ADVANCE-D Programme for men convicted of domestic abuse serving a community sentence

Submission date 01/05/2024	Recruitment status Recruiting	[X] Prospectively registered [_] Protocol
Registration date 02/05/2024	Overall study status Ongoing	 Statistical analysis plan Results
Last Edited 03/12/2024	Condition category Mental and Behavioural Disorders	 Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

40% of men convicted for domestic abuse have problems with alcohol or drugs. Despite this, official group work programmes are unavailable for these men in probation services. Domestic abuse costs the UK £66 billion each year. These costs could be reduced if suitable domestic abuse programmes were provided during probation.

Who can participate?

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

What does the study involve?

32 areas in the UK will be allocated by chance to provide either ADVANCE-D (16 areas) or their usual services (16 areas) to men on probation or parole for domestic abuse. 450 men will be invited to take part in the study within two weeks of being mandated by the court to a community sentence for domestic abuse. All support will be provided by probation staff in England and Wales, and by criminal justice social workers in Scotland. Men and women will be interviewed separately by researchers at the start of the study, and 4 and 12 months later. 4 and 12 months after men are allocated to ADVANCE-D or usual probation services, their use of domestic abuse will be compared. Men in both groups will also be asked about their substance use, health and service use. The men's current or ex-female partners will also be about their own health and service use and about any domestic abuse from their partner. Consent will be obtained to check participants' health and domestic abuse status over the long term. This will be done by tracking these men and women in health, social services, police and criminal justice data 2 years after the study starts. This will allow the research team to work out what works best to reduce domestic abuse - ADVANCE-D or the usual support offered by probation.

What are the possible benefits and risks of participating?

The study will help to show whether the new intervention helps men who use substances reduce their abusive and violent behaviour towards their female partners. It is hoped that if this happens, it will improve the well-being of their partners and children. To ensure that the women and their children are safe, staff from the substance use treatment service and the women's support service worker will talk to each other regularly to share information that relates to the women's safety and risk. Participating in the study could improve relationships and improve the well-being of women and children in the future. The feedback received from both men and their current or ex-female partners will help to show whether the intervention and the study can be done. All participants are given the opportunity to get support for their relationship and are provided with a range of national and local contact numbers and services that will be able to help.

Where is the study run from? King's College London (UK), University of Edinburgh (UK), University of Manchester (UK), Cardiff University (UK)

When is the study starting and how long is it expected to run for? November 2023 to October 2027

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact? Prof. Gail Gilchrist Gail.Gilchrist@kcl.ac.uk

Study website https://www.kcl.ac.uk/research/advance

Contact information

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 328020

ClinicalTrials.gov number Nil known

Secondary identifying numbers CPMS 61731, IRAS 328020, NIHR154546

Study information

Scientific Title

A UK multi-centre cluster randomised control trial, with an 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

Acronym

ADVANCE-D

Study objectives

To conduct a UK multi-centre cluster-randomised controlled trial, with an 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.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 20/03/2024, His Majesty's Prison and Probation Services (HMPPS) National Research Committee (102 Petty France, London, SW1H 9AJ, United Kingdom; -; National.Research@justice. gov.uk), ref: 2023-262 2. Approved 18/07/2024, NHS West of Scotland Research Ethics Service (Ground Floor Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 141 314 0212; WoSREC1@ggc.scot.nhs.uk), ref: 24/WS/0068

Study design

Multicentre cluster-randomized controlled trial with internal pilot

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s)

Built environment/local authority, Internet/virtual, Medical and other records, Telephone

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Reduce intimate partner violence (IPV) for men convicted of IPV who misuse substances

Interventions

Current interventions as of 16/10/2024:

32 probation delivery units (PDU)/Justice Social Work Teams (JSWT) will be randomised (1:1) to deliver ADVANCE-D or usual community justice offender management (CJOM). The PDU/JSWT and researchers will be blinded to (not know which) treatment allocation until all 14 men from their cluster have been recruited and baselined and researchers have recruited and baselined the (ex)-partners. 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. It highlights individual risks for intimate partner violence (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]; and 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.

32 probation delivery units (PDU)/Justice Social Work Teams (JSWT) will be randomised (1:1) to deliver ADVANCE-D or usual community justice offender management (CJOM) using an online randomisation system divided (stratified) by probation region/JSW area, managed by King's Clinical Trials Unit (KCTU). The PDU/JSWT and researchers will be blinded to (not know which) treatment allocation until all 14 men from their cluster have been recruited and baselined and researchers have recruited and baselined the (ex)partners. 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. It highlights individual risks for intimate partner violence (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]: and 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.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 30/07/2024:

Intimate partner violence (IPV) perpetration reduction for men who misuse substances subject to probation/CJSW supervision measured using the (Adapted) Abusive Behavior Inventory (ABI) in the past 4 months at 12 months post-baseline

Previous primary outcome measure:

Intimate partner violence (IPV) perpetration reduction for men who misuse substances subject to probation/CJSW supervision measured using the Abusive Behavior Inventory (ABI) in the past 4 months at 12 months post-baseline

Secondary outcome measures

Current secondary outcome measures as of 16/10/2024:

1. Intimate partner violence (IPV) victimisation, experienced by partners, measured using the (Adapted) Revised Abusive Behavior Inventory (ABI-R) (women only) at 4 and 12 months postbaseline

2. 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.

3. Implementation, mechanisms of impact, and contextual factors of delivering ADVANCE-D measured using a nested process evaluation with participants and practitioners at 4 and 12 months post-baseline

4. Children's well-being as reported by men and their (ex)-partners at 4 and 12 months postbaseline.

5. Comparison of costs and outcomes of ADVANCE-D with CJOM over and above usual CJOM using cost-consequences analysis at 4 and 12 months post-baseline

6. Health, social services, and criminal justice outcomes between men offered ADVANCE-D with CJOM or usual CJOM and their (ex)-partners measured using data linkage of participants to routine databases and electronic records at 24 months post-baseline

Previous secondary outcome measures as of 30/07/2024:

2. Other IPV outcomes (Adapted) Revised Controlling Behaviors Scale (CBS-R), technology facilitated abuse, stalking/harassment, locked in and using children against partner), well-being (PHQ-9; GAD-7; Primary Care PTSD Screen for DSM-5 (PC-PTSD-5); Propensity for Abusiveness Scale [anger subscale] (men only); self control (Brief Self-Control Scale (men only); children's well-being; substance use (Treatment Outcomes Profile (partial)) and quality of life (EQ-5D-5L) for participants and their current or ex-partners.

3. Implementation, mechanisms of impact, and contextual factors of delivering ADVANCE-D measured using a nested process evaluation with participants and practitioners at 4 and 12 months post-baseline

4. Children's well-being as reported by men and their (ex)-partners at 4 and 12 months postbaseline.

5. Comparison of costs and outcomes of ADVANCE-D over and above usual CJOM using costconsequences analysis at 4 and 12 months post-baseline

6. Health, social services, and criminal justice outcomes between men offered ADVANCE-D or usual CJOM and their (ex)-partners measured using data linkage of participants to routine databases and electronic records at 24 months post-baseline

Previous secondary outcome measures:

^{1.} Intimate partner violence (IPV) victimisation, experienced by partners, measured using the (Adapted) Revised Abusive Behavior Inventory (ABI-R) (women only) at 4 and 12 months postbaseline

^{1.} Intimate partner violence (IPV) victimisation, experienced by partners, measured using the Revised Abusive Behavior Inventory (ABI-R) (women only) at 4 and 12 months post-baseline 2. Other IPV outcomes (Controlling Behaviours Scale (partial), technology-facilitated abuse, locked in, stalking and using children against partner), well-being (PHQ-9; GAD-7; PC-PTSD-5; PAS [anger subscale] (men only)); BSCS (men only); substance use (TOPS) and quality of life (EQ-5D-5L) for participants and their current or ex-partners at 4 and 12-months post-baseline 3. Implementation, mechanisms of impact, and contextual factors of delivering ADVANCE-D measured using a nested process evaluation with participants and practitioners at 4 and 12 months post-baseline

^{4.} Comparison of costs and outcomes of ADVANCE-D over and above usual CJOM using costconsequences analysis at 4 and 12 months post-baseline

^{5.} Health, social services, and criminal justice outcomes between men offered ADVANCE-D or

usual CJOM and their (ex)-partners measured using data linkage of participants to routine databases and electronic records at 24 months post-baseline

Overall study start date 01/11/2023

Completion date 31/10/2027

Eligibility

Key inclusion criteria

Current inclusion criteria as of 03/12/2024:

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. Able to provide contact details for (ex)-partner – victim of index crime will be invited to participate in the trial.

4. Able to communicate in and understand English for the purpose of research interviews.

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.

Previous inclusion criteria as of 16/10/2024:

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 and alcohol linked to criminogenic need recorded on OASys (England) or LS/CMI (Scotland).

3. Able to provide contact details for (ex)-partner – victim of index crime will be invited to participate in the trial.

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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.

Previous inclusion criteria as of 30/07/2024:

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 and alcohol linked to criminogenic need recorded on OASys (England) or LSCMI (Scotland)

3. Alcohol and/or drug use not daily or almost daily in the substance use screen (England) or SARA V3 in Scotland

4. Not suitable for existing probation-based perpetrator interventions

5. Not involved with the private family law court

6. Able to provide contact details for (ex)-partner – victim of index crime will be invited to participate in the trial

7. Able to communicate in and understand English for the purpose of research interviews. ADVANCE-D is available in Polish, Romanian, Urdu, or Panjabi to allow men to complete it in their first language.

8. Digital literacy assessed using the eHealth Literacy Scale (eHEALS) (ineligible if answers 'strongly disagree' to all 8 items)

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. ADVANCE-D is available in Polish, Romanian, Urdu, or Panjabi to allow men to complete it in their first language.

Previous 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. Alcohol or drug misuse assessed via the Spousal Assault Risk Assessment (SARA) and the Offender Assessment System completed by Probation Practitioners (PP) or the Level Service /Case Management Inventory (LSCMI) completed by JSW

3. Not suitable for an existing probation perpetrator intervention

4. Able to provide contact details for (ex)-partner

5. Able to communicate in and understand English,Polish,Romanian,Urdu,or Panjabi (languages that the ADVANCE-D Programme is available in)

6. Digitally literate - digital literacy assessed using the eHealth Literacy Scale (eHEALS)

For current or ex-partners (women):

1. Adult (18+) women who have a current or ex-partner participating in the trial

2. Lives in the UK

3. Able to communicate in and understand English,Polish,Romanian,Urdu,or Panjabi (languages that the ADVANCE-D Programme is available in)

Participant type(s)

Patient

Age group Adult

Lower age limit

18 Years

Sex Both

Target number of participants

Planned Sample Size: 450; UK Sample Size: 450

Key exclusion criteria

Current exclusion criteria as of 02/12/2024:

For participants (men):

- 1. Suitable for or attending an existing probation-based perpetrator intervention.
- 2. Man involved with the private family law court.
- 3. History of sex offences against children.

4. Answers 'strongly disagree' to all 8 items on the eHealth Literacy Scale (eHEALS).

5. 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).

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 partner at risk. These will be considered on a case-by-case basis by the research team and the clinical team e.g. where both participants share a mobile phone number, the female participant has a court case pending for IPV or there is a child protection hearing pending.

3. Female partner discloses that there is an order preventing her male current or ex-partner from contacting her (i.e. contradicting what he has said in his screening interview). In such cases the man would not be withdrawn, unless the clinical team felt there was an increased risk to either party in his continuing in the study.

Previous exclusion criteria as of 16/10/2024:

For participants (men):

1. Suitable for or attending an existing probation-based perpetrator intervention.

- 2. Man involved with the private family law court.
- 3. History of sex offences against children.

4. Answers 'strongly disagree' to all 8 items on the eHealth Literacy Scale (eHEALS). 5. 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).

For current or ex-partners (women):

Current order preventing her from contacting current or ex male partner recruited to the trial.
 Other safety concerns that may put the male partner at risk. These will be considered on a case-by-case basis by the research team and the clinical team e.g. where both participants share

a mobile phone number, the female participant has a court case pending for IPV or there is a child protection hearing pending.

3. Female partner discloses that there is an order preventing her male current or ex-partner from contacting her (i.e. contradicting what he has said in his screening interview). In such cases the man would not be withdrawn, unless the clinical team felt there was an increased risk to either party in his continuing in the study.

Original 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. History of sex offences against children

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 partner at risk. These will be considered on a case-by-case basis by the research team and the clinical team e.g. where both participants share a mobile phone number, the female participant has a court case pending for IPV or there is a child protection hearing pending.

3. Female partner discloses that there is an order preventing her male current or ex-partner from contacting her (i.e. contradicting what he has said in his screening interview). In such cases the man would not be withdrawn, unless the clinical team felt there was an increased risk to either party in his continuing in the study.

Date of first enrolment

02/12/2024

Date of final enrolment 31/10/2026

Locations

Countries of recruitment United Kingdom

Study participating centre Probation Service Greater Manchester Redfern Building, Sadler's Yard, 30 Hanover Street Manchester United Kingdom M4 4AH

Study participating centre

Probation Service North West

Albert Edward House, The Pavilions, Port Way Preston United Kingdom PR2 2YB

Study participating centre The City of Edinburgh

Justice Social Work Department, Grindlay Street Court Edinburgh United Kingdom EH3 9AR

Sponsor information

Organisation King's College London

Sponsor details Room 8.11, 8th Floor Melbourne House, 44-46 Aldwych London England United Kingdom WC2B 4LL +44 (0)2078487306 vpri@kcl.ac.uk

Sponsor type University/education

Website https://www.kcl.ac.uk/

ROR https://ror.org/0220mzb33

Funder(s)

Funder type Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type Government organisation

Funding Body Subtype

National government

Location United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/10/2028

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality. Documents, such as the study protocol, and statistical analysis plan, can be requested from the CI. Prof. Gail Gilchrist Gail.Gilchrist@kcl.ac.uk.

IPD sharing plan summary

Not expected to be made available