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

Submission date
24/02/2021

Recruitment status
No longer recruiting

Registration date
06/10/2021

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271242

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Condition
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 measure
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 websites 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

Secondary outcome measures

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

Overall study start date
01/10/2020

Overall study end date
30/09/2021

Eligibility

Participant 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60 men who have perpetrated IPA in the past 12 months measured by the Abusive Behavior Inventory (ABI) - partner form (perpetration) and their current or ex female partners

Participant 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

Recruitment start date
15/04/2021

Recruitment end date
31/07/2021

Locations

Countries of recruitment
England

United Kingdom

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
Canynge Hall
39 Whatley Road
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United Kingdom
BS8 2PS

Study participating centre

University of Edinburgh
School of Health in Social Sciences
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8HQ 9NW

Sponsor information

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Sponsor type
University/education

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

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

Sponsor details
R&D Department Room W1.08 Institute of Psychiatry
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Sponsor type
Hospital/treatment centre

Website
https://www.slam.nhs.uk/

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

Publication and dissemination plan
Additional documents (such as study protocol, statistical analysis plan) can be requested from the CI. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
31/01/2022

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?
Protocol article		30/07/2022	01/08/2022	Yes	No
Plain English results			04/10/2022	No	Yes