

# Online intervention to improve intimate relationships for men in substance use treatment

<b>Submission date</b> 24/02/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/10/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 04/10/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Intimate partner abuse (IPA) includes physical, sexual, psychological and financial abuse and/or controlling behaviours by a current/ex-partner. IPA impacts negatively on victims' health. Men who use substances are more likely to be abusive towards their partners than men who do not. This study will recruit 60 men from substance use treatment in England, Wales and Scotland who have been abusive towards a female current or ex-partner in the past year. Men will receive the ADVANCE online intervention which aims to improve relationships and substance use treatment. Before the coronavirus pandemic, the ADVANCE intervention was delivered to groups of men in substance use treatment. We have adapted the ADVANCE intervention to be delivered by phone and online. The adapted intervention includes telephone individual support and coaching, website sessions and video group sessions. The study aims to find out whether it is feasible to adapt and deliver the ADVANCE intervention online and to find out whether men find the intervention acceptable, attend sessions, and stay in the study.

### Who can participate?

Men who have perpetrated abusive or violent behaviour towards a current or former female partner in the last 12 months.

### What does the study involve?

Men will receive the 14-week ADVANCE intervention, along with substance use treatment as usual. A booster session one month after the intervention ends will also be offered. Their current /ex-partners are offered support for IPA and are invited to take part in the study by providing information about their partner's behaviour and their own well-being. The man's keyworker and the women's support worker share information that relates to women's safety and risk. Women are updated about their current/ex-partner's overall progress in the intervention. Data on IPA, substance use, emotional well-being, quality of life and service use are collected from both men and women at the start and end of the intervention.

### What are the possible benefits and risks of participating?

The study will help to show whether it is feasible to deliver the ADVANCE online intervention,

and whether men in substance use treatment find it acceptable. To ensure that 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 on a regular basis to share information that relates to the women's safety and risk. Participating in the study could improve men's relationships with their current or ex-female partner and the wellbeing of women and children in the future. 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)

When is the study starting and how long is it expected to run for?  
October 2020 to September 2021

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

Who is the main contact?  
Prof. Gail Gilchrist  
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## Contact information

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

271242

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

IRAS 271242, CPMS 44092

## **Study information**

### **Scientific Title**

Feasibility of adapting and delivering the ADVANCE technology-enabled intervention to reduce intimate partner abuse by men receiving substance use treatment

### **Acronym**

ADVANCE-D

### **Study objectives**

To explore the feasibility and acceptability of adapting the ADVANCE intervention for technology-enabled delivery to reduce intimate partner abuse (IPA) by men in treatment for substance use.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 25/01/2021, Yorkshire & The Humber - Sheffield Research Ethics Committee (Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)207 104 8364, +44 (0)207 104 8222, +44 (0)207 104 8131; sheffield.rec@hra.nhs.uk), REC ref: 19/YH/0431

### **Study design**

Feasibility and acceptability study with nested process evaluation

### **Primary study design**

Interventional

### **Study type(s)**

## Treatment

### Health condition(s) or problem(s) studied

Substance use and intimate partner abuse

### Interventions

All men will receive substance use treatment as usual plus the ADVANCE digital intervention. The ADVANCE digital intervention consists of: an individual goal setting session; a group video session on the preparation for group; 12 self-completion website sessions; 12 individual telephone coaching sessions; 6 group video sessions and a group video booster session

### Intervention Type

Behavioural

### Primary outcome(s)

Feasibility parameters:

The feasibility of adapting the ADVANCE group perpetrator intervention for technology-enabled delivery to men in substance use treatment will be assessed by:

1. Number of men eligible to participate/number of men screened (eligibility rates)
2. Number of men consenting to take part in the study/number of eligible men at screening (recruitment rates men)
3. Number of recruited men completing at least one session of the intervention by the end of the 14-week intervention/number of recruited men (uptake of intervention rates men)
4. Number of current or ex- female partners recruited/number of men recruited (recruitment rates women)
5. Number of women taking up the offer of support from a women's integrated support service by the end of the 14-week intervention/total number of female partners contacted by integrated support service (uptake of support women)
6. Number of recruited women viewing at least one session of the intervention and safety messages by the end of the 14-week intervention/number of recruited women (uptake of intervention rates women)

Acceptability parameters:

The acceptability of the technology-enabled ADVANCE intervention to end-users and substance use treatment staff will be assessed at the end of the 14-week intervention by:

1. Number of sessions of the technology-enabled intervention attended (out of a possible goal setting session, 12 website sessions, 12 telephone coaching sessions and 7 video group sessions/ total number of sessions offered (intervention attendance/completion rates for male and female participants)
2. Number of sessions with the integrated support service during the 14-week intervention/ total number of sessions offered (attendance with integrated support service worker rates for female participants)
3. Men's experience of using the website sessions assessed using a rating scale developed for the study at the end of each of the 12 website sessions. Men will also be asked to rate how they are feeling by selecting an emoji at the start and at the end of each of the 12 website sessions
4. Men's experience of using the technology-enabled intervention and any behaviour change, assessed with up to four brief individual qualitative interviews during the 14-week intervention
5. Women's experience of using the technology-enabled intervention and safety messages and any behaviour change, assessed with up to four brief individual qualitative interviews during the 14-week intervention
6. Intervention delivery staff's experience of delivering the intervention, assessed with up to

- four individual brief qualitative interviews or focus groups during the 14-week intervention
7. Number of men interviewed at the end of the intervention/number of men recruited (follow-up rate men)
  8. Number of women interviewed at the end of the intervention/number of women recruited (follow-up rate women)
  9. Number of serious adverse events (e.g., hospitalisation and self-harm) during the 14-week study/number of participants recruited (adverse events rate)

#### Engagement

1. Engagement with each of the 12 website sessions for men and women (how male and female participants used each of the 12 website sessions including frequency/times/duration of login, number of tasks completed) measured using Google Analytics
2. The number out of a possible 12 telephone coaching sessions attended by men will be recorded
3. The number of telephone support sessions attended during the 14-week intervention by female partners will be recorded
4. Men's perception of therapeutic alliance assessed using the Working Alliance Inventory – applied to Virtual and Augmented Reality (WAI-VAR) and the California Psychotherapy Alliance Scale- Short Form at 4 months post-baseline

#### Key secondary outcome(s)

Evaluated for men at 4 post-baseline:

1. Intimate partner abuse (IPA) perpetration assessed in the past 4 months at baseline and 4 months post-baseline using:
  - 1.1. Abusive Behavior Inventory (ABI) - partner form (perpetration) in the previous 4 months
  - 1.2. Controlling Behaviours Scale (partial) in the past 4 months
  - 1.3. Use of social media, stalking, locked in and using children against partner in the past 4 months
2. Substance use measured at baseline and 4 months post men's baseline using:
  - 2.1. Number of alcohol-free days in past 28 days assessed using the Treatment Outcome Profile
  - 2.2. Number of drug-free days in past 28 days assessed using the Treatment Outcome Profile
3. Mental well-being measured using:
  - 3.1. Depressive symptoms in the past 2 weeks assessed using the PHQ-9 at baseline and 4 months post men's baseline
  - 3.2. Anxiety symptoms in the past 2 weeks assessed using the GAD-7 at baseline and 4 months post men's baseline
  - 3.3. PTSD symptoms in the past month assessed using the Primary Care PTSD Screen at baseline and 4 months post men's baseline
  - 3.4. Propensity for male abusiveness of a female partner in intimate relationships, measured using the Propensity for Abusiveness Scale [anger subscale] at baseline and 4 months post baseline
4. Self-control measured using the Brief Self-Control Scale at baseline and 4 months post baseline
5. Quality of life measured using the EQ-5D-3L at baseline and 4 months post baseline
6. Capability measured using the ICECAP-A at baseline and 4 months post baseline
7. Service use and medication in the past 4 months, measured at baseline and 4 months post baseline

To investigate the impact of the ADVANCE intervention in a follow-up study, the following measures will be collected at follow-up from female current or ex-partners at 4 months post-baseline of male current or ex-partner:

1. IPA assessed in the past 4 months at baseline and 4 months post men's baseline using:

- 1.1. IPA victimisation measured using the Revised Abusive Behavior Inventory (ABI-R) in the previous 4 months
- 1.2. Controlling Behaviours Scale (partial) in the past 4 months
- 1.3. Use of social media, stalking, locked in, and using children against partner in the past 4 months
2. Substance use measured at baseline and 4 months post men's baseline using:
  - 2.1. Number of alcohol-free days in past 28 days using the Treatment Outcome Profile
  - 2.2. Number of drug-free days in the past 28 days using the Treatment Outcome Profile
3. Mental well-being measured using:
  - 3.1. Depressive symptoms in the past 2 weeks assessed using the PHQ-9 at baseline and 4 months post men's baseline
  - 3.2. Anxiety symptoms in the past 2 weeks assessed using the GAD-7 at baseline and 4 months post men's baseline
  - 3.3. PTSD symptoms in the past month assessed using the Primary Care PTSD Screen at baseline and 4 months post men's baseline
4. Quality of life measured using the EQ-5D-3L at baseline and 4 months post baseline
5. Capability measured using the ICECAP-A at baseline and 4 months post baseline
6. The self-reported use of healthcare, social and civil services, and legal and justice system contacts in the past 4 months, assessed at baseline and 4 months post men's baseline for men and women. Medications prescribed by a doctor or health professional in the past 4 months recorded at baseline and 4 months post men's baseline for men and women

### **Completion date**

30/09/2021

## **Eligibility**

### **Key inclusion criteria**

Inclusion criteria - men receiving community substance use treatment:

1. Male participant has perpetrated abusive or violent behaviour towards a current or ex female partner in the last 12 months
2. Contact with current or ex female partner at least once in the past 4 months – in person, or by phone/text/email/social media
3. Agrees to provide contact details of current and/or ex female (and male partner if bisexual) partner for safeguarding reasons
4. Ability to understand and communicate in English
5. Able to attend the intervention (digital literacy ability to participate, technology and data can be supplied by the research team)
6. Substance use treatment service assesses as suitable to participate in the trial

Inclusion criteria – current or ex-female partners of men in the study:

1. Current or ex-partner participating in the study
2. Aged 18 years or older
3. Lives in the UK
4. Ability to understand and communicate in English

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Exclusion criteria - men receiving community substance use treatment:

1. Men reporting current order preventing him from contacting current or ex female partner
2. Currently attending an intervention for IPA
3. Previously attended the ADVANCE intervention for IPA
4. Participant is not/ no longer attending the substance use treatment service
5. Other safety concerns that may put the female partner at risk. These will be considered on a case by case basis by the research team and the substance use treatment service e.g. where both participants share a mobile phone number, the male participant has a court case pending for IPA or there is a child protection hearing pending.

Exclusion criteria – current or ex-female partners of men in the study:

1. Current order preventing her from contacting current or ex male partner recruited to the study
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 IPA 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.

Male partners and non-English speaking female partners will not be eligible to take part in the study but will be offered support for their IPA victimisation.

If a female partner is excluded because she has a current order preventing her from contacting her current or ex male partner – her current or ex male partner will remain in the study.

Selection for suitability will be conducted by substance use service/clinical staff and based on:

1. Meeting the inclusion criteria
2. Not meeting any exclusion criteria
3. Based on specific IPV risk assessment screening (Brief Spousal Assault Form for the Evaluation of Risk (B-SAFER) for male perpetrators

**Date of first enrolment**

15/04/2021

**Date of final enrolment**

31/07/2021

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

### King's College London

Institute of Psychiatry, Psychology and Neuroscience National Addiction Centre

4 Windsor Walk

London

United Kingdom

SE5 8BB

## Study participating centre

### University of Bristol

Centre for Academic Primary Care Population Health Sciences

Bristol Medical School

Canynges Hall

39 Whatley Road

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United Kingdom

BS8 2PS

## Study participating centre

### University of Edinburgh

School of Health in Social Sciences

8-9 Hope Park Square

Edinburgh

United Kingdom

8HQ 9NW

# Sponsor information

## Organisation

King's College London

## ROR

<https://ror.org/0220mzb33>

## Organisation

South London and Maudsley NHS Foundation Trust

## ROR

<https://ror.org/015803449>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health 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

### 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.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		30/07/2022	01/08/2022	Yes	No
<a href="#">Plain English results</a>			04/10/2022	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes