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Group intervention to reduce intimate partner abuse by men in substance use treatment

Submission date
15/01/2020

Recruitment status
Stopped

Registration date
20/01/2020

Overall study status
Stopped

Last Edited
06/10/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 be abusive towards their partners than men who do not. This study will recruit 378 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 be recruited by chance to the ADVANCE group intervention which aims to improve relationships and substance use treatment. The aims are to find out whether this new intervention is any better than usual substance use treatment with a keyworker, to compare the costs, to explore whether the intervention can be delivered in substance use treatment, 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?
Male participants are randomly allocated to the intervention group or the control group. The intervention group attend 13 weekly 2-hour group sessions, along with substance use treatment as usual. The control group receive substance use treatment as usual (e.g., sessions with keyworker, group attendance and/or opiate therapy). The men's' 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 the ADVANCE intervention helps men who use substances reduce their abusive and violent behaviour towards female partners. It is hoped that if this happens, this will improve the wellbeing of their partners and children. 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 relationships 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?
February 2020 to September 2021

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

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

Study website
https://www.kcl.ac.uk/ioppn/depts/addictions/research/drugs/advance

Contact information

Type(s)
Scientific

Contact name
Prof Gail Gilchrist

ORCID ID
http://orcid.org/0000-0002-5616-6283

Contact details
National Addictions Centre
King's College London
4 Windsor Walk
London
United Kingdom
SE5 8BB
+44 (0)7708255859
Gail.Gilchrist@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

271242

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RP-PG-1214-20009, IRAS 271242, CPMS 44092

Study information

Scientific Title
A randomised controlled trial of the ADVANCE integrated group intervention to reduce intimate partner abuse perpetration by men receiving treatment for substance use, compared to substance use treatment as usual

Acronym
ADVANCE

Study objectives
The ADVANCE integrated intervention to reduce intimate partner abuse (IPA) by men in treatment for substance use + substance use treatment as usual (TAU) will be more effective and cost effective than substance use treatment as usual only

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/02/2020, Yorkshire and the Humber – Sheffield Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8208; nrescommittee.yorkandhumber-sheffield@nhs.net), ref: 19/YH/0431

Study design
Interventional multi-centre parallel group individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Intimate partner abuse and substance use

Interventions
Intervention condition:
The group intervention consists of 13 x 2-h group sessions + substance use treatment as usual. This includes a pre-group individual motivational and preparation session followed by 12 core group sessions.

Control condition:
Substance use treatment as usual (TAU) will be permitted for both treatment arms. This is usually individual sessions with a keyworker or attendance at groups. It may also include opiate substitution treatment. Men randomly allocated to the control condition will receive only TAU. They will not receive the intervention at the end of the trial.

Randomisation methods:
Male participants will be allocated to the intervention group + TAU or TAU only (ratio 2:1) within service strata via an independent online system based at the King's Clinical Trials Unit (King's CTU) at King's College London. Allocation will be at the level of the individual participant and stratified by service. Randomisation will take place after a set of 24 men has been recruited in a service. The whole set will be randomised at the same time (16 men to the intervention arm and 8 to the control arm). A minimum set of 18 men will be required for randomisation to take place.

Delivery of intervention:
All sessions will take place in the substance use treatment service and will be facilitated by two facilitators (one male and one female): a substance use worker and a worker with experience of IPA where possible. The group intervention will be delivered to closed groups consisting of a maximum of 16 men. Men allocated to the control arm would not be able to join.

Follow up study:
To investigate the impact of the ADVANCE intervention measures will be collected at follow-up from female current or ex-partners.at 4- and 12-months post randomisation of male current or ex-partner.

Intervention Type
Behavioural

Primary outcome measure
Total score in self-reported perpetration of IPA by men in substance use treatment measured using the adapted 29-item Abusive Behavior Inventory (ABI) - partner form (perpetration)in the previous 4 months at 12 months post-randomisation

Secondary outcome measures
Evaluated for men at 4 and 12 months post-randomisation:
1. Other IPA perpetration
1.1. Abusive Behavior Inventory (ABI) - partner form (perpetration) in the previous 4 months at 4 months post randomisation only
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

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
3.1. Depressive symptoms assessed using the PHQ-9 in the past 2 weeks
3.2. Anxiety symptoms assessed using the GAD-7 in the past 2 weeks
3.3. PTSD symptoms assessed using the Primary Care PTSD Screen in the past month
3.4. Propensity for Abusiveness Scale [anger subscale]
4. Self-Control: Brief Self-Control Scale
5. Quality of life will be measured using the EQ-5D-3L
6. Capability will be measured using the ICECAP-A
7. Service use and medication in past 4 months at 4 month follow-up and in the past 8 months at 12 month follow-up

8. Measures obtained to describe the therapy experience:
8.1. Therapeutic alliance
Men in the intervention arm and group facilitators will complete evaluation forms at the end of each session to assess the acceptability of the intervention. At the end of the intervention, men' s perception of therapeutic alliance will be assessed using the Working Alliance Inventory – Short Revised and the California Psychotherapy Alliance Scale- Short Form
8.2. Nested process evaluation
A process evaluation will be undertaken to understand the intervention's functioning. Six priority areas will be assessed: context (local factors that influence implementation), fidelity (extent to which intervention is delivered as conceived), dose delivered (amount of intervention offered to participants), dose received (extent of participants' engagement in intervention), reach and recruitment. We will also assess how the intervention was delivered (e.g. the training and resources necessary to achieve full implementation), and the quantity and quality of what was delivered), intervention components (what is to be implemented), mechanisms of impact (the mechanisms through which an intervention will work) and intended outcomes. Treatment integrity (Treatment Design, Training Providers, Delivery of Treatment, Receipt of Treatment, and Enactment of treatment skills) will be measured on a random sample of 10% of video recorded sessions using a pre-determined checklist. All sessions will be video recorded.

9. To investigate the impact of the ADVANCE intervention in follow-up study, the following measures will be collected at follow-up from female current or ex-partners.at 4- and 12-months post randomisation of male current or ex-partner:
9.1. IPA victimisation using the Revised Abusive Behavior Inventory (ABI-R) in the previous 4 months
9.2. Other IPA victimisation
9.2.1. Controlling Behaviours Scale (partial) in the past 4 months
9.2.2. Use of social media, stalking, locked in, and using children against partner in the past 4 months
9.3. Substance use
9.3.1. Number of alcohol free days in past 28 days using the Treatment Outcome Profile
9.3.2. Number of drug free days in past 28 days using the Treatment Outcome Profile
9.4. Mental Well-being
9.4.1. Depressive symptoms assessed using the PHQ-9 in the past 2 weeks
9.4.2. Anxiety symptoms assessed using the GAD-7 in the past 2 weeks
9.4.3. PTSD symptoms assessed using the Primary Care PTSD Screen in the past month
9.5. Quality of life will be measured using the EQ-5D-3L
9.6. Capability will be measured using the ICECAP-A
9.7. Service use and medication in past 4 months at 4 month follow-up and in the past 8 months at 12 month follow-up

Overall study start date
03/02/2020

Completion date
30/09/2021

Reason abandoned (if study stopped)
Pandemic

Eligibility

Key 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. Plans to stay in current location for the next 6 months
4. Agrees to provide contact details of current and/or ex female partner
5. Ability to understand and communicate in English
6. Able to attend the intervention (believe that the proposed day and time the group is planned to be delivered is suitable)
7. Substance use treatment service assesses as suitable to participate in the trial

Current or ex-female partners of men in the trial:
1. Current or ex-partner participating in the trial
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
378

Key exclusion criteria
Men receiving community substance use treatment
1. Male 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.

Current or ex-female partners of men in the trial
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 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 trial 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 current or ex male partner – her current or ex male partner will remain in the trial.

Date of first enrolment
03/02/2020

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

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
Bristol
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

Sponsor details
Room 5.31
James Clerk Maxwell Building
57 Waterloo Road
London
England
United Kingdom
SE1 8WA
+44 (0)20 7848 6390
reza.razavi@kcl.ac.uk

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, Psychology & Neuroscience
DeCrespigny Park
London
England
United Kingdom
SE5 8AF
+44 (0)20 7848 0339
slam-ioppn.research@kcl.ac.uk

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
31/12/2021

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