuse or mental health programmes. An estimated 55,000 DAPOs will be made annually. For DAPOs to be successful, perpetrator programmes must be quality assured and responsive to the needs of perpetrators who misuse substances. The Proposed Domestic Abuse (Prevention) (Scotland) Bill[28] also requires mandated treatment. Both Acts require new intervention provision. Post-reunification, the National Probation Service is looking to redress this.[29] Likewise, the Scottish Community Justice Strategy[30] calls for effective community-based treatment options to be available at court to address substance use and IPV simultaneously to reduce re-victimisation and repeat offending and avoid short prison sentences that do not work to rehabilitate offenders.[31] There remains a need to deliver and test integrated IPV and substance misuse perpetrator programmes across UK jurisdictions.

Lack of (probation) perpetrator interventions tailored for men who misuse substances

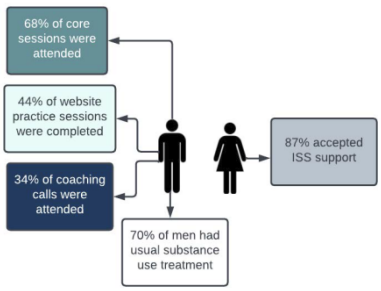
Engagement with the Probation Service is a critical juncture at which assessment, intervention and appropriate referral for IPV can take place.[32] However, a recent review found insufficient evidence that court mandated perpetrator programmes compared to community service, judicial monitoring or no treatment were superior in reducing re-assault among men convicted of IPV and concluded that *"new programs/*

approaches… should be explored".[33] Targeted risk-need-responsivity treatments to address offenders' individual risk factors or criminogenic needs,[34,35] have demonstrated promise in the short-to-medium term.[36] Such treatments consider the risk that offenders present, what treatment/ support they need, and what kinds of environments they should be placed in to reduce recidivism.

There are very few examples of evidence-based interventions that target substance misuse and IPV together.[37,38] While substance misuse treatment may reduce IPV by improving relationships, it does not stop it.[39] Perpetrator programmes can reduce IPV, yet no single approach can be definitively supported.[35,37,40-43] Previous integrated substance misuse and IPV programmes revert to a model of explaining violent incidents resulting from intoxication.[37] Male perpetrators that misuse substances are a high-risk group who require a tailored response targeting the complex ways that substance misuse and IPV perpetration intersect in a manner that includes intoxicated abuse, but also recognises the role of acquisition, craving, withdrawal, and lifestyle, as identified in our research.[44,45]

The ADVANCE digitally-supported integrated perpetrator intervention

A solution to the need for perpetrator interventions in probation that are responsive to substance misuse, is the bespoke ADVANCE integrated perpetrator programme for heterosexual men who misuse substances and are abusive towards a female (ex)-partner. ADVANCE was originally developed and tested for men in substance misuse treatment[46] as part of a NIHR Programme Grant (RP-PG-1214-20009) and has been offered to 94 men (54 in the treatment arm of a RCT and 40 in a feasibility study).[47,48] We found it was feasible for trained substance misuse treatment staff to deliver and acceptable to men on the programme. Men offered the ADVANCE group intervention, compared to usual substance misuse treatment only, reported promising clinical outcomes and positive behaviour change, including reductions in IPV.[47,49] In 2020-21, ADVANCE was adapted for digitally-supported delivery (ADVANCE-D) and piloted with 40 men in substance misuse treatment during Covid-19 restrictions.[48] At the end of the 16-week intervention: 68% of the 25 men followed-up reported reductions in IPV (physical, sexual or psychological) perpetration (73% of the 11 (ex)-partners followed-up reported reductions in experiencing IPV), 40% of men reported reductions in controlling behaviours (46% of their (ex)-female partners reported a reduction in experiencing controlling behaviours). Women also reported reductions in men using their children against them. Some women reported positive behaviour changes in their partner from attending the programme: *"He'd normally hold everything and then throw it in my face in an argument, but now we're having conversations about it"*. Women valued the linked support stating: *"To be able to say that I do feel scared sometimes. To know there is somebody who can check up and… ask if I feel okay… feels like I have back up"* Facilitators also reported behaviour change among men in the group: *"By the end of it, they were completely able to identify with behaviours… (and) reflect on the positive influence it had on their relationships..."*. The content of ADVANCE-D was well-received by both men and facilitators. Men rated the sessions highly and understood the aims of each session. Some men preferred digital over in-person sessions as they offered increased accessibility and flexibility. Attendance at ADVANCE-D was comparable with other perpetrator programmes for men who misuse substances in the US[50] and the Netherlands.[51] 44% of ADVANCE-D website sessions offered were completed. This finding is similar to a study of non-court-mandated, non-substance misusing perpetrators which found 44% completed the eight online modules (guided self-help delivered via the Internet with a therapist who provided support and guidance of therapeutic activities).[52]



Lessons from pilot study of ADVANCE-D that will be implemented in the current trial

1. Alongside the provision of monthly mobile data, the provision of tablets to men and smartphones to women is required to address digital poverty and enhance engagement.
2. Due to the small proportion of female (ex)-partners recruited, it is not possible to use women's reports of IPV as the primary outcome.
3. Supervising ADVANCE-D website sessions and delivering coaching sessions in-person could enhance men's attendance, completion, and engagement, and ensure intervention adherence.
4. Integrated support for female (ex)-partners alongside regular case management meetings and clear information sharing protocols, are essential components of ADVANCE-D to ensure the safety of women.

5. Co-training of facilitators and women's integrated support services builds strong professional relationships across services working with men and supporting women.
6. Not all facilitators and integrated women's support workers were able to adhere to every aspect of the intervention delivery. Ongoing integrity support for facilitators and women's support services promotes and ensures adherence to the intervention delivery plan.[35]

Importance and costs

Healthcare costs are 42% higher for IPV survivors, persisting for years after IPV stops.[53] IPV costs the lives of almost 2 UK women a week.[54] Social and economic costs of IPV are around £66bn a year in the UK.[55] In the UK, perpetrator programmes reduce IPV by 30-65%,[56,57] an investment return of £14 for every £1 spent.[56] Annually illicit drug use costs £20bn.[58] Every £1 spent on drug treatment saves £4 to society.[58] It costs £44,600 a year to imprison someone.[59] Therefore, providing targeted perpetrator programmes to court-mandated offenders who misuse substances and are ineligible for existing perpetrator programmes will result in reduced costs to society, health and social care and improved well-being of men, their (ex)-partners and children. If (cost) effective, ADVANCE-D would reduce recidivism and future imprisonment and could be implemented across the UK and wider.

What works to reduce IPV by men with substance use problems

Reviews of IPV perpetrator interventions for men have shown mixed results and small effect sizes.[23,33,37,38,41-43] Perpetrator programmes can be effective in reducing IPV, as a meta-analysis of 13 studies has illustrated, (pooled estimate = -0.85; 95%CI -1.02 to -0.69).[43] The authors found better outcomes when interventions addressed, substance abuse or trauma components (substance abuse: CI = -3.20 to -1.08 and trauma: CI = -2.63 to -0.30). Our review of voluntary and court-mandated interventions to reduce IPV among men with substance use problems,[37] highlighted both the small number of trials and short duration of follow-up. Overall, the results of a small number of individual trials demonstrated some reductions in IPV outcomes in the short term - up to 3 months post treatment.

Programmes unresponsive to perpetrators' (substance misuse) needs have limited success.[36] There is a lack of evidence about what works to reduce IPV for men who misuse substances, although integrated approaches show some promise.[37,38,43] Pre-post intervention studies have shown that court-mandated perpetrator programmes are effective at reducing IPV short term.[41-43] A recent meta-analyses of court-mandated perpetrator interventions compared to community service, no treatment or judicial monitoring concluded that there was insufficient evidence these interventions are effective in reducing re-assault at least six months post-treatment, using official measures of recidivism including arrest, charges or convictions.[33] Moreover, the mean effect for survivor reported outcomes showed equal outcomes for both groups (e.g., no benefit or harm; odds ratio, 0.99; 95%CI 0.74–1.32). Strengths-based perpetrator interventions reduce the likelihood of re-arrest for IPV,[60] and perpetrator interventions incorporating motivational strategies improve retention.[61]

Rationale

Most studies have investigated physical IPV as the primary outcome and included short-term follow-ups.[62] Evaluations with longer term outcomes and comparisons with existing probation programmes are lacking. To address these shortcomings, also identified by NIHR, we will use a rigorous study design to evaluate the short, medium, and long-term outcomes of ADVANCE-D in probation with men who misuse substances but who are unsuitable for existing probation-based perpetrator interventions. Linkage with routinely collected data will ensure longer term follow-up at 24 months.

2. TRIAL DESIGN

A UK wide multicentre superiority cluster randomised controlled trial (cRCT) with nested process evaluation assessing IPV perpetration in 32 Probation Delivery Unit (PDU)/ Justice Social Work teams (JSWT) randomised to ADVANCE-D with community justice offender management (CJOM) compared to usual CJOM (1:1), combined with nested process evaluation. Outcomes of the ADVANCE-D Programme will be compared short (4 months), medium (12 months) and long-term (24 months) with usual CJOM for men who misuse substances convicted of IPV (serving a community sentence or on license post imprisonment) who

are subject to probation/ JSW supervision and are unsuitable for existing perpetrator interventions. Outcomes will also be collected from their current or ex-partners.

OBJECTIVES

2.1 PRIMARY OBJECTIVE

- To assess whether ADVANCE-D with CJOM is superior to only CJOM in reducing IPV perpetration in the past 4 months at 12-months post-baseline, measured using the (Adapted) Abusive Behavior Inventory (ABI), compared to usual CJOM for men who misuse substances subject to probation/JSW supervision.

2.2 SECONDARY OBJECTIVES

- To assess whether ADVANCE-D with CJOM is superior to only CJOM at 4 and 12-months in reducing IPV victimisation, experienced by partners measured using the (Adapted) Revised Abusive Behavior Inventory (ABI-R).
- To assess whether ADVANCE-D with CJOM is superior to only CJOM at 4 and 12-months in improving other IPV outcomes: (Adapted) Revised Controlling Behaviors Scale (CBS-R), technology facilitated abuse, stalking/harassment, locked in, using children against partner, feeling of safety (women only), (Adapted) Intimate Partner Violence Responsibility Attribution Scale (IPVRAS) (men only); well-being: Patient Health Questionnaire (PHQ-9), Generalised Anxiety Disorder symptoms (GAD-7), Primary Care PTSD Screen for DSM-5 (PC-PTSD-5), Propensity for Abusiveness Scale (PAS) [anger subscale] (men only); self-control: Brief Self-Control Scale (BSCS) (men only); substance use: Treatment Outcomes Profile (partial), Alcohol Use Disorder Identification Test (AUDIT), Drug Use Disorder Identification Test (DUDIT); quality of life: EQ-5D-5L for participants and their current or ex-partners.
- To conduct a nested process evaluation to explore the implementation, mechanisms of impact, and contextual factors of delivering ADVANCE-D with participants and practitioners.
- To assess whether ADVANCE-D with CJOM is superior to only CJOM at 4 and 12-months in improving children's well-being as reported by men and their (ex)-partners.
- To compare costs and outcomes of ADVANCE-D with CJOM over and above usual CJOM using cost-consequences analysis at 4 and 12-months.
- To link participants to routine databases and electronic records to compare health, social services, and criminal justice outcomes at 24-months between men offered ADVANCE-D with CJOM or usual CJOM and their (ex)-partners.

3. PARTICIPANTS

3.1 STUDY SETTING & RECRUITMENT

Courts mandate sentences to men convicted of IPV. Sentences include a rehabilitation activity requirement (RAR) in England; or a community payback order (CPO) in Scotland. These requirements/orders are given with a view to promoting the offender's rehabilitation and reduce the likelihood of reoffending. Men must see a Probation Practitioner (PP) at a Probation Delivery Unit (PDU; England)/ Justice Social Worker (JSW) at a Justice Social Work team (JSWT; Scotland) within 5 days post sentencing when sentence planning will take place. PDU/ JSW team make decisions on the offender management required to address any support recommended by court. Alongside the RAR or CPO, men will have a supervising PP/ JSW to monitor compliance to the community sentences. Any violation of conditions will be referred back to court.

There are 11 probation regions in England. PDU are the local units in each of these probation regions. For example, Greater Manchester (probation region) has 8 local PDU (see Table 1). Scotland has 32 Justice Social Work areas (JSW area) that provide statutory criminal justice services in JSWT. PDU and JSWT will be treated as clusters for the purpose of the trial.

To be eligible to take part in the trial, PDU and JSWT must have a central intervention delivery model (e.g. a central intervention delivery team in Greater Manchester deliver interventions across all 8 PDU); have trained and certified facilitators and partner support workers; and not be sites in other intervention trials. Facilitators in each Probation Region (England) and JSW area (Scotland) will be trained to centrally deliver the ADVANCE-D Programme and will be blind to allocation of PDU/ JSWT. Each PDU/ JSWT will recruit and consent 14 men to the trial before the outcome of allocation is known to them. Additional participants may be recruited within clusters from individuals newly entering the probation system after the initial baseline recruitment period. Where applicable, recruitment of this subsequent cohort was intended to occur at a consistent time point following the initial cluster baseline (e.g. approximately 6–8 months) to minimise temporal bias between clusters. In practice, this additional recruitment was implemented in the Greater Manchester cluster only.

A total of 32 PDU/ JSWT are required for the cRCT.
Twelve PDU/ JSWT (clusters) from the 24 clusters in Table 1 will be allocated at random for men to receive the ADVANCE-D Programme delivered by a central team + usual community justice offender management (CJOM) (Option 1) OR usual CJOM (Option 2) during the internal pilot from one probation region from England (Greater Manchester) and one JSWT from Scotland (Highland and Orkney).

Following the PHR programme decision to withdraw funding early, Table 1 lists the 10 PDU/JSWT included in the internal pilot.

Probation Region (England)	***Probation Delivery Units (PDU)***	
Greater Manchester (two cohorts)	1. Bolton 2. Bury and Rochdale 3. Manchester/Trafford 4. Oldham	5. Salford 6. Stockport 7. Tameside 8. Wigan
Justice Social Work Areas (Scotland)	***Justice Social Work Teams (JSWT)***	
Highland and Orkney	1. Highland 2. Orkney	

Table 1. PDU/JSWT sites in the internal pilot

Exceptional cases: update as of 12 May 2025
Some men in Greater Manchester Probation were court-mandated to receive a named intervention by the courts for domestic abuse offences. For men who no longer meet the threshold for this named intervention, Greater Manchester Probation will advise these men that they will now attend a replacement programme. ADVANCE-D meets the conditions for the replacement programme. Greater Manchester Probation will inform men in PDUs randomised to the intervention arm that they will receive ADVANCE-D + CJOM and advise men in PDUs randomised to the control arm they will receive usual CJOM only. In these cases it will not be possible for the probation practitioners to be blind to allocation when consenting men, and men will be aware of the intervention they have been assigned to. Separate PIS and consent forms have been developed for use with these men and their current or ex-female partners to enable this group of men and their current or ex-partners to be included in the trial. This exception will only be followed in cases where men have been mandated to a specific named programme for which they no longer meet threshold. Men who have not been court-mandated to a named programme will be recruited to the trial as usual.

3.2 ELIGIBILITY CRITERIA

3.2.1 INCLUSION CRITERIA FOR PARTICIPANTS (MEN)

1. Adult (18+) men serving a community sentence or post imprisonment on license for IPV towards a female current or ex-partner.

2. Drugs or alcohol linked to criminogenic need recorded on OASys (England) or LS/CMI (Scotland)*.
3. Male participants must have a named current or ex-partner (index victim) whose contact details can be provided by Probation/Justice Social Work or by the male participant.
4. Able to communicate in and understand English for the purpose of research interviews.

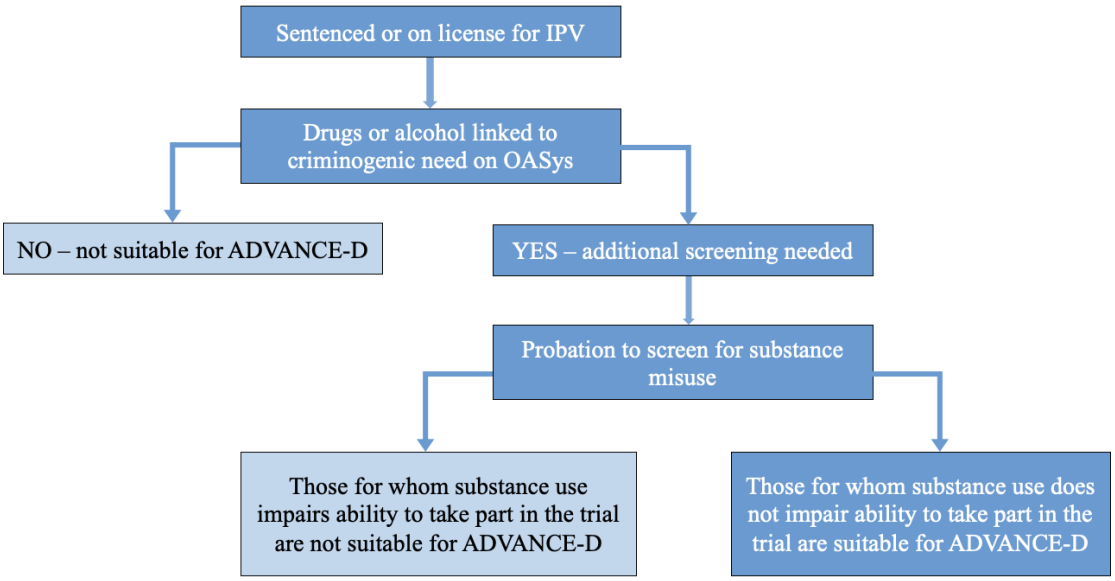


Figure 1. Flowchart for probation practitioners to determine suitability for ADVANCE-D based on level of substance use

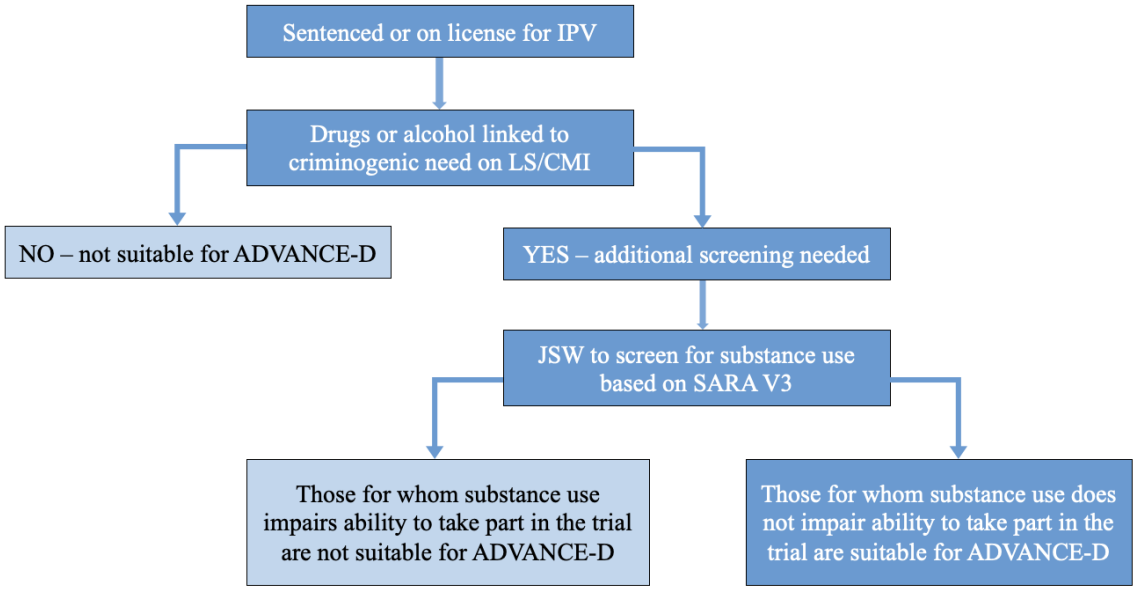


Figure 2. Flowchart for justice social workers to determine suitability for ADVANCE-D based on SARA V3

*Prisoner Offender Managers complete an initial Offender Assessment System (OASys) assessment within 10 weeks of being sentenced. The OASys measures eight criminogenic needs linked to offending behaviour including whether drugs or alcohol were linked to the offending behaviour. During the study timeframe, all men sentenced for IPV will be screened for eligibility for ADVANCE-D (Figure 3). Men who 1) have drugs or alcohol linked to criminogenic need recorded on OASys (England) or The Level of Service/Case Management Inventory (LS/CMI) (Scotland) AND 2) do not have substance use impairment (based on

practitioner assessment of frequency/amount of substance use, impact of substance use on daily activities/functioning, and health, social, legal or financial problems as a result of substance use) on the substance use screen (Table 2) administered by probation practitioners in England, or based on SARA V3 in Scotland are suitable for ADVANCE-D. The use of Rehabilitation Activity Requirements (RAR) in England or unpaid work or other activities in Scotland, such as ADVANCE-D, should be considered for this group.

Suitability screening tool for substance misuse interventions/treatment (V3)

Drug and Alcohol Needs assessment Please circle the score for each relevant substance		Alcohol	Cannabis	Cocaine	Amphetamine	Inhalants	Hallucinogens	Opioids	Other
Q1. In the past 6 months, how often have you used? (If never, the remaining questions do not need to be scored)	Never	0	0	0	0	0	0	0	0
	Once/twice	2	3	3	3	3	3	3	3
	Monthly	3	4	4	4	4	4	4	4
	Weekly	4	5	5	5	5	5	5	5
	Daily/almost	*6*	*6*	*6*	*6*	*6*	*6*	*6*	*6*
Q2. In the past 6 months, how often have you had a strong urge/ desire to use?	Never	0	0	0	0	0	0	0	0
	Once/twice	3	4	4	4	4	4	4	4
	Monthly	4	5	5	5	5	5	5	5
	Weekly	5	6	6	6	6	6	6	6
	Daily/almost	6	7	7	7	7	7	7	7
Q3. During the past 6 months, how often has your use led to health, social, legal or financial problems?	Never	0	0	0	0	0	0	0	0
	Once/twice	4	5	5	5	5	5	5	5
	Monthly	5	6	6	6	6	6	6	6
	Weekly	6	7	7	7	7	7	7	7
	Daily/almost	7	8	8	8	8	8	8	8
Q4. During the past 6 months, how often have you failed to do what was normally expected of you because of your use?	Never	0	0	0	0	0	0	0	0
	Once/twice	5	6	6	6	6	6	6	6
	Monthly	6	7	7	7	7	7	7	7
	Weekly	7	8	8	8	8	8	8	8
	Daily/almost	8	9	9	9	9	9	9	9
Q5. Has a friend/ relative or anyone else ever expressed concern about your use?	No, never	0	0	0	0	0	0	0	0
	Yes, in the past 6 months	6	7	7	7	7	7	7	7
	Yes, but not in the past 6 months	3	4	4	4	4	4	4	4
Q6. Have you ever tried to cut down on your use but failed?	No, never	0	0	0	0	0	0	0	0
	Yes, in the past 6 months	6	7	7	7	7	7	7	7
	Yes, but not in the past 6 months	3	4	4	4	4	4	4	4
	Totals								

1. Interpreting the Score

Brief intervention/Intervention advised	11-26	4-26	4-26	4-26	4-26	4-26	4-26	4-26
Treatment required - DRR/ ATR assessment	27+	27+	27+	27+	27+	27+	27+	27+
Alcohol Abstinence Monitoring Requirement (AAMR)	0-26	-	-	-	-	-	-	-

2. Court Assessments

2.1 Rehabilitation Requirement Activity Requirement (RAR)
Where an individual scores between 11-26, consider the use of RAR interventions for motivational interventions, advice, information, relapse prevention, constructive alternatives to substance misuse and assessment appointments. Brief interventions of this kind may be available nationally or could vary across Regions or Probation Delivery Units (PDUs). As such, it is imperative that the Effective Proposal Framework (EPF) Tool is used to identify the available and eligible interventions. EPF can be accessed here: EPF Tool
Note: if an individual scores below 27, but you feel there may be merit in pursuing an assessment for a DRR/ATR, please contact your local Treatment Provider for further discussion.

2.2 A Drug Rehabilitation or Alcohol Treatment Requirement
Where an individual scores 27+ **(*or if Q1 is scored 6+, regardless of the scores for remaining questions)** for at least **one** of the substances listed above contact the Treatment Provider in the locality that the person will be supervised for further assessment. Please use the free text below to provide information that you have gained that is relevant to the individual's substance misuse. This may include injecting behaviour and any mental health concerns (you may need to consider a combined order with a Mental Health Treatment Requirement). You will need to inform the Treatment Provider of your assessment of the level and nature of risk posed by the individual.

Note: A court can impose a DRR for any substance that is included in the Misuse of Drugs Act 1971. It is up to the court to decide if they think that any substance used by a person is covered by this. **However,** a DRR can only be imposed if there is a test for the drug of choice available in the community. There is no test routinely available for Psychoactive Substances (PS) in the community currently. The court would need to be advised that making a person who only used PS subject to a DRR would not meet the requirements to impose such an intervention. Most people are poly drug users. If someone presents as using any substance that can be tested for (Opiates, Cocaine, Amphetamines, Benzodiazepine and Cannabis) in combination with the above, a DRR can be recommended if agreed with a Treatment Provider.

Table 2. Suitability screening tool for substance use interventions

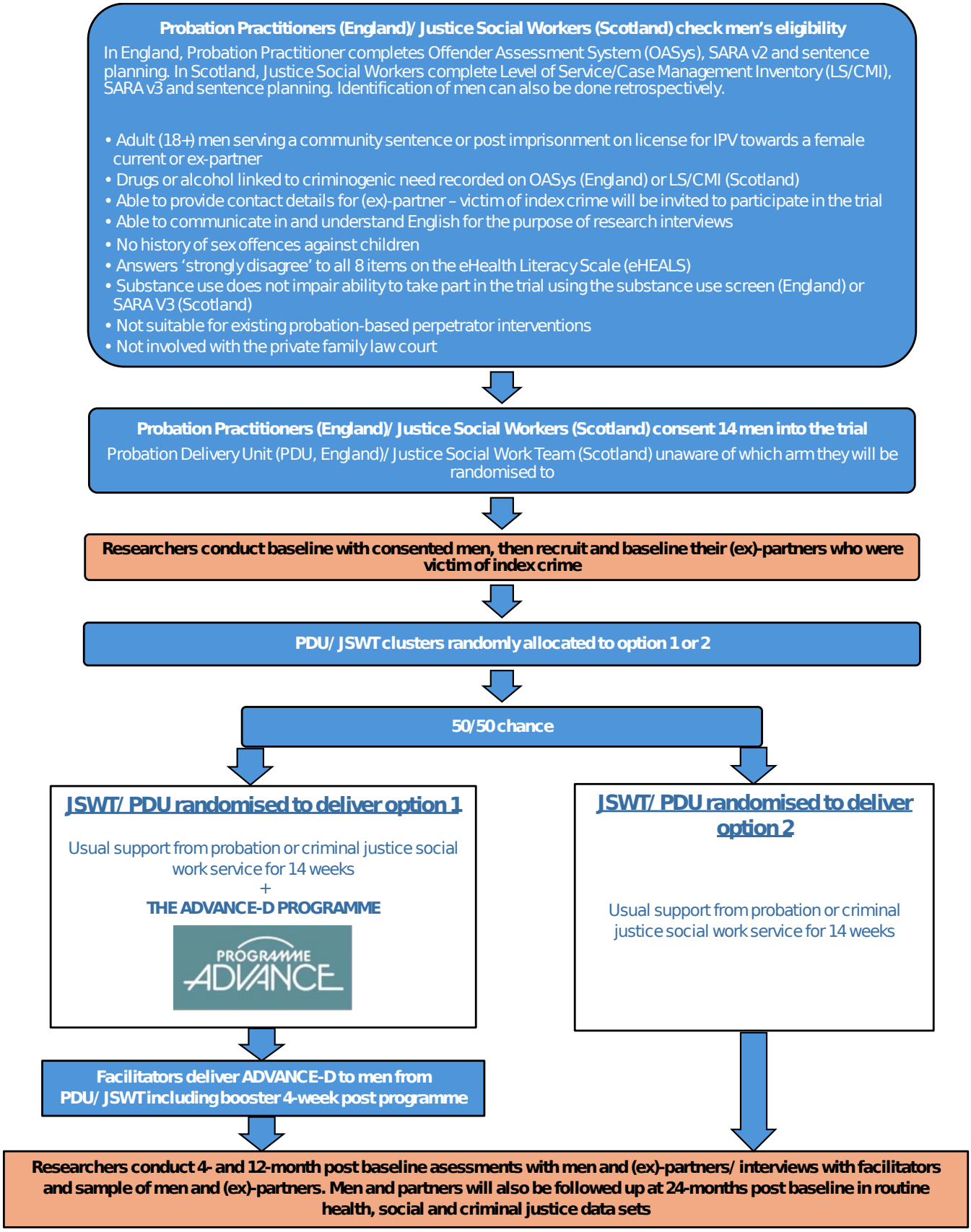


Figure 3. Study flowchart

Figure 3 illustrates the different phases of the cRCT for male participants.

3.2.2 EXCLUSION CRITERIA FOR PARTICIPANTS (MEN)

1. Suitable for or attending an existing probation-based perpetrator intervention.
2. Man involved with the private family law court.
3. Where no contact details are available for the index victim, men will not be eligible to participate in the trial.
4. History of sex offences against children.
5. Answers 'strongly disagree' to all 8 items on the eHealth Literacy Scale (eHEALS).
6. Substance use impairs ability to take part in the trial (based on practitioner assessment of frequency/amount of substance use, impact of substance use on daily activities/functioning, and health, social, legal or financial problems as a result of substance use) assessed using the substance use screen (England) or SARA V3 (Scotland).

3.2.3 INCLUSION CRITERIA FOR CURRENT OR EX-PARTNERS (WOMEN)

1. Adult (18+) women who have a current or ex-partner participating in the trial that was sentenced for IPV towards them.
2. Lives in the UK.
3. Able to communicate in and understand English for the purpose of research interviews.

3.2.4 EXCLUSION CRITERIA FOR CURRENT OR EX-PARTNERS (WOMEN)

1. Current order preventing her from contacting current or ex male partner recruited to the trial.
2. Other safety concerns that may put the male or female partner at risk. These will be considered on a case-by-case basis by Probation/Justice Social Work/the clinical lead e.g. where both participants share a mobile phone number, there are concerns about indirect contact between partners, the female participant has a court case pending for IPV or there are child protection concerns.
3.

3.2.5 INCLUSION CRITERIA FOR STAFF

For PP/ JSW

1. Identified men for ADVANCE-D; or
2. Supervising officer for men on ADVANCE-D.

For facilitators and partner support workers

1. Trained and certified to deliver ADVANCE-D or partner support for ADVANCE-D.
2. Delivered or attempted to deliver ADVANCE-D or partner support for ADVANCE-D.

3.2.6 INCLUSION CRITERIA FOR PDU/ JSWT

1. PDU/ JSWT must have a central intervention delivery model (e.g. a central intervention delivery team in Greater Manchester deliver interventions across all 9 PDU).
2. PDU/ JSWT must have trained and certified ADVANCE-D facilitators and partner support workers.

3.2.7 EXCLUSION CRITERIA FOR PDU/ JSWT

1. PDU/JSWT must not be participating sites in other intervention trials.

3.3 INFORMED CONSENT

For participants

Men who have received a community sentence for IPV from a judge or who have been released on license from prison after serving a sentence for IPV, must present to a PDU/JSWT where decisions on the CJOM required to address any treatment/support recommended by court or license conditions will be made. All men will be screened against the eligibility criteria by a probation practitioner (PP) or justice social worker (JSW) during first presentation to the PDU/ JSWT. All men presenting to PDU/ JSWT will routinely be assessed for alcohol or drug misuse using the Spousal Risk Assessment (SARA)[63] V2 (England) or V3 (Scotland) and the

Offender Assessment System (OASys) completed by PP (England) or the Level of Service/Case Management Inventory (LS/CMI) completed by JSW (Scotland).

Men who are eligible will provide their consent to participate in the study through one of two routes: By their PP/JSW or by a researcher, where written consent to contact has first been provided.

Men will be invited to take part in the trial by their PP/ JSW. PP/ JSW will receive training on gaining informed consent, that emphasises participation is voluntary, and be provided with a script about the study and its aims. PP/ JSW will:

1. Read the participant information sheet (PIS), explain what taking part involves and that taking part is voluntary.
2. Provide men with a copy of the PIS.
3. Invite men to participate in the research (baseline, 4- and 12-month follow-up interviews, qualitative interviews and data linkage at 24-months).
4. Explain limitations to confidentiality.
5. Inform them their (ex)-partner will be contacted to provide outcome data and offered support.

As the decision about CJOM required to address any treatment/support will be made on the second meeting with the PP/ JSW post court/release – men will need to decide whether they wish to participate in the trial at that meeting. This will give them approximately a week to decide whether they wish to take part in the trial. At the next visit, PP/ JSW will then gain informed consent from men agreeing to take part in the trial.

Alternatively, during the first meeting PP/JSW may seek men's written consent to be contacted by a researcher to allow the researcher to obtain informed consent. Consent to contact forms containing men's contact details and preferred method of contact will be sent in a password protected document via encrypted e-mail, a secure Microsoft Teams channel or via another secure method (e.g. Criminal Justice Secure Email). A researcher will then contact men via their preferred method to arrange a time to meet to obtain informed consent. Meetings will be held in person at the PDU/ JSWT or by phone or video call. During this meeting the researcher will re-explain the PIS, what taking part involves, the limitations of confidentiality and that taking part is voluntary. Men will be informed that their (ex)-partner will be contacted to provide outcome data through participation in the trial and offered support from a women's integrated support service. The researcher will then obtain informed consent from men who agree to take part in the trial.

Consent forms will be counter-signed in triplicate by both the male participant and the staff member taking consent (PP/ JSW/ researcher). Participants will receive a copy of the signed consent form; a copy will be filed in the Investigator Site File and a copy will be returned to the local research team and stored in a locked filing cabinet.

A researcher will then text or call the consented participant and complete the baseline interview with the participant in person at the PDU/ JSWT or by phone or video call. All men from a cluster should be baselined within two weeks. This call will not be undertaken in the presence of a PP/ JSW. During this call, researchers will check the participant still wishes to take part in the trial, that they have consented to take part in the trial of their own free will and are fully informed of what taking part in the study involves. Participants will have the opportunity to opt out of the trial at this point without any repercussions to their CJOM. This timeframe allows the participant up to two weeks from consenting to take part to decide whether they still wish to take part.

A researcher will be responsible for completing a baseline interview with consented men by phone, video conferencing, or in person at the PDU/JSWT. This will not be conducted in the presence of a PP/JSWT. Interviews will never be conducted in participants' homes.

Only after the men are consented and baselined in each PDU /JSWT and their female current or ex-partners have been consented and baselined; will participants and PDU/ JSWT team be told what treatment arm they have been allocated to.

For current or ex-partners

Probation/JSW areas may have different working practices in terms of contacting female current/ex-partners of men convicted of an IPV offence to offer them support. Depending on the working practice of the probation/JSW area, the facilitators will do one of the following (option A or B):

A: Where possible, probation/JSW will obtain the contact details of the men's current/ex-partner (index victim). During the consent process, men will be informed that their current/ex-partner will be contacted as part of the trial. The female current/ex-partner will be contacted by probation/JSW staff and will be informed that their male current/ex-partner is taking part in a trial. The probation/JSW staff will then ask the female current/ex-partner whether they agree to be contacted by a researcher to hear more about the research and be invited to take part. Should the current/ex-partner agree, the probation/JSW staff will provide them with a consent to contact form which will then be securely transferred to the research team who will contact the current/ex-partner and invite them to participate in the trial.

B: Where option A is not feasible, the probation/JSW staff will ask the men to provide the contact details of their current/ex-partner (index victim). These contact details will then be securely sent to the research team, and a researcher will make the initial contact, explain the trial, and invite them to participate in the trial.

The PP/ JSW will securely pass the contact details of victims/ survivors to the trial manager using a password protected document via encrypted e-mail, a secure Microsoft Teams channel or via another secure method (e.g. Criminal Justice Secure Email). This is standard practice in community perpetrator interventions to ensure safeguarding and risk are managed and is included in the Home Office Standards for Domestic Abuse Perpetrator Interventions.[64] In the case of option B, the Information Commissioner's Office have stated that a service can potentially use legitimate interest as a lawful basis to gather this information suggesting the individual (ex)-partner would reasonably expect you to use their data in this way (Case Reference Number ENQ0782120). Researchers need current or ex-female partners' details to invite them to take part in the research by providing outcome data, and to share their details with the women's support service who will contact them to offer support, assess risk and signpost for additional needs. Clear and regular lines of communication between probation/justice social work, women's support services and the research team are necessary so that any changes in risk can be identified and appropriate actions taken to ensure that current and ex-female partners are effectively safeguarded. While all current and/or ex-partners of men in the ADVANCE-D intervention will be offered support, only the current or ex-partner connected to the index IPV event will be recruited to the study. Following male participants' baseline assessment, researchers will text or email their (ex)-partners with brief information about the study and advise that they will be phoning them. A script and short explanation video about taking part in the study has been developed with the women's people with lived experience panel to facilitate this.

Text script *"Hi [current or ex-partner's name], this is [name] from [organisation]. We are contacting you to ask you to take part in our study that is evaluating the ADVANCE-D programme for men with drug and alcohol problems serving a community sentence for domestic abuse. Your current or ex-partner is involved in this study and your experience will be valuable to help understand whether the programme is beneficial and how to shape services for women in the future. Here is a short video about the study and what taking part involves [*https://youtu.be/-O2P0Jsg2JM*]. I will call you over the next few days. Please let me know the best time to call. Hope to talk soon.*

To maximise safety and convenience, there will be the option to select a time slot for the call. Within a week, a researcher will contact the (ex)-partners to:

1. Inform them their (ex)-partner is participating in the study.
2. Read the PIS and explain what taking part involves.
3. Invite them to participate in the research (baseline and follow up interviews, qualitative interviews and data linkage at 24 months).
4. Explain limitations to confidentiality.
5. Advise them that an integrated support service (ISS) worker will call to offer them support only if their current or ex-partner is allocated to receive the ADVANCE-D Programme.

Women interested in taking part in the research will be emailed, sent a message on WhatsApp or mailed a copy of the PIS and consent form by the researcher. Before the baseline assessment takes place, the researcher will check with participants whether they have somewhere quiet and private to talk and ensure that they are safe to talk. Researchers will be responsible for recruitment, consent and baseline interviews

with (ex)-partners. (Ex)-partners will be given the option for questionnaires to be administered by the researcher in person, by phone or video call. Face-to-face recruitment or interviews will take place in probation, women's support services or other services such as children's centres or libraries. The researcher that completes the questionnaires with the partner will be a different researcher to the one that completed the baseline assessment with the male participant to avoid inadvertent disclosure of information.[97] All research participants have the right to refuse to answer questions if they do not wish. Interviews will never be conducted in (ex)-partners' homes.

Only after recruitment and the baseline interview with (ex)-partners has been completed or the (ex)-partner has declined the offer to participate in the trial or the (ex)-partner is not contactable, will the allocation of PDU/ JSWT be known to researchers and PDU/ JSWT.

Women whose current or ex-partners are in a PDU/ JSWT allocated to receive the ADVANCE-D Programme, will be contacted by an ISS worker to offer support regardless of whether the woman wishes to take part in the research. If researchers have been unable to contact the female (ex)-partners, they will pass the contact details to the ISS workers who will attempt to call them to offer support. Women whose current or ex-partners are in the control arm of the study will receive whatever the usual support to partners would be, if any.

For staff

Staff at each service involved in delivering the intervention (PDU or JSWT) or supporting women whose partners are receiving the intervention (ISS) will be invited to take part in focus groups or interviews throughout the duration of the study about their experiences. This process is explained to services as part of their contract when they agree to be involved in the study.

Staff will first receive an email from the researcher inviting them to take part in the research. This email will also contain the PIS and consent form. Researchers will follow-up this email with a phone call several days later to verbally explain the aims of the study to staff and ask whether they are interested in taking part. Staff will be asked to return a completed copy of the consent form by email to the researcher prior to taking part in a focus group or interview. The option to return the consent form by post will also be available. In line with HRA and MHRA joint statement on seeking and documenting consent using electronic methods (eConsent) – Health Research Authority (2018), staff will be able to select yes or no for each item on the consent form, type their name in the signature box and add the date they completed the form to confirm their consent.

If the consent form has not been returned, researchers can witness and audio record informed consent following reading through the PIS and all items on the consent form and record it in writing. Study consent forms will all be electronic (audio recordings or emailed Word document) and will be stored on SharePoint. A suitable time will be organised to undertake the focus group or interview.

Interviews with staff will take place in-person or by phone or video call. These interviews will be recorded with consent.

3.4 PARTICIPANT TIMELINE

3.4.1 *PARTICIPANTS (MEN)*

Timepoint	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 20	Month 4 post baseline	Month 12 post baseline	Month 24 post baseline
1. Screening and eligibility	X																				
2. Risk assessment	X																				
3. Consent		X																			

4. Arrange baseline interview		X																		
5. Registration and Baseline			X																	
6. **ADVANCE-D**																				
a. Individual goal setting				X																
b. Welcome to ADVANCE-D group					X															
c. Follow-up call					X															
d. ADVANCE-D group session						X		X		X		X		X		X				
e. ADVANCE-D website session						X	X	X	X	X	X	X	X	X	X	X	X			
f. ADVANCE-D individual coaching						X	X	X	X	X	X	X	X	X	X	X	X			
g. ADVANCE-D booster																		X		
7. Follow-up assessment																			X	X	
8. Data linkage with health and criminal justice records																					X

Table 3. Schedule of events – male participants

Following the PHR programme decision to withdraw funding early, it will no longer be possible to conduct data linkage with health and criminal justice records at 24-months within the current contract. Additional funds will be sought to undertake this.

3.4.2 VISIT WINDOWS FOR MALE PARTICIPANTS

The ADVANCE-D Programme takes 14 weeks to be delivered. The research will take place over 24 months. Participants will be followed-up 4-months (+/- 4 weeks) and 12-months (+/-4 weeks) post-baseline interview and 24-month follow up will be undertaken by tracking the cohort in routine health and social care, and criminal justice databases.

3.4.3 SCREENING & ELIGIBILITY RISK ASSESSMENT FOR MALE PARTICIPANTS

Eligibility screening will be undertaken by PP/ JSW at PDU/ JSWT (Contact 1). During this contact, PP/ JSW will also conduct the risk assessment to determine suitability.

3.4.4 CONSENT FOR MALE PARTICIPANTS

PP/ JSW or researchers (where consent to contact is first provided) will gain informed consent from approximately 14 participants per PDU/JSWT to take part in the trial. The number of men a PDU/JSWT will consent before transferring details to the Trial Manager is estimated to be approximately 14, but will be decided ad hoc per site depending on recruitment levels. Where consent to contact is collected from men, PP/JSW will securely send men's contact details to the trial manager using a password protected document via encrypted e-mail, a secure Microsoft Teams channel or via another secure method (e.g. Criminal Justice Secure Email) and researchers will contact men to gain informed consent. Once all men from a cluster have provided informed consented, PP/ JSW will securely inform the trial manager of the contact details of the consented individuals and their (ex)-partners using a password protected document via encrypted e-mail, a secure Microsoft Teams channel or via another secure method (e.g. Criminal Justice Secure Email) (contact 2). Only one cluster will be recruited from each PDU/JSWT.

3.4.5 BASELINE VISIT FOR MALE PARTICIPANTS

The trial manager will allocate consented men to researchers to conduct the baseline interview by phone or video call or in person at the PDU/ JSWT within two weeks of all men in the cluster being consented.

During contact 3, consented participants will be called by the researcher to arrange a convenient time for the baseline interview. During the call/meeting the researcher will:

1. Confirm willingness to participate.
2. Re-explain PIS (participant will already have a copy prior to consenting).
3. Arrange a convenient time to call/ meet to conduct the baseline interview.

During this call/ meeting to conduct the baseline interview (contact 4), the researcher will:

1. Re-explain the PIS and check consent.
2. Register the participant into the study (initials and age required).
3. Provide contact details of support services for IPV perpetration and substance use.
4. Complete the baseline interview.

Baseline data collected from participants using the following assessment tools. For IPV perpetration: (Adapted) Abusive Behavior Inventory (ABI) [primary outcome], (Adapted) Revised Controlling Behaviors Scale (CBS-R), technology facilitated abuse, locked-in, stalking/harassment, using children against partner, (Adapted) Intimate Partner Violence Responsibility Attribution Scale (IPVRAS); Alcohol Use Disorder Identification Test (AUDIT), Drug Use Disorder Identification Test (DUDIT), Treatment Outcomes Profile (partial) (substance use free days); Patient Health Questionnaire (PHQ-9) (depression), Generalised Anxiety Disorder symptoms (GAD-7) (anxiety), Primary Care PTSD Screen for DSM-5 (PC-PTSD-5), Propensity for Abusiveness Scale (PAS) (anger), Brief Self-Control Scale (BSCS) (self-control); EQ-5D-5L (Quality of Life), children's well-being, service use and medication.

3.4.6 4 MONTH FOLLOW-UP VISITS FOR MALE PARTICIPANTS

Four months post baseline interview, participants will be called by the researcher to arrange a convenient time for the 4-month follow-up interview (contact 5). During the call/meeting, the researcher will:

1. Confirm willingness to participate.
2. Re-explain what the interview will entail.
3. Arrange a convenient time to call/ meet to conduct the 4-month follow-up interview (contact 6).

During this call/ meeting to conduct the 4-month follow-up interview (contact 6), data will be collected from participants using the following assessment tools. For IPV perpetration: (Adapted) ABI [primary outcome], (Adapted) CBS-R, technology facilitated abuse, locked-in, stalking/harassment, using children against partner, (Adapted) IPVRAS; Treatment Outcomes Profile (partial) (substance use free days); PHQ-9 (depression), GAD-7 (anxiety), PC-PTSD-5, PAS (anger), BSCS (self-control); EQ-5D-5L (Quality of Life), children's well-being, service use and medication. Participants in the intervention clusters will also be asked to complete the (Adapted) Working Alliance Inventory applied to Virtual and Augmented Reality (WAI-VAR) and the (Adapted) California Psychotherapy Alliance Scale-Short Form (CALPAS-P).

A purposively selected sample (age, IPV type, area, lives with partner, has children) of 40 participants, their (ex)-partners and the facilitators delivering ADVANCE-D will be invited to participate in a brief qualitative interview to explore their experience of taking part in the intervention and any impact on their relationship (see process evaluation). This interview can be undertaken during contact 6 or arranged for a separate time.

Following the PHR programme decision to withdraw funding early, the sample for the brief qualitative interview at 4 months will be less than 40 men.

3.4.7 12 MONTH FOLLOW-UP VISITS FOR MALE PARTICIPANTS

Twelve months post baseline interview, participants will be called by the researcher to arrange a convenient time for the 12-month follow-up interview (contact 7). During the call/meeting the researcher will:

1. Confirm willingness to participate.
2. Re-explain what the interview will entail.
3. Arrange a convenient time to call/ meet to conduct the 12-month follow-up interview (contact 8).

During this call/ meeting to conduct the 12-month follow-up interview (contact 8), data will be collected from participants using the following assessment tools. For IPV perpetration: (Adapted) ABI [primary outcome], (Adapted) CBS-R, technology facilitated abuse, locked-in, stalking/harassment, using children against partner, (Adapted) IPVRAS; AUDIT, DUDIT, Treatment Outcomes Profile (partial) (substance use free days); PHQ-9 (depression), GAD-7 (anxiety), PC-PTSD-5, PAS (anger), BSCS (self-control); EQ-5D-5L (Quality of Life), children's well-being, service use and medication.

The same purposively selected sample of participants described above will be invited to participate in a brief qualitative interview to explore their experience of taking part in the intervention and any impact on their relationship (see process evaluation). This interview can be undertaken during contact 8 or arranged for a separate time.

Following the PHR programme decision to withdraw funding early, the sample for the brief qualitative interview at 12 months will be less than 40 men.

3.4.8 ADVANCE-D PROGRAMME

ADVANCE-D is a 14 week, 33 session programme that consists of an individual goal setting session with the facilitator, a welcome to ADVANCE-D group, a follow-up call post group, 6 group sessions (one each fortnight), 12 self-complete website sessions (one a week) and 12 invidual coaching sessions with a facilitator (one a week). One month after the last group session, a booster group will be held. ADVANCE-D website sessions are available in Polish, Romanian, Urdu, or Panjabi to allow participants to complete it in their first language.

3.4.9 CURRENT OR EX-PARTNERS OF MEN IN THE TRIAL

Timepoint	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 20	Month 4 post baseline	Month 12 post baseline	Month 24 post baseline
1. Introductory call		X																			
2. Screening and eligibility		X																			
3. Registration and consent			X																		
4. Baseline			X																		
5. **ADVANCE-D**																					
a. Initial contact from partner support worker				X																	
b. Risk assessment					X																
c. Weekly support from partner support worker						X	X	X	X	X	X	X	X	X	X	X	X				
d. Weekly access to ADVANCE-D website						X	X	X	X	X	X	X	X	X	X	X	X				
6. Follow-up assessment																			X	X	
7. Data linkage with health and criminal justice records																					X

Table 4. Schedule of events – current or ex-partners of men in the trial

Following the PHR programme decision to withdraw funding early, it will no longer be possible to conduct data linkage with health and criminal justice records at 24-months within the current contract. Additional funds will be sought to undertake this.

3.4.10 VISIT WINDOWS FOR CURRENT OR EX-PARTNERS

The research will take place over 24 months. (Ex)-partners of men in the trial will be followed-up 4-months (+/- 4 weeks) and 12-months (+/- 4 weeks) post-baseline interview and 24-month follow up will be undertaken by tracking the cohort in routine health and social care, and criminal justice databases. Research contacts/visits will take place in person or by phone/video call. Research interviews will never be conducted in participants' or (ex)-partners' homes.

3.4.11 INTRODUCTORY CALL, SCREENING & ELIGIBILITY OF CURRENT OR EX-PARTNERS

Probation/JSW will securely send the contact details of current/ex-partners either via consent to contact (see option A in section 3.3) or as provided by the male participant (see option B in section 3.3).
Researchers will initially send a text to current or ex-partners of men in the trial to inform them they will ring them to invite them to take part in the research (contact 1) and arrange a time for an introductory call.
During the introductory call (contact 2) researchers will:

1. Inform them their (ex)-partner is participating in the study.

2. Read the PIS, explain what taking part involves.
3. Invite them to participate in the research (baseline and follow up interviews).
4. Advise them that an integrated support service (ISS) worker will call to offer them support only if their current or ex-partner is allocated to receive the ADVANCE-D Programme.
5. Arrange a convenient time to call/ meet to conduct the baseline interview (contact 3)

If (ex)-partners are interested, researchers will send a message on WhatsApp, email or post a copy of the PIS and consent form.

3.4.12 CONSENT AND BASELINE INTERVIEW WITH CURRENT OR EX-PARTNERS

A different researcher from the researcher who conducted the interview with the male participant (to avoid inadvertant disclosure of information) will gain consent or check consent (if eConsent given) and conduct the baseline interview (contact 3). The researcher will:

1. Gain informed consent (audio or written) or check willingness to participate if consent already received (eConsent or by post).
2. Re-explain PIS (participant will already have a copy prior to consenting).
3. Register the participant into the study (initials and age required).
4. Provide contact details of support services for IPV perpetration and substance use.
5. Complete the baseline interview.

Researchers will collect baseline data from current or ex-partners using the following assessment tools. For IPV victimisation: (Adapted) ABI-R, (Adapted) CBS-R, technology facilitated abuse, locked-in, stalking/harassment, using children against partner; feeling of safety, AUDIT, DUDIT, Treatment Outcomes Profile (partial) (substance use free days); PHQ-9 (depression), GAD-7 (anxiety), PC-PTSD-5; EQ-5D-5L (Quality of Life), children's well-being, service use and medication.

3.4.13 4 MONTH FOLLOW-UP VISITS FOR CURRENT OR EX-PARTNERS

Four months post baseline interview, current or ex-partners will be called by the researcher to arrange a convenient time for the 4-month follow-up interview (contact 4). During the call/meeting, the researcher will:

1. Confirm willingness to participate.
2. Re-explain what the interview will entail.
3. Arrange a convenient time to call/ meet to conduct the 4-month follow-up interview (contact 5).

During this call/ meeting to conduct the 4-month follow-up interview (contact 5), data will be collected from participants using the following assessment tools. For IPV victimisation: (Adapted) ABI-R, (Adapted) CBS-R, technology facilitated abuse, locked-in, stalking/harassment, using children against partner, feeling of safety; Treatment Outcomes Profile (partial) (substance use free days); PHQ-9 (depression), GAD-7 (anxiety), PC-PTSD-5; EQ-5D-5L (Quality of Life), children's well-being, service use and medication.

Current or ex-partners of men purposively selected for the longitudinal qualitative interviews will be invited to participate in a brief qualitative interview to explore their experience of taking part in the intervention and any impact on their relationship (see process evaluation). This interview can be undertaken during contact 5 or arranged for a separate time.

3.4.14 12 MONTH FOLLOW-UP VISITS FOR CURRENT OR EX-PARTNERS

Twelve months post baseline interview, current or ex-partners will be called by the researcher to arrange a convenient time for the 12-month follow-up interview (contact 6). During the call/meeting, the researcher will:

1. Confirm willingness to participate.

2. Re-explain what the interview will entail.
3. Arrange a convenient time to call/ meet to conduct the 12-month follow-up interview (contact 7).

During this call/ meeting to conduct the 4-month follow-up interview (contact 7), data will be collected from participants using the following assessment tools. For IPV victimisation: (Adapted) ABI-R, (Adapted) CBS-R, technology facilitated abuse, locked-in, stalking/harassment, using children against partner; feeling of safety, AUDIT, DUDIT, Treatment Outcomes Profile (partial) (substance use free days); PHQ-9 (depression), GAD-7 (anxiety), PC-PTSD-5; EQ-5D-5L (Quality of Life), children's well-being, service use and medication.

3.4.15 *SUPPORT FOR (EX)-PARTNERS OF MEN IN THE ADVANCE-D PROGRAMME*

The offer of partner support is only routine in probation/JSW when perpetrator programmes are being delivered. Support will be offered to all (ex)-partners of men in the intervention arm of the cRCT. All women whose (ex)-partners are allocated to receive ADVANCE-D will be offered support regardless of whether they choose to participate in the research. Women engaging with the integrated support service (ISS) will be updated about their (ex)-partner's overall progress in the group. They will be offered access to the same 12 ADVANCE-D Programme website sessions as their (ex)-partner for information, alongside support messages (e.g., "If your (ex)-partner talks to you about using a 'time out', know that a safe time out is one that is agreed in advance between the two of you and is not used to continue abuse"). (Ex)-partners will not get access to their (ex)-partner's user-generated information. They will also receive weekly in-person or telephone/ video call support from their ISS worker throughout the duration of the trial as required. Data on attendance with the partner support service will only be collected for (ex)-partners who have given consent to take part in the study.

Safety of current or ex-partners of men in the ADVANCE-D (intervention arm)

Support for IPV victimisation will be offered to all female victims/survivors (i.e. male participants' current or ex-partners) whose (ex)-partners are allocated to receive the ADVANCE-D Programme (intervention arm). Women can take up the offer of support from the women's support service without taking part in the research. An ISS worker (as recommended by *Respect* accreditation standards for perpetrator interventions) will provide information to the victim/survivor to ensure that their expectations of the perpetrator intervention are based on realistic expectations and that they and others do not rely solely on the intervention to bring about an immediate cessation of IPV. The ISS may also contact the women whose partners are attending the ADVANCE-D Programme on at least three occasions to update them on their current or ex-partner's overall progress. They will also contact partners of men in the study if there is anything that they need to know to keep themselves and their families safe. Where men are eligible to take part in the study but their female partner does not speak English and lives in the UK, women will still be offered support and if their partner is attending the ADVANCE-D Programme, also the integrated support service, with the use of translators. This reflects current practice at women's integrated support services.

3-4 weekly case management meetings are scheduled throughout the ADVANCE intervention for keyworkers/facilitators to discuss the safety of female participants with the ISS worker. These case management meetings will take place after the facilitators have conducted their 1-1 phone calls with the men, followed by the case management meeting with the ISS worker. Ideally the ISS worker will have their contact with the partner/ex-partner at a similar time, or prior to these phone calls so that they are all well briefed when they meet. We would request both men and women's workers set aside a block of time to make their calls so all participants receive the phone call the same day, and not on a Friday, to minimise the identification of risk which then cannot be addressed before the weekend.

The DASH risk checklist (*Domestic Abuse*, *Stalking and Harassment and Honour Based Violence*)[65] will be administered by the integrated support services to women who take up the offer of support to assess and manage risk. DASH is a simple tool for practitioners who work with adult victims of domestic abuse to help them identify those who are at high risk of harm and whose cases should be referred to a Multi Agency Risk Assessment Conference (MARAC) meeting in order to manage their risk (score of 14 or above).

Women's version of the ADVANCE-D Programme

Women who take up the offer of support will get access to the same 12 online ADVANCE-D Programme sessions for information, alongside safety messages. They will not get access to the information that their

current or ex-partner completes. They will receive weekly telephone or video call support from their integrated support service worker throughout the duration of the intervention.

A specific platform has been developed for female current or ex-partners of men completing the ADVANCE-D Programme - this will ensure that women can access the same material as their partners/ex-partners, so the knowledge is not restricted to the men and the men are not privileged over women. Within the content of each session, safety messages tailored to women will be presented so that she can see the skills being taught to men each week. Women will be encouraged to contact integrated support services if abuse increases. In cases of immediate danger, women will be signposted to emergency services. The platform will include an "Exit to safety" button, returning the woman to a generic webpage in case she needs to click out of the ADVANCE-D platform quickly.

3.5 DATA ENTRY

Authorised research staff at sites will transcribe baseline and follow up participant data from source data (SDs) to the study eCRF by going to www.ctu.co.uk and clicking the link to access the electronic data capture (EDC).

Data will be collected via paper questionnaires. Data from the paper questionnaires will be entered by the researchers into a web based eCRF system hosted at KCTU. The system is Good Clinical Practice compliant with full audit trail and database lock functionality and a range of validations will be programmed to minimise data entry errors. A full audit trail of data entry and any subsequent changes to entered data will be automatically date and time stamped, alongside information about the user making the entry/changes within the system. Only one current or ex-partner will be registered into the MACRO database per male. If male participants have more than one current or ex female partner, the one who was the victim of the index crime will be invited to participate in the research.

Study site staff will be delegated by the site PI to access the eCRF and randomisation systems via a Study Site Delegation Log. The request for user access must go to the UK Trial Manager, who will submit user requests for all sites to the KCTU team upon receipt of completed Study Site Delegation Logs. Requests for user access will be processed within a maximum of 5 working days.

Training videos for data entry staff, study site monitors and trial managers / trial co-ordinators are available at www.ctu.co.uk under the 'Training' section. Users can self-register and should select the relevant training videos.

3.6 PRE-RANDOMISATION DATA COLLECTION

After PP/ JSW gain informed consent from male participants, they will securely transfer their name and contact details and those of their (ex)-partner to the trial manager. The trial manager will allocate consented participants to researchers who will contact them to undertake the baseline interview.

Researchers will complete the baseline interview (Table 5). Participants who have given their consent to be followed up in routine databases will be asked for the following personal details to enable data linkage to take place:

- Full name
- Date of birth
- Sex
- Full postcode
- Local Authority
- NHS number (England)/ CHI number (Scotland)

Contact details for up to 3 friends or family members and of services they are attending will be gathered to increase follow-up rates. All personal identifiers will be kept separately from the EDC data. PP/ JSW and researchers will be blind during pre-randomisation data collection. For details about the randomisation method, see section 5.1 Randomisation method.

3.7 EFFICACY DATA

Participant self-report measures will be administered by the researcher in the absence of the PP/ JSW (men only) and (ex)-partners. Short, medium, and longer-term outcomes for men and their (ex)-partners will be

assessed by research interview at 4 and 12-months and via linkage with health and criminal justice records at 24 months post-baseline. Researchers will collect outcome data, conducting interviews by phone, Microsoft Teams or in-person at PDU/ JSWT (men) or ISS, library or children's centre (women) 4 and 12-months with both men and their (ex)-partners. Outcomes will be analysed using the modified intention to treat (ITT) population at 4 and 12 months. Even if the male participant has dropped out of the intervention, they will be followed-up, unless they have asked to be withdrawn from the study. All measures have been successfully used in our previous studies.[47,48] In our previous trial of ADVANCE,[47] the suitability and acceptability of outcome measures were assessed with both male and female participants using the researchers' perceptions of participants' understanding (language and meaning of questions) and acceptability (participant refused to answer, got annoyed/frustrated or asked to end the interview) for each outcome measure using a predetermined rating scale scored from 1 (lowest rating) to 3 (highest rating). Completeness of outcome data was determined for each measure for both male and female participants. Therefore, the measures selected for primary and secondary outcomes for the proposed study have been demonstrated to be understandable and acceptable to participants. In addition, the time required to complete the assessments in person and by phone are also acceptable to participants. Record linkage will be performed at 24 months.

The table below outlines the instruments administered to male perpetrators and their female current or ex-partners to be included in the study.

Outcome	**Male perpetrators**		**Female survivors**	
	Baseline	**4 & 12- months post baseline interview**	**Baseline**	**4 & 12- months post male baseline interview**
IPV (perpetration for males, victimisation for females)	(Adapted) ABI; (Adapted) CBS-R; Technology facilitated abuse; Locked in; Stalking/Harassment; Using children against partner, (Adapted) IPVRAS	(Adapted) ABI; (Adapted) CBS-R; Technology facilitated abuse; Locked in; Stalking/Harassment; Using children against partner, (Adapted) IPVRAS	(Adapted) ABI-R; (Adapted) CBS-R; Technology facilitated abuse; Locked in; Stalking/Harassment; Using children against partner, feeling of safety	(Adapted) ABI-R; (Adapted) CBS-R; Technology facilitated abuse; Locked in; Stalking/Harassment; Using children against partner, feeling of safety
Substance use	AUDIT; DUDIT; Treatment Outcomes Profile (partial)	AUDIT; DUDIT (12 months f/up only); Treatment Outcomes Profile (partial)	AUDIT; DUDIT; Treatment Outcomes Profile (partial)	AUDIT; DUDIT (12 months f/up only); Treatment Outcomes Profile (partial)
Well-being	PHQ-9; GAD 7; PC-PTSD-5; PAS [anger subscale]	PHQ-9; GAD 7; PC-PTSD-5; PAS [anger subscale]	PHQ-9; GAD 7; PC-PTSD-5	PHQ-9; GAD 7; PC-PTSD-5
Self-control	BSCS	BSCS		
Quality of life	EQ-5D-5L	EQ-5D-5L	EQ-5D-5L	EQ-5D-5L
Children's well-being	Children's well-being	Children's well-being	Children's well-being	Children's well-being
Economic evaluation	Service use and medication in past 4 months	Service use and medication in past 4 months at 4 month follow-up/ in past 8 months at 12 month follow-up	Service use and medication in past 4 months	Service use and medication in past 4 months at 4 month follow-up/ in past 8 months at 12 month follow-up
Therapeutic alliance		(Adapted) WAI-VAR; (Adapted) CALPAS-P (4 months only for men in intervention cluster only)		

Table 5. Instruments and timeframes of administration to participants and their (ex)-partners

A reminder telephone call, text or email will be sent out to all participants between one to two weeks before each of the brief qualitative interviews and the follow-up interviews is due to arrange a time to undertake it. A reminder telephone call or text will be sent the day before the arranged time for interview to confirm the appointment.

3.7.1 PRIMARY OUTCOME

Self-reported IPV perpetration towards (ex)-partner will be measured using the (Adapted) ***Abusive Behavior Inventory (ABI)***[67] in the past 4 months **at 12 months post-baseline**. The (Adapted) ABI is a 29-item instrument administered to measure the frequency of physical (12 items, 2 of which assess sexual abuse) and psychological IPV perpetration (17 items). Items are scored from 1 (never) to 5 (very frequently). Higher total scores in each subscale and total score indicate greater abuse. The ABI is one of the only validated scales to measure IPV perpetration and was chosen over the Conflict Tactics Scale-Revised[68] as it includes a wide range of both physically and psychologically abusive behaviours.

Rationale for primary outcome being male self-reported IPV

Due to the low partner recruitment and follow-up rates reported in our and other studies,[37,47,48] IPV victimisation from a (ex)-partner was not selected as the primary outcome. Male IPV perpetrators are consented to the trial and complete a baseline questionnaire prior to the researcher contacting and inviting their (ex)-partners to participate. Whilst we will attempt to recruit and follow-up all men's (ex)-partners, in our previous trial of ADVANCE[47] and feasibility study of ADVANCE-D,[48] only 26% and 47% of men's female (ex)-partners were recruited, and 63% and 52% of them were followed-up at 4 months, respectively. Therefore, men's self-reported IPV perpetration was selected as the primary outcome and was used in our previous studies. Our review highlighted that the majority of trials used male IPV self-report as a primary outcome.[37] In our feasibility study of ADVANCE-D, similar proportions of women (73%) reported reductions in IPV victimisation compared to men (68%) reporting reductions in IPV perpetration.[48] These findings support the use of men's self-report of IPV perpetration as the primary outcome. We will, nevertheless, make every attempt to recruit and follow-up (ex)-partners of men in the study. We will also collect qualitative data on their experiences. Outcomes for all women and men consenting to take part in the study will be followed up in routine data sets at 24 months to overcome this.

3.7.2 SECONDARY OUTCOMES: IPV PERPETRATION (MEN)/VICTIMISATION (WOMEN)

Eight scales or partial scales/items are required to ensure all types of abusive behaviour are assessed. This section includes 47 items for men (perpetration) and 61 items for women (victimisation). In all instruments, the higher the score, the greater the frequency of experiencing or perpetrating the behaviour.

- ***(Adapted) Revised Abusive Behavior Inventory (ABI-R)[69] (women only)*** The 25-item ABI-R will measure experiences of physical (13 items), psychological (9 items) and sexual abuse (3 items) victimisation. Total scores range from 25 (never) to 125 (very frequently).
- ***(Adapted) Revised Controlling Behaviors Scale (CBS-R)[70]*** The 24-item Revised Controlling Behaviors Scale (CBS-R) will measure the use and experience of controlling behaviours (e.g., want to know where your partner went and who they spoke to when not together). Response options range from 0 (never) to 16 (always).
- ***Technology facilitated abuse[71]*** Three questions from a non-validated scale on the use of technology-facilitated abuse will be included (e.g., 'Used mobile technology to check her location'). Total scores range from 3 (never) to 15 (very frequently).
- ***Locked in*** One question will ask about frequency of stopping/being stopped by a partner from leaving the house against their will, scored from 1 (never) to 5 (very frequently).
- ***Stalking/Harassment*** Two questions will be asked about stalking behaviours scoring from 2 (never) to 10 (very frequently).
- ***Using children against partner[72]*** Five questions will be used to assess the use of children against a partner (e.g., 'Asked the children to report on what she is doing or where she has been'). Total scores range from 4 (never) to 20 (very frequently).
- ***Feeling of safety[72] (women only)*** One question on how safe the woman feels is asked. Total scores range from 1 (not safe at all) to 4 (very safe).
- ***(Adapted) Intimate Partner Violence Responsibility Attribution Scale (IPVRAS) (men only)[101]*** Twelve questions will be used to assess men's IPV responsibility attribution across three domains: responsibility attribution to the legal system, responsibility attribution to the victim, and responsibility attribution to their own personal context. A five-point response scale is used from 1 (strongly disagree) to 5 (strongly agree).

3.7.3 SECONDARY OUTCOMES: SUBSTANCE USE

- ***Treatment Outcomes Profile*** (partial - total alcohol and drug free days in past 28 days).[73]
- ***Alcohol Use Disorder Identification Test (AUDIT)*** total score in the past 12 months at 12 months follow-up.[74]
- ***Drug Use Disorder Identification Test (DUDIT)*** total score in the past 12 months at 12 months follow-up.[75]

3.7.4 SECONDARY OUTCOMES: WELL-BEING

Well-being will be measured using 21 items for women and 46 items for men.

- ***Patient Health Questionnaire (PHQ-9)***[76] Depressive symptoms in the past 2 weeks will be measured using the 9-item PHQ-9. A score ≥ 10 out of a possible 27 reliably identifies major depression.
- ***Generalised Anxiety Disorder symptoms (GAD-7)***[77] General anxiety symptoms in the past 2 weeks will be assessed using the 7-item GAD-7. A score of ≥ 10 out of a possible 21 reliably identifies GAD cases.
- ***Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)***[78] The 5-item PC-PTSD-5 will assess past month post-traumatic stress disorder (PTSD) symptoms. A score of ≥ 3 out of a possible 5 indicates PTSD.
- ***Propensity for Abusiveness Scale (PAS) [anger subscale]***[79] ***(men only)*** Anger will be assessed using the 12-item anger subscale from the PAS, with scores ranging from 12 (completely undescriptive of you) to 60 (completely descriptive of you). Higher scores indicate a greater propensity for anger.
- ***Brief Self-Control Scale (BSCS)***[80] ***(men only)*** The 13-item BSCS will assess general self-control, with scores ranging from 13 (not at all like me) to 65 (very much like me). Higher scores indicate greater self-control.
- The ***Children's well-being***[72] will be measured using 8 items scored from 1 (never) to 5 (very frequently). Both men and their (ex)-partners will be asked these questions. Total scores range from 8 (never) to 40.

3.7.5 SECONDARY OUTCOMES: QUALITY OF LIFE

- EQ-5D-5L[81] will be used to measure five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no (Level 1), slight, moderate, severe and extreme (Level 5) problems. Health states range from 11111 (full health) to 55555 (worst health). EQ-5D-5L health states are converted into a single index 'utility' score from -0.281 to 1, where values lower than 0 represent states considered to be worse than death. The EQ VAS records the participant's self-rated health from 'The best health you can imagine' (100) to 'The worst health you can imagine' (0). EQ-5D-5L will be used to calculate Quality Adjusted Life Years (QALYs).

3.7.6 ECONOMIC EVALUATION

- Self-reported use of primary and secondary healthcare including prescribed medication, social services, legal and civil services, and criminal justice contacts in the past 4 months at baseline and 4-month follow up, and in the past 8 months at 12-month follow-up will be recorded on a bespoke **Service Use Questionnaire** (SUQ) used in our previous studies.[47,48]

3.7.7 THERAPEUTIC ALLIANCE (MEN IN ADVANCE-D TREATMENT ARM ONLY) ASSESSED AT 4 MONTHS FOLLOW-UP ONLY

On both forms, higher scores represent better therapeutic alliance.

- ***(Adapted) Working Alliance Inventory applied to Virtual and Augmented Reality (WAI-VAR)*** [82] The 12-item self-report questionnaire designed to assess the therapeutic alliance on a seven-point Likert scale, ranging from 1 (never) to 7 (always). The total score ranges from 12 to 84.
- ***(Adapted) California Psychotherapy Alliance Scale-Short Form (CALPAS-P)***[83] The 12-item CALPAS-P Short Form uses four subscales: the patient's working capacity, patient commitment, working strategy consensus and therapist understanding and involvement. Participants are asked to describe the degree

that each item describes their experience from 1 (not at all) to 7 (very much so). The total score is the mean of the four subscales.

3.7.8 **EXPLANATORY VARIABLES**

Participants' age, gender, ethnicity, highest education level attained, living arrangements, current employment status, number of children, sexual orientation, relationship status and previous arrests/convictions for domestic violence (men only) will be recorded.

3.7.9 **RECORD LINKAGE**

At 24 months with participants' consent, we will apply to the following information systems to follow up the cohort under general processing purposes to check whether our participants appear in their datasets. Data will be linked on date of birth, full name, sex, postcode, local authority and NHS/CHI number. A Data Access Request Service (DARS) will be made to NHS Digital, Ministry of Justice and to the National Drug Treatment Monitoring System (NDTMS) for England. A request has been made to the Electronic Data Research and Innovation Service (eDRIS) in Scotland. The following information will be linked:

- Convictions/arrests for IPV (Health and Justice Information Service; Police National Computer; Prison database)
- Death (Death Register)
- Health/Substance use treatment and prescriptions (National Drug Treatment and Monitoring Service (NDTMS)/ Hospital Episode Statistic (HES) (NHS Digital)/ Scottish Morbidity Record (SMR (Public Health Scotland))

We will seek approval from relevant Public Benefit and Privacy Panels at the start of the project to avoid delays. This will require a data sharing agreement to be in place between each agency and the sponsor. We will consult with the Data Protection Officer and legal team at King's College London to complete the legal basis documentation.

Following the PHR programme decision to withdraw funding early, it will no longer be possible to conduct data linkage with health and criminal justice records at 24-months within the current contract. Additional funds will be sought to undertake this.

3.7.10 **PROCESS EVALUATION**

Context, fidelity, dose delivered, dose received, reach and recruitment for ADVANCE-D will be evaluated.[85] Longitudinal qualitative interviews (at 4- and 12- months) with 40 men receiving ADVANCE-D and their (ex)-partners and with staff post intervention will provide in-depth understanding of mechanisms of action, how context affects implementation, engagement, and behaviour change.

Following the PHR programme decision to withdraw funding early, the sample size for the process evaluation will not reach 40 men.

The process evaluation will assess six priority areas:

1. Context – what are the local factors that influence intervention implementation

End of intervention focus groups/interviews will be conducted with the probation/JSW staff and women's support workers/ integrated support services that supported the intervention delivery to understand its implementation in practice and understand local context.

2. Fidelity – to what extent is the intervention delivered as conceived

All group sessions will be video recorded with consent. A random sample of 10% will be checked for fidelity. In addition, notes from integrity management meetings between the facilitators and the practitioners in the ADVANCE research team will contribute to these findings.

Co-applicants of the NIHR Programme grant that is funding the study, and that developed the intervention from King's College London, The University of Edinburgh, The University of Edinburgh, Mary McMurran, Independent Consulting Psychologist (UK), and the University of Manchester will have access to the video recordings of the sessions to assess fidelity of the delivery of the intervention.

3. Dose delivered – what amount of the intervention were participants offered

The number of ADVANCE-D intervention sessions offered will be recorded for all male study participants. The number of ISS worker contacts offered will be provided, where consent has been given.

4. Dose received – attendance

Quantitative data on attendance and retention in the intervention group and TAU (number of sessions attended in group intervention and number of times participant has attended for TAU and duration of these contacts) and with women's support services for victims/ survivors (number of times the female participant has attended a session in person or by phone with the women's support worker or has had a follow-up call with the women's support worker and duration of these contacts) will be recorded and collated with participants' consent by the service providers and shared with the research team.

5. Acceptability and outcomes

Two brief qualitative interviews with 40 men and their current or ex-female partners throughout the duration of the study will explore the acceptability of taking part and the outcomes/ impact associated with participation. Separate researchers will interview the man and his current or ex-partner to avoid inadvertent disclosure of information (see Standard Operating Procedures for more detail).

6. Satisfaction and acceptability

Men attending the intervention session will complete a brief evaluation of each session. Facilitators and women's support services will be invited to participate in brief interviews/focus groups throughout the duration of the study.

3.8 SAFETY DATA

3.8.1 ADVERSE EVENTS (AE)

An Adverse Event (AE) is any untoward medical occurrence in a participant taking part in a research study, including occurrences which do not necessarily have a causal relationship with the research. This includes any psychological distress incurred by the participants, which could be caused by threatening phone messages or aspects of their probation.

Following the baseline interview, researchers will record any adverse events disclosed by participants and/or their (ex)-partners.

3.8.2 ADVERSE EVENTS EXPERIENCED BY PARTNERS/ EX-PARTNERS CONSENTED INTO THE TRIAL CAUSED BY THE PROBATIONER

When an event occurs that has been initiated by the probationer that leads to harm to the consenting partner/ex-partner it will be recorded under the AE log of the probationer as occuring on the partner/ex-partner. If any of the adverse events caused by the probationer fall under notifibale probation incidents and offences this will be recorded. This includes death, attempted murder, murder, manslaughter, rape, grevious bodily harm and terrorism-related offence. To report non-medical notifiable incidences and offences, see section 3.9 Non-medical Criminal Justice Occurences.

3.8.3 ADVERSE EVENTS EXPERIENCED BY INDIVIDUALS NOT CONSENTED INTO THE TRIAL CAUSED BY THE PROBATIONER

When an event that has occured that has been initiated by the probationer that leads to harm experienced to individuals outside of the trial it will be recorded under the AE log of the probationer as occuring on another person. This information can only be learned through the probation officer. No identifying characteristics of the person harmed will be collected. This will include children of the participants as well as others (e.g.,

partners not consented and other members of the public and emergency services). If any of the adverse events caused by the probationer fall under notifibale probation incidents and offences, this will be recorded. This includes death, attempted murder, murder, manslaughter, rape, grevious bodily harm and terrorism-related offence. To report non-medical notifiable incidences and offences, see section 3.9 Non-medical Criminal Justice Occurances.

3.8.4 SERIOUS ADVERSE EVENTS (SAE)

A Serious Adverse Event (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 or consists of a congenital anomaly or birth defect. Other 'important events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

3.8.5 SERIOUS ADVERSE EVENTS EXPERIENCED BY INDIVIDUALS NOT CONSENTED INTO THE TRIAL CAUSED BY THE PROBATIONER

All SAEs will be followed up by the researcher, the PP/ JSW or ISS worker. If men are rearrested for IPV during the trial, a case management meeting will be held to determine whether the participant can remain in the trial and to provide additional safeguarding to their (ex)-partner if required. As listed above, when an event occurs that has been initiated by the probationer that leads to harm experienced to individuals outside of the trial it will be recorded under the AE log of the probationer as occuring on another person. This information can only be learned through the probation officer. No identifying characteristics of the person harmed will be collected. An adverse event will be upgraded to a serious adverse event if the harm caused falls into the category of an SAE i.e. results in death; is life-threatening; requires inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity or consists of a congenital anomaly or birth defect.

3.8.6 RECORDING AND REPORTING

All deaths will be reported to the sponsor within 24 hours of receiving the notification by the CI. All SAEs will be recorded on the relevant form of the CRF and the Trial Manager will report this to the CI and DMC chair within 24 hours of receiving the report. The CI and DMC chair will consider whether the SAE is: not related to participation in the trial; possibly related to participation; or definitely related to participation within 24 hours of receiving the report. Judgement will be made on whether to report the possibly related cases on to the Sponsor and REC chair, but all cases of definitely related will be reported onwards.

Where safeguarding or distress protocols are followed, or where interviewers' safety is threatened, an incident report form will be completed by the researcher. The CI will be notified of any incidents as soon as possible. All incidents and resulting actions will be recorded on an incident report and emailed to the trial manager who will store them on SharePoint. Only ID numbers will be included on the incident form. A cumulative review of all safety information by the DMC will be made on a six-monthly basis.

Judgement will be made on whether to report the possibly related cases on to the Sponsor and ethics committee chair, but all cases of definitely related SAE will be reported onwards. All SAEs will be followed up where appropriate by the researcher, the intervention facilitator, PP/JSW or the women's worker. If it is felt that a child or adult are at significant risk, then the standard safeguarding procedure for the service will be followed.

Only unexpected and related serious adverse events (SAE) resulting from trial participation will be reported to the REC and the sponsor within 24 hours of receiving the report.

3.8.7 CONCOMITANT INTERVENTIONS/ TREATMENT

During each research interview, participants will be asked about their use of other interventions/ treatment. All concomitant interventions/ treatment will be recorded in an ongoing concomitant interventions/treatment log.

3.8.8 WITHDRAWAL

Withdrawal will be categorised as 1) Participant withdrawal; 2) PDU/JSWT or researcher withdrawal of participant. If the male or female participant withdraws or is withdrawn from the trial, their (ex)-partner will still be followed-up.

(1) Participant wishes to withdraw from the trial and not provide outcome data

Participants have the right to withdraw from the trial at any time for any reason. Should a participant decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as accurately as possible. If participants do choose to withdraw from the study or if they are no longer able to give their consent to continue in the study, the research team will delete their contact details but will need to use the anonymous data collected up to the point of withdrawal. This is explained to participants in the PIS If men withdraw from the study and had been given a tablet by the research team, they will be asked to return this by courier (organised and paid for by the research team) or to the substance use treatment service. Participants have the right to withdraw from future record linkage with health or social care services or the criminal justice system. Current or (ex)-partners will not be informed of withdrawal.

(2) Participant is withdrawn from the trial by PDU/JSWT or research team

PDU/JSWT or the research team also have the right to withdraw participants from study in the event of adverse incidents or severe adverse events (SAEs) or other reasons which would be discussed on a case-by-case basis with the ADVANCE-D Clinical lead. Unnecessary withdrawal of participants should be avoided.

3.9 NON-MEDICAL CRIMINAL JUSTICE OCCURRENCES

The notifiable probation Incidents and Offences will be collected. These include death, attempted murder, murder, manslaughter, rape, grievous bodily harm and terrorism-related offence. As five of these items will be collected though Adverse Events or Serious Adverse Events, only two items will be captured as Non-medical Criminal Justice Occurrences for male participants and their (ex)-partners. These items are Non-medical Attempted Murder and Non-medical Terrorism-related offence.

In the event of non-medical attempted murder, the date of the first occurrence, the last occurrence and frequency will be collected. Examples of non-medical attempted murder include tampering with a partner or ex-partners brakes (car) and planning an arson attack/fire setting e.g. getting the materials together to set a fire at a domestic dwelling, with the intention of causing significant harm. In both cases the intended victim would not necessarily know and not suffer any direct physical or psychological damage.

In instances of non-medical terrorism-related offences, they will be classed under one of four categories following the definition of the Terrorism Act 2000. These categories are 1) Created a serious risk to the health or safety of the public or a section of the public, 2) Action designed seriously to interfere with or seriously to disrupt an electronic system 3) A threat is designed to influence the government or to intimidate the public or a section of the public and 4) A threat is made for the purpose of advancing a political, religious or ideological cause.

3.10 MEASURES TO PROMOTE PARTICIPANT RETENTION

Researchers will record participants and (ex)-partners contact details (mobile, WhatsApp, house phone, email) to maintain contact. To enhance retention, participants will be asked for the contact details of up to 3 family members or friends and of the services they attend (e.g. pharmacy, GP, alcohol and drug treatment service, social worker) in case the researchers cannot contact the participant using their contact details.

Researchers will keep in regular contact (monthly) with the participants and (ex)-partners to remind them about key timepoints in the study. They will be reminded of their interview dates by text and email. Consent to follow participants up through these contacts if it is not possible to contact them using their contact details will be sought. All personal data will be stored on SharePoint separate to the research data.

Addressing digital poverty and literacy

Participants will be provided with tablets with 5GB of mobile data to address digital poverty. Additional monthly mobile data throughout the duration of the study is contingent on ADVANCE-D engagement and attendance. If men prefer to use their own technology, they will be reimbursed for their data. If men do not

attend any sessions each month (group or website), researchers will ask men to return the tablet and their monthly mobile data will not be topped-up. Participants will be asked to return their tablet to probation /JSW at the end of the study. These will be collected by the research team and reused at other sites where possible. Mobile data allowance will be used only for the purpose of taking part in the ADVANCE-D Programme.

The responsibility for returning the device rests with the participant. Participants' engagement with probation may be longer than the 14-week ADVANCE-D Programme. Participants will be expected to return the tablet to probation or someone acting for them if not possible. Participants will be prompted twice and offered/ sent a free return envelope to encourage return. If participants are arrested for further offending and/or returned to custody, they would be asked to make arrangements for a friend or support worker to return the device to probation or the ADVANCE-D team. If the device is not returned, it will be remotely wiped as far as is possible, remove website access for the participant and record their details as having been offered ADVANCE-D and not completed, for research and operational purposes. The rate of devices reported as lost/stolen/broken will be tracked.

To address digital literacy, participants will be provided with a written and video guide of how to use the tablet to participate in the ADVANCE-D Programme.

Reimbursement for time

Reimbursement of men taking part in the research will be a decision made locally by each PDU/ JSWT. All men's current or ex-female partners recruited will be reimbursed for their time.

Men who consent to participation in the trial will receive a £20 voucher for their time for participating in baseline and follow-up research interviews post intervention (£20 x up to 3 interviews = £60). They will also receive a £20 voucher for participating in each brief semi-structured interview (£20 x up to 2 interviews = £40). (Ex)-partners will also receive a £20 voucher for their time for participating in the baseline interview (women) and follow-up research interviews (£20 x up to 3 interviews = £60). Women will also receive a £20 voucher for participating in each brief semi-structured interview (£20 x up to 2 interviews = £40).

4. INTERVENTIONS

4.1 INTERVENTION AND COMPARATOR DESCRIPTION

Regardless of allocation, all participants will have a supervising officer to manage risk and enforce the order/license. The supervising officer will oversee progress of the order to support them in successfully completing the requirements they are subject to.

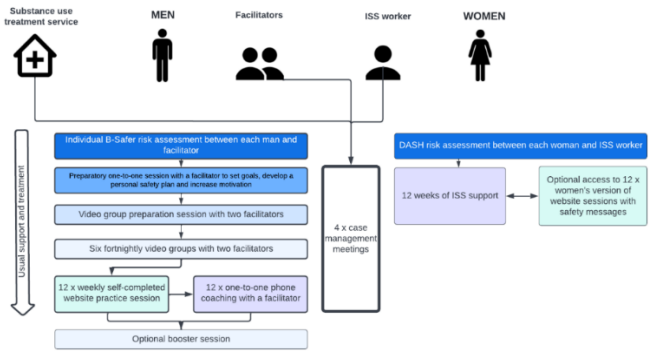
4.1.1 ACTIVE

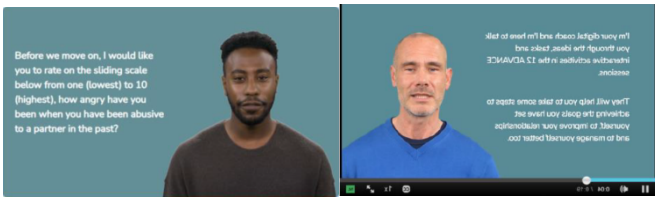
Intervention

ADVANCE-D proposes that behaviour change is facilitated by increasing understanding of the function of abusive behaviours and the contribution made by substance misuse and gendered attitudes.[46] It highlights individual risks for IPV including substance misuse, poor emotional regulation, and poor stress-coping. It teaches men how to reduce these risks by promoting self-regulation and personal goal setting. ADVANCE-D is a 33-session (14-week) programme (+ refresher session 4 weeks later) delivered in-person, remotely or hybrid. It includes: a 1:1 goal-setting session; a welcome to group preparation session; 6 group sessions [these are the 8 core sessions]; 12 self-directed website sessions with a digital coach (avatar) to recap and practise skills learned in the group each followed by 1:1 coaching sessions with a facilitator (12 weekly coaching sessions in total). It is delivered by 2 facilitators (ideally one female), trained in supervising PP/JSW. To manage risk, 4 case management meetings are scheduled with the ISS. Men offered ADVANCE-D can receive concomitant support for substance misuse.

Website sessions (n=12)
1: Introduction
2: Managing myself
3: Being a man
4: Impact on her
5: Children and parenting
6: Relating
7: Improving communication
8: Dealing with distress
9: Planning to be better
10: Positive relationships
11: New futures
12: Recap 'what have we learned?

Group sessions (n=6)
1: Understanding abuse
2: Handling challenges
3: Difficulties in families
4: Times of distress
5: Relating well
6: Doing it differently





Supervising Officers would also be expected to see the ADVANCE-D participants face-to-face in addition to the structured intervention to meet national standards.

To give an example of a fortnight in the programme, the diagram below illustrates that there is an online group delivered every fortnight; in the two weeks following each group, participants complete two practice website sessions each followed by a coaching call. Participants advise the facilitator when they were intending to complete the session so that the coaching call is booked in to follow. The 12 weekly self-directed website sessions are guided by a digital coach (avatar) to recap and practice skills learned in the online group sessions. The online coach verbalises the content and the text also appears on screen, so participants have the option to listen to the coach and/or read the text. Coaching calls are delivered by a facilitator to go over the materials in the previous group and website session, check in with the participant around their relationship and substance use, especially any change in risk, and continue to enhance motivation and revisit goals. A refresher session is offered one month after the last online group takes place.



The online content is managed by Maudsley Learning. As an NHS Trust, Maudsley Learning hosts digital products and services within Microsoft Azure Cloud Services. Specifically, the ADVANCE-D intervention online will be hosted on a Virtual Machine within Azure using resource groups within the stack, managing user accounts with Azure Active Directory B2C, and working within Azure security policies. Maudsley Learning work with a Microsoft Gold Certified Partner for management of the cloud architecture,

applications and Active Directory within the stack. The Microsoft Azure Data centre region is UK South (location London). Maudsley Learning work to the following compliance guidance, standards and policies:

- Government Cloud Security Guidance
- NHS Digital Standards for web products
- South London and Maudsley NHS Foundation Trust. Personal information and data protection policy
- South London and Maudsley NHS Foundation Trust. Privacy policy

Adherence

If a participant stops attending the ADVANCE-D Programme the reason for this will be recorded e.g. 1) participant reason given; 2) violation of condition. Should a participant withdraw from the ADVANCE-D Programme, efforts will be made to continue to obtain follow-up data, with the permission of the participant. Men in both treatment arms will have a supervising PP/ JSW to monitor compliance to the community sentences. Any violation of conditions will be referred back to court. If participants are finding it hard to attend scheduled sessions, then a meeting between their facilitator, PP/ JSW and a member of the ADVANCE-D research team will develop a strategy to address this issue. Options will range from offering specific 1-1 input to catch the participant up; linking with a buddy to help attendance, devising personalised reminders e.g. texts to remind participants of day and time of attendance or personalised support, help to log on via phone, to address barriers for engagement or additional motivational input to minimise ambivalence or 1-1 to enhance understanding. Where participants appear unable to attend despite bespoke support, they will be considered for alternative input, including different content or different delivery mode. As ADVANCE-D will not be specified on the order but fall within the requirement to undertake offence-focussed work, there is no need to return to court to vary the order if men decline to participate.

Adherences will be reported as per the Statistical Analysis Plan.

Integrity Support

Receiving supervision from other staff when delivering IPV perpetrator programmes has been shown to reduce IPV recidivism.[35] Fortnightly online integrity support meetings for ADVANCE-D facilitators will be led by clinical lead and co-CI Professor E Gilchrist (Chartered Forensic Psychologist) and to discuss delivery issues and address any expected problems with the next two sessions. These integrity support meetings will check intervention fidelity, cover the core material to be delivered in the forthcoming sessions and review any issues that have arisen when delivering previous sessions to promote fidelity to the model and reduce likely non-adherence. Any deviation from delivery as planned will be noted and included as a factor in the evaluation of acceptability and feasibility. Separate online fortnightly integrity support meetings for ISS workers will be led by Sara Kirkpatrick, CEO of Welsh Women's Aid to support ISS to respond to any issues raised when supporting women. A register of attendance will be kept.

Fidelity

All online group sessions will be recorded within Microsoft Teams with participants' and facilitators' consent. Researchers will check a random sample of 10% of the recording intervention fidelity, using a pre-defined checklist for each group session. Recordings of the integrity management meetings will contribute to understanding fidelity.

4.1.2 CONTROL

Usual CJOM will vary but details will be recorded including type of intervention and number and duration. Existing group probation-based perpetrator programmes will not be used as a comparator. Options to address offending behaviour will be grouped into the following categories:

- mental health treatment
- drug treatment
- alcohol treatment
- education, training and employment
- relationships
- lifestyle and associates

- emotional management
- attitudes, thinking and behaviour
- compulsory unpaid work/ volunteering
- finance, benefits and debt

MONITORING COMPLIANCE: Men in both treatment arms will have a supervising PP/JSW to monitor compliance to the community sentences. Any violation of conditions will be referred back to court.

TRAINING: Facilitators, ISS workers and supervising PP/JSW will complete an online training course. Training and facilitator certification are delivered online and require a maximum of 30 hours of self-directed learning/ assessment for Probation Officers (3 per PDU required) and 20 hours for integrated support service workers. The training includes the use of the SARA tool, a structured professional judgement tool specifically designed to assess risk and vulnerabilities in situations of IPV (the clinical/ risk lead is an accredited trainer).[63] Training includes modules on the ADVANCE-D intervention's theory of change; the importance of enhancing and maintaining motivation throughout; the content of the individual, group and website sessions and coaching phone calls, understanding the role of ISS, risk identification and reporting, case management and integrity support. The final two days will provide the opportunity for ADVANCE-D facilitators to practice delivery and be accredited to deliver.

4.2 DISCONTINUING ALLOCATED INTERVENTIONS

Any violation researchers become aware of will be referred to the PP/ JSW to consider referral to court. Alongside the RAR or CPO, men will have a supervising PP/ JSW to monitor compliance to the community sentences. Any violation of conditions will be referred back to court.

4.3 CONCOMITANT INTERVENTIONS PERMITTED OR PROHIBITED DURING THE TRIAL

Men can receive treatment and support for their substance use. They should not be receiving (structured) interventions for IPV perpetration. Men in the control arm will NOT receive ADVANCE-D at the end of the 20 weeks of delivery to the treatment arm.

5. ASSIGNMENT OF INTERVENTIONS

5.1 RANDOMISATION METHOD

To reduce selection and recruitment bias, PDU/JSWTs will be randomly allocated to experimental or control arms in a 1:1 ratio to deliver ADVANCE-D+CJOM or usual CJOM. The sequence will be generated by the King's Clinical Trials Unit (KCTU)-affiliated statistician, using block covariate minimisation at the cluster level developed by Carter and Hood.[66] The following covariates will be used for the clusters: % non-white ethnicity, size of unit/team, index of multiple deprivation (IMD) by decile[a] and classification of region (urban/rural)[b]. Cluster allocation will then be communicated to the trial manager, who will then inform the PDU/JSWT. PDU/ JSWT make decisions on the CJOM required to address any treatment/support recommended by court.

[a]IMD data obtained from:
England: https://imd-by-postcode.opendatacommunities.org/imd/2019
Scotland: https://www.gov.scot/publications/scottish-index-of-multiple-deprivation-2020v2-postcode-look-up/

[b]Classification of region data obtained from:
England: https://www.nomisweb.co.uk/sources/census_2021_pc
Scotland: https://www.gov.scot/publications/scottish-government-urban-rural-classification-2020/pages/1/

5.2 CONCEALMENT MECHANISM

Randomisation sequence is generated, and the clusters are assigned treatment groups after baseline data is collected. These allocations will be communicated to the trial manager. The sequence will be generated following a randomisation protocol that will ensure that the senior statistician remains blinded throughout the duration of the study. Facilitators who are not responsible for supervising men in probation will be trained to centrally deliver ADVANCE-D and therefore will be blind to which PDU/ JSWT men are attending. Supervising officers in probation or JSWT will be blind when they consent men to the trial. Researchers will be blind when they conduct baseline interviews with men in the trial.

5.3 RANDOMISATION IMPLEMENTATION

5.3.1 ALLOCATION SEQUENCE GENERATION

A KCTU statistician will generate the randomisation sequence. This allocation list will be communicated to the trial manager who holds the randomisation key assigning A or B to intervention in order to implement the assigned allocations within the clusters. This process will continue per PDU/JSWT until all clusters have been allocated. Once the sequence is generated, a PDF of the allocations will be stored as source data. The Chief Investigator, Senior Statistician and TMG will be blinded to the sequence generation.

5.3.2 ENROLMENT OF PARTICIPANTS

Participants will be enrolled in the study for the purpose of CONSORT[84] reporting at the point of signing a consent form and will be part of the target N=450 at the point of randomisation.

5.3.3 ASSIGNMENT OF PARTICIPANTS TO INTERVENTIONS

PDU/ JSWT will be assigned by a KCTU statistician and they will inform the trial manager of allocation. We will close recruitment once we have an adequate number of men consented and baselined at each PDU/ JSWT within a period of two weeks. At this point, the trial manager will advise the PDU/ JSWT of allocation.

5.4 BLINDING STATUS OF RESEARCHERS

Researchers (outcome assessors) will be blind to group allocation when baseline interviews with male participants and their current or ex female partners are conducted. After the men are baselined from each PDU/ JSWT and their (ex)-partners have been completed their baseline assessment or declined to take part in the research or were not contactable, they will be informed of allocation. Probation practitioners and principal investigators/other staff at PDU/ JSWT will be blind during eligibility and consent.

Individual blinding status	Blinded	Unblinded
Chief Investigators	**X**	
Principal Investigators and all other PDU/JSWT staff at site (blinded until post baseline)		**X**
Co-applicants$^{\alpha}$	**X**	
Trial Manager		**X**
Facilitators		**X**
Senior Trial Statistician	**X**	
Trial Statistician$^{\alpha}$	**X**	
Senior Health Economist	**X**	
Health Economist (blinded until after data collection)	**X**	

Trial Participants		**X**
Outcome Assessors (blinded during baseline interview)		**X**
Partner Support Workers		**X**
Trial Steering Committee (TSC)	**X**	
Data Monitoring Committee (DMC)		**X**

Table 6. Blinding Status

[α]The blinding status of the research team is detailed in Table 6 above. Note the Trial Statistician will become partially blinded at the point of reporting to the Data Monitoring Committee outcome and safety data partitioned in groups labelled A and B. The time of when this planned change in blinding status of the Trial Statistician is will be reported. The Clinical Lead (co-applicant Liz Gilchrist) will be unblinded.

**For roles not listed please refer to study delegation logs.*

5.5 EMERGENCY UNBLINDING

Not appropriate as PIs and site staff will be unblinded to the allocation once baseline measures have been collected.

6. DATA MANAGEMENT

Information with regards to the study participants will be kept confidential and managed in accordance with UK data protection laws (meaning the Data Protection Act 1998 until 24 May 2018, and from 25 May 2018 the EU General Data Protection Regulation (GDPR) and applicable UK legislation that enshrines GDPR into UK law) and the Research Ethics Committee (REC) approval.

Data generated by the researchers will be stored and managed on a King's College London (KCL) SharePoint https://emckclac.sharepoint.com/sites/IOPPNaip. The primary function of SharePoint is the online file storage for secure collaborative working with the other researchers on the trial. Any work practice which involves storing, sharing, or archiving data and documents can be supported by SharePoint, helping to reduce reliance on local storage (e.g. hard-drives) and emails, whilst improving data retention practices, collaboration between individuals, compliance, and flexible working.

A "data risk model" for the data to be stored on SharePoint determine the Risk Profile Class III. With SharePoint files are stored in the cloud and protected by both Microsoft and King's College London IT. SharePoint is backed up daily. The research team external to KCL will be given access. Restricted access to research participants' personal data will be established to contact to follow up or send out reports of findings at the end of the trial. Names and contact details of consenting participants will be stored on a secure password protected folder on SharePoint user-based permissions for authorised researchers only to access these data, for the purposes of assisting in follow-ups during the trial. Personal data will be stored separately from research data on a secure password protected folder on SharePoint to allow researchers to arrange interviews during the study. With participant's consent, personal details will be stored for 10 years to allow future data linkage to determine longer term outcomes of ADVANCE-D. Names and contact details will also be used to send out a summary report at the end of the study if participants want one.

6.1 DATA MANAGEMENT

There are two datasets in the trial: the KCTU randomisation dataset and the KCTU eCRF system dataset. The CI will act as custodian for the trial data. The KCTU eCRF will have two databases – one for research

data and a therapy database. Personal identifier information needed to contact participants for follow up and for data linkage will not be held in the research database. Data will be transcribed from the source to the eCRF system, ideally within 7 days of the study visit. Participant year of birth and age will be entered into the systems. No more identifiable data will be entered into the eCRF system. Trial sites will maintain a master participant log linking participant identifiers to study numbers. No data will be entered unless a participant has signed a consent form to participate in the trial. More details of the data coding will be available in the statistical analysis plan.

Source data worksheets will be supplied to all recruiting sites by the co-ordinating centre for the region. These will be prepared after the database specification is finalised and database testing is complete. Participating Sites will complete source data location lists defining the source data at their site.

6.2 DATA SECURITY

The clinical trial will involve the sharing of deidentified data of subjects for research purposes, both during and after the trial for the purposes of monitoring and analysis. All applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including, where applicable, medical confidentiality) in relation to such trial subjects or their legal guardians.

Data Management Plans will be provided to the Trial Manager, detailing relevant security information about both data systems. Systems access will be strictly restricted through user-specific passwords to the authorised research team members. It is a legal requirement that passwords are not shared, and that only those authorised to access the system are allowed to do so. If new staff members join the study, a user-specific username and password must be requested and a request for access to be revoked must be requested when staff members leave the project.

All record linkage will require a data protection impact assessment to be completed and a data sharing agreement to be in place.

6.3 DATA QUALITY PROCESSES

At the database design stage, validations will be programmed into the systems to minimise data entry errors by querying the data entered in real time with sites. The CI team will undertake appropriate reviews of the entered data, in consultation with the project analyst, where appropriate for the purpose of data cleaning and will request amendments to the eCRF system data as required. No data will be amended independently of the study site responsible for entering the data.

No data can be amended in the randomisation system, however the CI or delegate (e.g., Trial Manager) may request King's Clinical Trials Unit to add notes against individual participant entries to clarify data entry errors. Any errors should be reported by site staff to the Trial Manager as soon as possible once they are detected. The trial manager will onward report errors to KCTU and retain records in the Trial Master File.

The KCTU will provide the Trial Manager with Data Management Plans for both the eCRF system and the randomisation system once the systems are made live. Those documents will be filed in the Trial Master File. A regular Data Management Report will be produced by KCTU and passed to the Trial Manager, who will raise Data Clarification Requests (DCRs) with sites in the eCRF system. The Trial Manager will raise DCR's. Study sites will periodically review raised DCR's and respond to the queries raised.

During site monitoring visits, the trial manager will raise any queries with sites via the Source Data Verification (SDV) function.

6.4 DATABASE LOCK

At the end of the trial, the site PI's will review all the data for each participant in the eCRF system and provide electronic sign-off to verify that all the data are complete and correct.

The trial manager will confirm all checks are complete and all monitors queries have been resolved prior to database lock after 12 month data collected. At this point, with the agreement of the senior statistician, all data can be formally locked.

When the final data extract is requested, KCTU will remove all data entry user access prior to data extract and will retain only 'monitor' access for site PI's and other relevant individuals. Upon request, KCTU will provide a copy of the final exported dataset to the CI in .csv format and the CI will onward distribute to sites as appropriate. Once sites have received copies of their individual datasets and confirmation of receipt has been received, the Trial Manager will request that all user access is removed from the eCRF system. A copy of the dataset will be stored in the Trial Master File at the end of the study.

7. ADVERSE EVENT MANAGEMENT AND REPORTING

An Adverse Event (AE) is any untoward medical occurrence in a participant taking part in a research study, including occurrences which do not necessarily have a causal relationship with the research. All adverse events will be recorded in the participant's notes, the study source data worksheets and the eCRF. SAE's will be additionally reported, within 24 hours of site becoming aware of the event, to KCTU. All SAEs will be reported immediately (and certainly no later than 24hrs) as per the instructions on the SAE report form.

The sponsor will report SAEs and/or suspected unexpected serious adverse reactions as required to regulatory authorities, investigators/institutions, and the ethics committees in compliance with all reporting requirements according to local regulations and good clinical practice.

- Serious Adverse Event (SAE): Any adverse event that:
    - results in death
    - is life-threatening
    - required hospitalisation or prolongation of existing hospitalisation
    - results in persistent or significant disability or incapacity
    - consists of a congenital anomaly or birth defect

The CI will be notified of any incidents as soon as possible. All incidents and resulting actions will be recorded in an incident report form and resulting actions will be emailed to the Trial Manager who will store these on SharePoint. No personal data will be recorded on the form. A cumulative review of all safety information by the DMC will be made on a six-monthly basis.

7.1 EVALUATING SAES OR ADVERSE INCIDENTS

7.1.1 ASSESSMENT OF INTENSITY

The Investigator will make an assessment of intensity for each SAE and adverse incident reported during the study. The assessment will be based on the Investigator's clinical judgement. The intensity of each SAE and adverse incident recorded in the eCRF should be assigned to one of the following categories:

- Mild; An event that is easily tolerated by the participant, 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, which is incapacitating and prevents normal everyday activities

7.1.2 ASSESSMENT OF CAUSALITY

The Investigator is obligated to assess the relationship between ADVANCE-D and the occurrence of each SAE or adverse incident. The Investigator will use clinical judgment to determine the relationship. Alternative causes, such as natural history of the underlying diseases, concomitant therapy, other risk factors, and the temporal relationship of the event to ADVANCE-D will be considered and investigated.

The causal relationship to the study product assessed by clinical lead should be assessed using the following classifications:

- Not Related:
- Unlikely:
- Possible:
- Likely:
- Definitely:

There may be situations when an SAE has occurred, and the Investigator has minimal information to include in the initial report to the Sponsor. However, it is very important that the Investigator always assesses causality for every event prior to transmission of the SAE form to the Sponsor. The Investigator may change his/her opinion of causality considering follow-up information, amending the SAE form accordingly. The causality assessment is one of the criteria used when determining regulatory reporting requirements.

7.1.3 FOLLOW-UP OF AES AND SAES

After the initial SAE or adverse incident report, the Investigator is required to proactively follow each participant and provide further information to the Sponsor on the participant's condition. All reports documented at a previous visit/contact and are designated as ongoing, will be reviewed at subsequent visits/contacts. All reports will be followed until resolution, until the condition stabilises, until the event is otherwise explained, or until the participant is lost to follow-up. Once resolved, the adverse event log will be updated. The Investigator will ensure that follow-up includes any supplemental investigations as may be indicated to elucidate the nature and/or causality of the SAE or adverse event. This may include consultation with other health, social or criminal justice professionals. New or updated information will be recorded on the originally completed SAE form, with all changes signed and dated by the Investigator. The updated SAE form should be resent to the Sponsor.

7.1.4 POST-STUDY SAES AND ADVERSE INCIDENTS (AI)

A post-study SAE or adverse incident is defined as any event that occurs outside the SAE/AI detection period. Investigators are not obligated to actively seek SAEs/ AIs in former study participants. However, if the Investigator learns of any SAE or AI, including death, at any time after a participants has been discharged from the study, and he/she considers the event reasonably related to the investigational product, the Investigator will promptly notify the Sponsor.

7.2 ADVERSE EVENT PROCESSING RESPONSIBILITIES

The Trial Manager will provide a blinded report to the DMC. The Trial Statistician will report relevant adverse events to the Data Monitoring Committee.

8. SAFEGUARDING

8.1 SAFEGUARDING PROTOCOL

If the participant discloses information which indicates a risk of death or serious harm, either to themselves or others (e.g. their children), researchers will break confidentiality and disclose this information to the duty worker at the probation/social work PDU/ JSWT where the male participant attends, the women's support worker or to relevant authorities. If the participant does not consent to the sharing of this information, it may

be necessary to break confidentiality. If participants do describe current/future intent to harm themselves or others, the researcher will be under obligation to ensure the incident is reported to the service staff (e.g. PP/ JSW or women's support worker) where the participant is receiving care, preferably with the participant present. Staff will then follow their usual safeguarding protocol under their duty of care. In addition, researchers and staff will report to the ADVANCE-D clinical lead to review safeguarding issues as they arise. Male participants will be interviewed in PDU/ JSWT. Female participants will be interviewed in treatment or support services, children centres or libraries. If a participant discloses current or future intent to harm themselves or others, the researcher will:

- Stop the interview and provide sympathetic and non-judgemental recognition of any emotional distress the participant is expressing.
- If safe to do so, inform the participant that what they have said will need to be shared with their PP/ JSW (if available) or duty worker, or the women's support worker at the service where the interview is taking place, or the relevant authorities. If it is possible and safe to do so, the participant should stay in the PDU/ JSWT or on the phone if online.
- Discuss the nature of the disclosure with the key/duty worker or women's support service, with the participant present.
- PP/ JSW or women's support service will follow their services' protocol on safeguarding and conduct a risk assessment.
- The Chief Investigator will be informed; and an adverse events form will be completed. The Ethics Committee will be informed if the adverse event is serious.
- All adverse events forms will be stored on SharePoint. Adverse events forms contain only participant ID numbers not participants' names.

To ensure that the women and their children are safe, staff from the PDU/ JSWT that their current or ex-partner is attending and the women's support worker will talk to each other on a regular basis to share information that relates to the women's safety and risk. This helps to ensure that work with perpetrators attending the intervention is informed by current understanding of survivors' experiences.

8.2 PARTICIPANT DISTRESS PROTOCOL

Talking about past or current violence in a relationship may make participants feel upset. If this happens, participants will be given the opportunity to speak to a PP/ JSW at the PDU/ JSWT or to women's support services (women only) about how they feel if they wish to, at that time or in the future. All participants will be provided with a range of local contact numbers and services that will be able to help after each research assessment/ interview. We have developed a distress protocol. If any participant (male or female) involved in the research becomes upset as a result of their involvement in the study, the researcher will:

- Stop the interview and provide sympathetic and non-judgemental recognition of any emotional distress the participant is expressing.
- Refer the participant back to their PP/ JSW; or women's support worker (if interviewed at a ISS).
- If a participant discloses an immediate intention to harm themselves or others, the *safeguarding protocol will be followed* (see under Limitations to Confidentiality above).
- The researcher will call the Chief Investigator (Dr Gail Gilchrist, KCL) on her mobile (or a designated deputy from the co-investigators if the Chief lnvestigator is on leave) to inform them of the event and the action taken.
- On returning to the office, an incident form describing the disclosure and the action taken will be completed by the researcher using only the participant ID. The Ethics Committee will be informed if the adverse event is serious.
- All incident forms will be stored on SharePoint. Incident forms contain only participant ID number not participant name.

Participants who have a court order preventing them or someone on their behalf from contacting a current or former partner (e.g. restraining order/bail restriction/exclusion order/non molestation order etc.) will be ineligible. This will be based on self-report by the perpetrator in the first instance (but confirmed where possible by his current or ex-partner and the substance use treatment service). The man's keyworker at the

substance use treatment service will make the final decision on whether the man is suitable to take part in the study.

8.3 INTERVIEWER SAFETY

The following measures will be taken to ensure interviewer safety:

- The majority of interviews will be conducted remotely (phone or video call).
- Researchers will always inform their line manager, the PI or the trial manager of their interview schedule and whereabouts, including informing them when the interview is complete.
- If interviews are being conducted in-person, researchers will only interview male participants in PDU/ JSWT.
- Similarly, researchers will interview female participants in rooms in services, women's support services, libraries or children's centres.
- Researchers will never interview participants in the participant's home.
- A work mobile number rather than a personal mobile number will be given to potential participants. While interviews will be conducted using Microsoft Teams, calls and text message reminders will be sent to participants throughout the trial.
- Debriefing/supervision for the researcher will be available from their line manager.
- Clinical debriefing will be provided to all researchers.
- When interviewing from home using video calling, researchers are advised to blur their background and ensure there is nothing that could identify where they live.

Telephone interviews will be scheduled within normal working times (where possible) when researchers have access to discussing safeguarding issues with staff at the substance use treatment service and/or the ADVANCE-D clinical lead. If interviews are conducted after office hours, researchers will ensure access to the ADVANCE-D clinical lead is organised.

9. ETHICS APPROVAL

This protocol and related documents will be submitted for review to the Integrated Research Application Service (IRAS Project ID 328020) and the study has been approved by His Majesty's Prison and Probation Service (HMPPS) National Research Committee (NRC Reference 2023-262) and by NHS West of Scotland Research Ethics Service (REC 24/WS/0068).

9.1 PROTOCOL AMENDMENTS AND VERSION CONTROL OF STUDY DOCUMENTS

The Trial Manager will be responsible for preparing and submitting protocol amendments to the ethics committees. The Trial Manager will be responsible for updating the ISRCTN register subsequent to relevant protocol amendments.

10. STATISTICAL METHODS

A senior statistician will oversee the analysis conducted by the trial statistician performed using Stata version 18 (or later). A detailed statistical analysis plan (SAP) drafted by a Statistician following KCTU Standard Operating Procedures blinded to any outcome data and agreed with the TSC prior to assessing outcome data will ensure the study is conducted according to CONSORT guidelines.[84]

The estimand framework will be described in full in the SAP and will cover the population, endpoint (ABI-Total Score), treatment condition (comparison of ADVANCE-D versus usual CJOM), intercurrent events (such as: suicide, all-cause mortality (non-suicide), returning to prison, and population summarise (adjusted mean difference). Rationale for the estimand is to describe the comparison between ADVANCE-D versus usual CJOM under routine practice.

10.1 PRIMARY OUTCOME

1. (Adapted) Abusive Behavior Inventory (ABI) total score at 12 months[67]

10.2 SECONDARY OUTCOMES

1. IPV perpetration/victimisation (eight domains)
   (Adapted) Revised Abusive Behavior Inventory (ABI-R) (women only);[69]
   (Adapted) Revised Controlling Behaviors Scale (CBS-R);[70]
   Technology facilitated abuse;[71]
   Locked in;
   Stalking/Harassment;
   Using Children against partner;[72]
   Feeling of safety;[72] (women only)
   (Adapted) Intimate Partner Violence Responsibility Attribution Scale (IPVRAS) (men only)[101]
2. Substance use
   Treatment Outcomes Profile (partial - total alcohol and drug free days in past 28 days);[73]
   Alcohol Use Disorder Identification Test (AUDIT) total score in the past 12 months at 12 months follow-up;[74]
   Drug Use Disorder Identification Test (DUDIT) total score in the past 12 months at 12 months follow-up[75]
3. Well-being
   Depression symptoms (PHQ-9);[76]
   Generalised Anxiety Disorder symptoms (GAD-7);[77]
   Primary Care PTSD (PC-PTSD-5);[78]
   Propensity for Abusiveness Scale (PAS) [anger subscale][79] (men only)
4. Self-control: Brief Self-Control Scale (BSCS)[80] (men only)
5. Children's well-being[72]
6. Quality of Life: EQ-5D-5L[81]

10.3 SAMPLE SIZE JUSTIFICATION

To detect an effect size of 0.4,[85,86] with 90% power and 5% significance (2-sided), a sample of 266 is required for an individually randomised trial. To inflate to a cluster RCT design, by randomising 26 PDU/JSWT with an average cluster size of 13.5 and an ICC=0.03,[87] the number analysed is inflated to 358. To account for 18% drop out of both offenders[37] and PDU/ JSWT we will plan to randomise 32 PDU/ JSWT (1:1) and enrol 450 offenders (14 per PDU/ JSWT).

Following the PHR programme decision to withdraw funding early, recruitment has ended and 34 men and 2 women were consented to the trial, of whom 30 men and 2 women completed a baseline interview.

10.4 STATISTICAL METHODS FOR PRIMARY AND SECONDARY OUTCOMES

10.4.1 STATISTICAL METHODS FOR PRIMARY OUTCOME

We will analyse the primary outcome using multi-level linear regression model, including assessments at 4 and 12 months to assess the difference in ADVANCE-D and control at 12-months (primary assessment time-point). Participants and PDU/JSWT will be fit as random effects, and pre-specified fixed effects for participant age, baseline IPV severity, and baseline ABI total score, and region. The adjusted mean difference (aMD) in the Abusive Behavior Inventory (ABI) total score between those from ADVANCE-D with CJOM compared to Usual CJOM will be presented with the associated two-sided confidence intervals (95% CI) and p-value, and intraclass correlation coefficient (ICC). The analysis will use the ITT population that will include all participants who were followed up at either the 4- or 12-month time-point. Pattern missingness will explore the missing data. A CACE will be developed as a sensitivity analysis to the primary analysis. Sensitivity analyses will be used for modelling the different intercurrent events. An additional sensitivity analysis will use the partner IPV data.

As recruitment has stopped early and is not expected to reach target, the study is likely to be underpowered to detect the originally specified target effect size. Therefore, the final analysis should be interpreted as exploratory. Specifics will be detailed in the Statistical Analysis Plan

10.4.2 Statistical methods for secondary outcomes

10.4.3 Continuous outcomes

Continuous secondary outcomes will be analysed similarly to the primary outcome

10.4.3.1 Binary outcomes

Logistic regression will be used to analyse secondary binary outcomes.

10.4.4 Adherence

To be defined in the Statistical Analysis Plan.

10.5 INTERIM ANALYSES (STATISTICAL)

No formal interim analyses.

10.6 INTERNAL PILOT

INTERNAL PILOT: 168 participants from 12 clusters will be randomised in the internal pilot.

PROGRESSION CRITERIA: A year after randomising the first PDU/JSWT, we will assess the feasibility of the trial with the following progression criteria: 12 PDU/JSWT randomised (>9 modifications needed, ≤ 8 stop trial); letters of support received from the remaining 24 PDU/JSWT (>19 modifications needed, ≤ 18 stop trial); 168 participants enrolled (>123 modifications needed, ≤ 122 stop trial); 80% followed-up at 4 months and 80% intervention adherence (>65% modifications needed, ≤ 64% stop trial). If all criteria are met, we will ask the Trial Steering Committee (TSC) to recommend progression to the trial.

Progression Criteria	Go	Revise strategy	Stop Trial
PDU/ JSWT randomised	≥ 12	9 to 11	≤ 8
PDU/ JSWT letters of support	≥ 24	19 to 23	≤ 18
Offenders enrolled	≥ 168	123 to 167	≤ 122
Adherence to the programme by offenders	≥ 80%	65 to 79%	≤ 64%
Follow up of offenders	≥ 80%	65 to 79%	≤ 64%

STOPPING CRITERIA: The trial may be prematurely discontinued by the Sponsor or CI on the basis of new safety information (e.g. that the ADVANCE-D Programme caused harm or greater risk) or for other reasons given by the Data Monitoring Committee (DMC) regulatory authority or ethics committee concerned. The trial may also be prematurely discontinued due to lack of recruitment or upon advice from the Trial Steering Committee (TSC), who will advise on whether to continue or discontinue the study and make a recommendation to the sponsor. If the study is prematurely discontinued, active participants will be informed, and no further participant data will be collected.

The DMC will provide advice to the TSC, who will advise the Sponsor in making the final decision on continuing or stopping the trial.

The PHR programme decided to withdraw funding early due to low recruitment to the internal pilot. A total of 34 men and 2 women were consented into the trial, of whom 30 men and 2 women completed a baseline interview.

10.7 METHODS FOR ADDITIONAL ANALYSES

SUBGROUP ANALYSIS: If sample size allows, we will carry out the following pre-specificed subgroup analyses: by IPV type, by severity of IPV, by whether remain with partner, baseline ABI total score, and baseline age.

RECORD LINKAGE: At 24 months with participants' consent, we will apply to the following information systems to conduct 'Names Enquiries' under general processing purposes to check whether our participants appear in their datasets.

- Convictions/arrests for IPV (Health and Justice Information Service; Police National Computer; Prison database)
- Death (Death Register)
- Health/Substance use treatment and prescriptions (National Drug Treatment and Monitoring Service (NDTMS)/ Hospital Episode Statistic (HES) (NHS Digital)/ Scottish Morbidity Record (SMR) (Public Health Scotland))

We will seek approval from relevant Public Benefit and Privacy Panels at the start of the project to avoid delays. This will require a data sharing agreement to be in place between each agency and the sponsor. We will consult with the Data Protection Officer and legal team at King's College London to complete the legal basis documentation. All record linkage will require a data protection impact assessment to be completed and participants' consent. With NDTMS for example, probabilistic sampling will be used for data linkage. The probabilistic linkage model allows for different fields to have higher discriminatory power than others (for example, if 2 records have the same sex, that is less discriminatory for linking purposes than the 2 records having the same set of first name and surname initials). For small data sets, it is possible to compare each record in one data set with each record in another data set, but the software allows us to incorporate 'blocking rules'. This helps us to narrow down the number of record pairs being compared and enhance the efficiency of the linkage. Blocking rules are a set of criteria that any 2 records must meet (for example, initials and dates of birth must match) before any other comparisons are done. In practice, we can develop multiple blocking rules (for example, initials and dates of birth must match or initials and postcodes must match). This approach reduces how many record pairs are compared by discarding implausible matches. For example, if there was one data set with 10,000 records and another with 100,000 records, there are potentially a billion comparisons that could be made. The blocking rules allow for most of this potential billion to be ignored.

Conducting the probabilistic linkage involves calculating 3 fundamental statistics.
1. The m-probability is the likelihood that 2 records match on a given field, if the records are a true match (the records belong to the same person).
2. The u-probability is the likelihood that 2 records match on a given field, if the records are a false match (the records belong to different people).
3. Lamda is the overall probability that any 2 randomly selected records are a match. We can then apply Bayes' formula to assign a single probability that each pair of records is related to the same individual across the 2 systems.

Splink is a Python package designed to implement the Fellegi-Sunter algorithm at scale. This is implemented on a secure partition of UKHSA's network (where NDTMS is also stored) with limited personnel access.

Other data linkage will be conducted using participants full name.

PROCESS EVALUATION: Context, fidelity, dose delivered, dose received, reach and recruitment for ADVANCE-D will be evaluated.[88] Longitudinal qualitative interviews (at 4- and 12- months) with 40 men receiving ADVANCE-D and their (ex)-partners and with staff post intervention will provide in-depth understanding of mechanisms of action, how context affects implementation, engagement, and behaviour change.

ANALYSIS OF RECORD LINKAGE: A long term follow-up will be carried out at 24-month via record linkage. This analysis will be described in the SAP and assess recidivism (criminal justice data), mortality (via Office for National Statistics), drug treatment (via NDTMS/SMR), prescription (NHS Digital/ Public Health Scotland) and hospital admission data (via HES/SMR). Mortality will be analysed with a multi-level logistic regression in a similar manner to the primary outcome.

ECONOMIC EVALUATION: A senior health economist will oversee the analysis conducted by the trial health economist. We will calculate the costs of delivery for the trial treatment using bottom-up costing. We will apply unit costs to the quantities of resource used in delivery and also report training costs separately. Health care utilisation data for contacts with NHS primary care, secondary care, personal social services (PSS), will be collected using a SUQ by self-report at each follow up. We will report the quantities of wider service use as derived from the service use questionnaires to demonstrate the wider services used by this population.
Study participants will also complete EQ-5D-5L at baseline and each follow up and we will calculate QALYs using the area under the curve.[91] We will use the tariff as recommended by NICE at the time of analysis to derive health related quality of life (HRQoL) utility scores from the EQ-5D-5L data. We will present QALYs for the treatment and usual care samples.

QUALITATIVE ANALYSIS: Standards for Reporting Qualitative Research (SRQR) will be followed when analysing the qualitative research.[95] Multiple perspectives data (i.e., from couples (dyads) and intervention staff) will be collected with brief semi-structured interviews at three points in a qualitative longitudinal process evaluation. Interviews will be audio recorded and transcribed verbatim. To expedite the management and analysis of longitudinal data, techniques from rapid data analysis[96] will involve researchers transferring summaries of responses and fieldnote reflections directly into a matrix that corresponds to the three semi-structured interview schedules for each group to be interviewed. Summarised data will be entered into frameworks composed of three excel spreadsheets (one sheet for each interview), in which each column is titled with the topic guide questions. Data for each time point interview and category of interviewee will then be merged into a single framework that will enable comparison, interpretation, and synthesis of longitudinal data. Codes will be developed and refined, and thematically analysed. Data for each time point interview and category of interviewee will then be merged into a single framework that will enable comparison, interpretation, and synthesis of longitudinal data. Data will be managed using Nvivo. The five steps of the framework approach will be used for analysis: familiarization; identifying a thematic framework; indexing; charting; and mapping and interpretation.[97] Coding will be attentive to contradictions and tensions within and between men's, (ex)-partners and practitioners' accounts of behaviour change. The *COREQ* (Consolidated criteria for Reporting Qualitative research) Checklist will be followed when analysing and reporting the qualitative research.[98] Interviews with men and (ex)-partners will be conducted by different researchers to avoid inadvertent information sharing.[99] Five researchers will code and analyse interviews, under the supervision of qualitative research co-applicant.

TRIANGULATION: The integration of qualitative and quantitative process data with study outcomes will help understand the study findings. The results from the process evaluation and changes in outcomes will be triangulated into an overall analysis and interpretation of key implementation lessons, presented as a strengths, weaknesses, opportunities, and threats (SWOT) analysis.[99] The Standards for Reporting Qualitative Research (SRQR)[95] will be followed when analysing the qualitative research. Focus groups and semi-structured interviews will be conducted by phone or video call, digitally recorded and transcribed verbatim. Data will be organized and coded using Nvivo. Multiple coders will enhance the rigour of the analysis.

10.8 METHODS TO HANDLE MISSING DATA

Patient completion rates will be monitored by being reported to the DMC and TSC. Missing data will be described in detail in the SAP and will include the following types: mising item level data (to be pro-rated); missing domain data; missing instrument level data; missing. Missing data will be explored using pattern mixture.

10.9 POPULATIONS UNDER INVESTIGATION

Men who have been convicted for IPV and received a community sentence.

10.10 METHODS TO HANDLE COMPLIANCE

Compliance will be defined in the SAP.

10.11 SENSITIVITY ANALYSIS

A CACE will be developed as a sensitivity analysis to the primary analysis. Sensitivity analyses will be used for modelling the different intercurrent events. An additional sensitivity analysis will use the partner IPV data. The SAP will detail all pre-planned subgroup analysis.

Subgroup analysis will include types of IPV perpetrated and whether the couple are living together.

10.12 PLANS TO GIVE ACCESS TO THE FULL PROTOCOL AND PARTICIPANT LEVEL-DATA

It is anticipated the full protocol and all results will be available as open access according to the rules of the funding bodies.

11. OVERSIGHT AND MONITORING

11.1 TRIAL MANAGEMENT GROUP (TMG)

The trial management group consisting of the research team will meet at least monthly. Changes in individuals filling these roles will not require a protocol update but will be documented in the TMG minutes.

Title	Name	Role
Chief Investigator – KCL	Gail Gilchrist	Chair
Senior Statistician – KCL	Ben Carter	Member
Trial Statistician - KCL	Meredith Martyn	Member
Trial Manager - KCL	Alexander Baker & Sean Hovland	Member
Data Manager – KCL	TBC	Member
Senior Health Economist - University of York	Steve Parrott	Member
Trial Health Economist - University of York	Jinshuo Li	Member
Process Evaluation Lead - KCL	Polly Radcliffe	Member
Research Associate - KCL	Emma Smith	Member
Local PI/ Co-CI/ Clinical Lead - University of Edinburgh	Liz Gilchrist	Member
Research Associate – University of Edinburgh	Lucia Dahlby	Member
Local PI – University of Manchester	David Gadd	Member
Research Associate - University of Manchester	Isobel Johnston	Member
Local PI – Cardiff University	Amanda Robinson	Member

Research Associate – Cardiff University	Sharmila Kumar	Member

11.2 TRIAL STEERING COMMITTEE (TSC)

The TSC will be composed of 7 independent members, 1 non-independent member and 2 observers. The TSC is an executive committee, reporting to the funder (NIHR) and the sponsor. The TSC is formally appointed by NIHR and members will receive individual letters from NIHR confirming their role. Independent members will be independent of the Sponsor organisations and of any recruiting study sites.

The trial may be prematurely discontinued by the Sponsor, Chief Investigator or Regulatory Authority on the basis of new safety information or for other reasons given by the Data Monitoring Committee/ Trial Steering Committee regulatory authority or ethics committee concerned. If the trial is prematurely discontinued, active participants will be informed, and no further participant data will be collected. The Competent Authority and Research Ethics Committee will be informed within 15 days of the early termination of the trial.

Name	Organisation	Email	Role/ Expertise
Simon Coulton	University of Kent	s.coulton@kent.ac.uk	Chair
Patty Chondros	University of Melbourne	p.chondros@unimelb.edu.au	Statistician
Jason Davies	University of Swansea	jason.davies@swansea.ac.uk	Psychologist
Colin McCowan	University of St Andrews	cm434@st-andrews.ac.uk	Data Linkage
Rachael Hunter	University College London	r.hunter@ucl.ac.uk	Health Economist
Kate O'Brien	Durham University	kate.o'brien@durham.ac.uk	Qualitative
Mhairi McGowan	VAWG Independent Consultant	Mhairi30@googlemail.com	PPI
Gail Gilchrist	KCL	gail.gilchrist@kcl.ac.uk	Non-independent member (Chief Investigator)
Liz Gilchrist	University of Edinburgh	Liz.Gilchrist@edinburgh.ac.uk	Observer (Clinical Lead)
Ben Carter	KCL	ben.carter@kcl.ac.uk	Observer (Trial Statistician)

Name	Organisation	Email	Role/ Expertise
Dorothy Newbury-Birch	Teesside University	d.newbury-birch@tees.ac.uk	Chair
Dawid Gondek	Swiss Centre of Expertise in the Social Sciences	dawid.gondek@fors.unil.ch	Statistician
Erica Bowen	Nottingham Trent University	erica.bowen@ntu.ac.uk	Forensic Psychologist
Mireia Jofre-Bonet	Office of Health Economics	mjofre-bonet@ohe.org	Health Economist
Alastair Roy	University of Central Lancashire	ANRoy@uclan.ac.uk	Qualitative
Kyla Kirkpatrick	Drive (Safe Lives)	Kyla.Kirkpatrick@safelives.org.uk	PPI

Gail Gilchrist	KCL	gail.gilchrist@kcl.ac.uk	Non-independent member (Chief Investigator)
Liz Gilchrist	University of Edinburgh	Liz.Gilchrist@ediburgh.ac.uk	Observer (Clinical Lead)
Ben Carter	KCL	ben.carter@kcl.ac.uk	Observer (Trial Statistician)

11.3 DATA MONITORING COMMITTEE (DMC)

The DMC will be composed of 6 independent members, 1 non-independent member and 2 observers. The DMC is an advisory committee, reporting to the Trial Steering Committee. The DMC is formally appointed by NIHR and members will receive individual letters from NIHR confirming their role. Members will be independent of the Sponsor organisations and of any recruiting study sites. The DMC will work to the DAMOCLES guidance. The DMC charter will be circulared around the DMC and TSC prior to the first meeting, and stored in the Trial Master File within King's College London SharePoint.

11.4 MONITORING

The Investigator(s) will permit trial-related monitoring, audits, REC review, and regulatory inspections by providing the Sponsor(s), Regulators and REC direct access to source data and other documents (e.g., participants' case sheets, blood test reports etc.).

12. MISCELLANEOUS

12.1 PLANS FOR INDEPENDENT AUDIT

There are no current plans to commission an independent audit study conduct.

12.2 DISSEMINATION PLANS

The protocol, 4, 12 and 24 month outcomes will be disseminated at national and international conferences and published in peer reviewed open-source substance use or domestic violence journals. Recruiting sites will be informed of the results and participants will be asked to register their interest for receiving the results at the start of the study.

- Interim) findings will be shared with the Learning Alliances, PPI panels, Action on Perpetrators Network, All Party Parliamentary Groups on IPV, Domestic Abuse Commissioner for England and Wales and their Practice and Partnerships regional leads, Alcohol and Drug Partnerships, Public Health Commissioners, Police and Crime Commissioners and the Advisory Council on the Misuse of Drugs. This will allow feedback on the interpretation of findings, facilitate wide dissemination and inform the UK Government's Perpetrator Strategy and Crime and Justice Task Force, the Welsh Government's Violence Against Women Sexual Assault and Domestic Violence (VAWDASV) National Strategy, and the Scottish Government's Equality and Gender Based Violence strategies.
- 11 Conference Presentations including at the Society for the Study of Addictions, the British Society of Criminology, National Association of Probation Officers, European Conference on Domestic Violence or European Society of Criminology
- At least 6 publications in high impact peer review journals that follow the ICMJE recommendations of authorship criteria
- 3 Policy Briefings to share the trial findings at 4-, 12- and 24-month follow-up
- 4 Press Releases – we will work with University Press Offices to release statements announcing the award of funding and the need for research and to share the trial findings

- Regular updates on the trial will be shared via twitter @ADVANCE_PRGM and the corresponding ADVANCE website https://www.kcl.ac.uk/research/advance and blog https://blogs.kcl.ac.uk/advance/.
- Four hybrid dissemination events with workshops will be held in London, Manchester, Cardiff, and Edinburgh at the end of the trial to disseminate findings widely.
- At the conclusion of the trial a video of key findings and messages will be produced (similar to the ADVANCE-D study https://vimeo.com/725588324/4c3ce80940)
- PPI panels will co-produce and disseminate summary findings for study participants and other PWLE/ PPI Reports using accessible formats such as infographics and videos.

12.2.1 IMPACT STRATEGY

We will develop an impact strategy that will be a standing item for both the TSC and PPI panels. From the outset of the project, we will make direct conduct, via email and social media with organisations working in the domestic abuse, offender resettlement, mental health, substance use and homelessness arenas and provide regular project updates to these organisations. We will work our PPI panels and university impact officers to ensure all academic outputs will be remade in more accessible formats (brief research notes, infographics, blogs, press releases, short films and social media) to ensure the research findings are as accessible as possible. At the close of the project, we will produce video-based resources to explain the project's design, findings and recommendations to accompany our written report. We will invite the many organisations who are interested in our findings to utilise these outputs as training resources to support their workforces. Findings will be disseminated nationally and internationally, through publications, presentations at conferences, regional dissemination events and workshops, bespoke policy briefings, press releases, accessible reports, videos, and social media.

12.3 END OF TRIAL

Database lock will be defined as the end of the trial.

12.4 CONFIDENTIALITY

When consent forms are signed, a copy will be provided to the participant, a copy will be filed in the Site File and a copy will be returned to the local research team and stored in a locked filing cabinet. Participant's year of birth and age will be entered into the study database, but no more identifying information will be entered. Within site, a Site File will be maintained by the local site PI. Participants will be fully identifiable within these files. When the study is complete, a data sharing dataset will be created from the raw data by the study analyst, which will not include any other identifiable data and study PIN will be altered so that individuals are not recognisable from the dataset.

Personal data will be collected and not entered into the study database for the purposes of data linkage: date of birth, full name, sex, postcode, local authority and NHS/CHI number if known.

The study will comply with the General Data Protection Regulations (GDPR).

Use of direct quotations

Participants will be informed that we would like to use direct quotations from their semi-structured interviews or focus group in any publications, presentations or reports arising from the trial. As a result, they will be asked to give consent to use quotations from their interviews or focus groups for these purposes. They will be informed that data will be anonymised (their names will not be used) to protect their anonymity. It is possible that even if an individual's name is removed from their responses, statements made by them might be enough to identify them, i.e. the individual might refer to a specific incident or mention members of their family or their location. Therefore, where participants describe such incidents or name individuals, partners, staff members etc. in the interview, direct quotes will ensure that these incidents are removed from the text and that names are replaced with [name of partner] [name of staff member] etc. Time has been allocated for researchers to ensure that transcripts are de-identified.

12.5 FUNDING

NIHR Public Health Programme [NIHR154546] (1 November 2023-31 October 2027.)

12.6 AVAILABILITY OF DATA AND MATERIALS

The NIHR strongly supports the sharing of data in the most appropriate way. The NIHR recognises that the sharing of research data must: protect the confidentiality and privacy of individuals; respect the terms of consent by individuals who are involved in research; be consistent with relevant legal, ethical and regulatory frameworks; and guard against unreasonable costs.

Consideration will be given to deposit trial data with The King's Open Research Data System (KORDS), a research data repository, providing long-term storage and access for datasets at project-end and supporting publications. https://www.kcl.ac.uk/researchsupport/assets/kords-userguide.pdf

KORDS uses the Figshare data repository platform, providing a simple, self-deposit way for researchers to upload and share their data, and a publicly accessible showcase of datasets from King's research. It supports Open Research, enabling researchers to make datasets discoverable, accessible and citeable. All datasets have a DOI and a structured metadata record so that they can be shared and cited when re-used. Depositing meets the policy requirements of funders for data retention and sharing, and the requirements of many publishers for access to datasets supporting publications.

Consent will be sought from participants for reuse of anonymous trial data. The trial and data managers will be responsible for archiving data and materials.

12.7 INSURANCE AND INDEMNITY

King's College London provides no fault liability insurance in the event of harm arising from the study design. UK NHS recruiting sites provide indemnity in the event of clinical negligence.

13. ARCHIVING

The trial and data managers will be responsible for archiving data and materials. At the end of the study, data will be backed up on a secure server at King's College London. Prior to back up, IT will be consulted about the format to save files to ensure that they can still be read/processed in 10 years' time. Paper records (that contain no personal data, only an ID number) will be archived with King's College London. All data will be destroyed 10 years after the study findings have been published. Destruction is the responsibility of King's College London and the destruction date will be recorded when the data is stored/archived.

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