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

Submission date
21/05/2018

Recruitment status
No longer recruiting

Registration date
22/05/2018

Overall study status
Completed

Last Edited
19/06/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 explores whether 108 men in substance use treatment who have been abusive towards a partner in the past year can be recruited to an intervention to reduce IPA, or to substance use treatment as usual.

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 12 weekly 2 hour group sessions, with an additional 2 to 4 individual pre-group preparation sessions depending on need, along with substance use treatment as usual. The control group receive substance use treatment as usual (fortnightly individual sessions with keyworker). 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. 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 substance use, relationships, IPA, 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 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 would improve the wellbeing 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 on a regular basis to share information that relates to the women's safety and risk. Participating in the study could improve relationships and improve the wellbeing 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?
1. King's College London (UK)
2. University of Worcester (UK)
3. University of Bristol (UK)

When is the study starting and how long is it expected to run for?
January 2018 to March 2019

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

Who is the main contact?
Dr Gail Gilchrist

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

Contact information

Type(s)
Scientific

Contact name
Dr Gail Gilchrist

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

Contact details
King's College London
Institute of Psychiatry, Psychology and Neuroscience
National Addiction Centre
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London
United Kingdom
SE5 8BB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37647

Study information

Scientific Title
Feasibility and acceptability of a randomised controlled trial of an integrated group intervention to reduce intimate partner violence perpetration among men receiving treatment for substance use

Acronym
ADVANCE

Study objectives
An intervention to reduce intimate partner abuse by men in treatment for substance use compared to substance use treatment as usual, will be feasible and acceptable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fulham, NRES Committee London (Health Research Authority), 10/04/2018, ref: 18/LO/0492

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Intimate partner abuse

Interventions

Male participants will be allocated to the intervention group or TAU (ratio 1:1) by site via an independent online system based at the King's Clinical Trials Unit (King's CTU) based at King's College London. Allocation will be at the level of the individual participant, using randomly varying block sizes, stratified by a combination of sites and cycles (18 participants per site/cycle stratum).

The group intervention is 12 weekly 2 hour sessions, with an additional 2 (goal setting and safety planning compulsory sessions) to 4 individual pre-group preparation sessions depending on individual need + substance use treatment as usual (see control intervention).

The control intervention is substance use treatment as usual (fortnightly individual sessions with keyworker).

The trialists want to know if this new intervention is any better than usual substance use treatment with a keyworker, and will also compare the intervention costs to usual treatment. They will explore whether the intervention can be delivered in substance use treatment and whether men find the intervention acceptable, attend sessions, and stay in the study. Mens' current/ex-partners will be offered support for IPA, and invited to take part in the study by providing information about their partner's behaviour and their own well-being. The trialists will evaluate how many of them take up this offer, but estimate that about 76 will take part in the study. The man's keyworker and the women's support worker will share information that relates to women's safety and risk. Women will be updated about their current/ex-partner's overall progress in the intervention. Data on substance use, relationships, IPA, emotional well-being, quality of life and service use will be collected from both men and women at the start and end of the intervention. It is anticipated that if IPA stops, men's current/ex-partner's well-being will improve.

Intervention Type
Behavioural

Primary outcome measure
This is a feasibility trial. The objectives of the study are to explore the acceptability and feasibility of an intervention to reduce intimate partner violence (IPV) among men in treatment for substance use compared to substance use treatment as usual. The feasibility of recruiting and retaining men in substance use treatment who have perpetrated IPV in the past 12 months and their current and ex female partners to the feasibility trial will be determined.

To demonstrate the feasibility:
1. of recruiting and retaining men in substance use treatment who have perpetrated intimate partner violence (IPV) in the past 12 months to a trial comparing a group intervention to treatment as usual (TAU)
2. of delivering the group intervention across three regions in England (London, Wolverhampton and Bristol)
3. of recruiting and retaining current and ex female partners of these men in the trial as collateral informants

To evaluate:
1. the level of treatment engagement and retention for men, and explore through focus groups and qualitative interviews their views, acceptability and experiences of the intervention and the study process
2. the level of engagement and retention with women's support for IPV victimisation for female current and ex-partners, and explore through qualitative interviews their views, acceptability

and experiences of women's support and the study process
3. the views, acceptability and experiences of the facilitators who delivered the intervention
4. the suitability and acceptability of outcome measures

Secondary outcome measures
As a feasibility trial, this study is not powered to determine the effectiveness of the intervention. Outcomes will be assessed at baseline and end of the intervention (14-16 weeks post baseline) for men participating in the trial and their current and ex-partners. The following outcomes will be assessed for both IPV perpetrators and survivors:
1. Depressive symptoms, assessed using PHQ-9
2. Anxiety symptoms, assessed using GAD-7
3. Post-traumatic stress, assessed using Primary Care PTSD Screen
4. Perpetrator and survivor reports of IPV perpetration, assessed using Abusive Behavior Inventory
5. Risk (men only), assessed using Propensity for Abusiveness Scale
6. Substance use, assessed using Treatment Outcomes Profile; Addiction Severity Index
7. Quality of life, assessed using SF-12; EQ-5D-3L
8. Service use
9. Criminal justice involvement
Timepoint(s): 16 weeks post-randomisation (+ window of 4 weeks) for male participants in both the intervention and control arms, and their current or ex female partners.

The suitability and acceptability of potential outcome measures for use in a future efficacy trial will be considered by exploring:
1. Completeness of data
2. Researchers' perception of participants' understanding (e.g. of language and meaning of questions)
3. Researchers' perception of participants' acceptability (e.g. if participant refuses to answer or gets annoyed/frustrated or asks to end the interview)
Recorded for each outcome measure using a predetermined rating scale. Poor completeness of data and low ratings of researchers' perceptions of participants' understanding and acceptability of outcome measures will lead to these outcome measures being considered unsuitable for the future efficacy trial.

Overall study start date
01/01/2018

Completion date
31/07/2019

Eligibility

Key inclusion criteria
Male inclusion criteria:
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 month - 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. Keyworker assesses as suitable to participate in the trial

Female inclusion criteria:
1. Aged 18 years or older
2. 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
Planned Sample Size: 184; UK Sample Size: 184

Total final enrolment
133

Key exclusion criteria
Male exclusion criteria:
1. Current or ex-partner is not female
2. Pending court case for IPV or pending child protection hearing
3. Current restraining order
4. Currently attending an intervention for IPV
5. Declines to provide contact details of current and/or ex female partner

Female exclusion criteria:
1. Pending court case for IPV or pending child protection hearing

Date of first enrolment
17/07/2018

Date of final enrolment
30/04/2019

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 Worcester
Centre for Violence Prevention
St Johns Campus,
Henwick Grove
Worcester
United Kingdom
WR2 6AJ

Study participating centre
University of Bristol
Centre for Academic Primary Care
Population Health Sciences
Bristol Medical School
University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
South London and the Maudsley NHS Foundation Trust

Sponsor details
c/o Prof. Reza Razavi
Room 5.31 James Clerk Maxwell Building
Waterloo Campus London (King's College London)
London
England
United Kingdom
SE1 8WA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1214-20009

Results and Publications

Publication and dissemination plan
Additional documents (such as study protocol, statistical analysis plan) are not currently available but can be requested from the CI. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The data will be held at King's College London. As this is a feasibility study the data will not be available for supplementary analysis.

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	protocol	11/05/2020	23/11/2020	Yes	No
Results article		25/05/2021	27/05/2021	Yes	No
Other publications	intervention development	28/10/2021	19/06/2023	Yes	No
HRA research summary			28/06/2023	No	No