ISRCTN71797549 https://doi.org/10.1186/ISRCTN71797549

Trial of a group programme intervention for men who are concerned about their behaviour

Submission date
03/08/2017

Recruitment status
No longer recruiting

Registration date
27/05/2022

Overall study status
Completed

Last Edited
02/05/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
There are programmes for men who perpetrate domestic violence and abuse (DVA), but it is not known whether they work for the men or the survivors of DVA. The researchers and a group of experts consulted on which is the most promising programme and this has been adapted to be tested first in a small group of men who have perpetrated DVA and their partners or ex-partners, and if this looks promising, to be tested in a larger study. Men who have perpetrated DVA and their partners/ex-partners are recruited to measure the extent to which safety has increased and whether abuse has stopped/decreased. This work emerged from extensive consultation with established and new public and patient involvement (PPI) groups and the researchers will continue to work with (in separate consultations) DVA survivors and men who have attended a perpetrator programme to inform this programme of work. In addition, the researchers will consider the needs of minority groups who are often not included in service developments. This includes migrants, black and ethnic minority communities and people in gay or lesbian relationships. The researchers are focusing on male perpetrators who have relationships with women because these men form the largest group of perpetrators. However, alongside the study interviews are carried out to explore the needs of other groups of perpetrators such as gay men.

Who can participate?
Men aged over 21 who use violence/abuse in their relationships with women partner(s) or ex-partner(s) and are concerned about that behaviour. Women aged over 18 who are partners or ex-partners of men who use violence/abuse in their relationships.

What does the study involve?
Male participants are randomly allocated to attend a 26-week community-based perpetrator programme or to receive usual care with up to a 12-month follow up. The domestic violence perpetrator programme consists of a 26-week programme incorporating 22 weekly group sessions and four individual sessions. The sessions are run by two experienced facilitators (one male and one female in order to model good gender role behaviours). The programme starts as a rolling programme, allowing new intakes of participants to join at specified intervals but after

6 months becomes a closed programme, meaning that no new men are able to join. This is to ensure that men have completed the programme before the end of the study and to allow enough time for follow-up afterwards.

What are the possible benefits and risks of participating?
Men who agree to join the study have a 50% chance of getting a place on a group programme for men who are concerned about their behaviour in relationships with women. Currently, there are no other group programmes running in the area. The results of this study will help determine whether these programmes are helpful to men, if they can improve safety for women and children, and whether or not they should be funded throughout the UK. Men receive shopping vouchers up to the value of £50 for completing all questionnaires throughout the study. The disadvantages are that completing the questionnaires and possibly being interviewed over the course of 9 months takes up a few hours of time, and some men may find questions repetitive or difficult to answer. Men allocated to the domestic violence perpetrator programme are asked to commit to attending a 26-week programme. Attending weekly meetings may be a challenge, although it is hoped that the help and support provided by the group and the facilitators would make this worthwhile. Men allocated to receive usual care may feel disappointed and frustrated, but the valuable support they are providing will help to find out whether group programmes help men and their families.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
April 2017 to October 2018

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

Who is the main contact?
Prof. Gene Feder
reprovide-programme@bristol.ac.uk

Study website
http://www.bristol.ac.uk/primaryhealthcare/researchthemes/reprovide/group-intervention-for-men/

Contact information

Type(s)
Scientific

Contact name
Prof Gene Feder

Contact details
University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom

BS8 2PS
+44 117 928 9000
reprovide-programme@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
178666

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UoB RRC 2630, IRAS 178666, CPMS 33843

Study information

Scientific Title
Feasibility of a randomised controlled trial of a group programme for men who are concerned about their behaviour in relationships with women: a pilot study

Acronym
REPROVIDE

Study objectives
The overall objective of this pilot trial is to determine the acceptability and feasibility of the perpetrator programme intervention and trial design.

There will be a nested qualitative study within this pilot phase to explore processes of the intervention through observations/interviews to inform interpretation of the trial results. This will also improve understanding of the needs of men (and their partners) who do not fulfil our trial inclusion criteria (e.g. in same sex relationships or unable to read English).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/04/2017, South Central - Hampshire B Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 207 104 8089; hampshireb.rec@hra.nhs.uk), ref: 17/SC/0096

Study design
Pragmatic parallel-group randomized controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

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
Domestic violence and abuse

Interventions
48 male perpetrators are randomised to a 26 week community-based perpetrator programme or control arm (usual care) with up to a 12 month follow up. (Individual randomisation is done using minimisation based on age and relationship status).

The domestic violence perpetrator programme (DVPP) consists of a 26-week programme incorporating 22 weekly group sessions and four individual sessions. The sessions are run by two experienced facilitators (one male and one female in order to model good gender role behaviours). The programme starts as a rolling programme, allowing new intakes of participants to join at specified intervals but after six months becomes a closed programme, meaning that no new participants are able to join. This is to ensure that participants have completed the programme before the end of the pilot trial and to allow sufficient time for post-completion follow-up.

Intervention Type
Behavioural

Primary outcome measure
Acceptability of the recruitment and randomisation process for men and their (ex)partners, measured by number recruited and randomised in the pilot trial. 48 male perpetrators and their partners/ex-partners must be recruited and randomised in order to meet progression criteria.

Secondary outcome measures
The following are measured at baseline, three, six and nine months:
1. Acceptability of the pilot intervention to perpetrators is measured by number retained over a 9-month period
2. Acceptability of and willingness to complete questionnaires is measured by completed data sets from PHQ-9, GAD-7, PTSD, EDQ5, DUDIT and Audit, and SF12 scale, and Impact Toolkit questionnaire completion at baseline and 3, 6 and 9 months post-randomisation
3. Development of a fidelity framework for intervention to use to assess fidelity in the main trial
4. Use of health and social care services and other related costs associated with the trial
5. Acceptability of the intervention to perpetrators, associated victims/survivors and staff measured through the collection of qualitative data throughout the pilot study period
6. Acceptability of, and risks faced by, female partners and ex-partners to be involved in the pilot trial, measured by impact toolkit questionnaire, qualitative interviews, and collection of adverse

incidents/adverse events/serious adverse events
7. Ways of improving retention in both the intervention and control arms for male and female participants, assessed and measured through engagement with PPI groups and qualitative interviews
8. The mechanisms of support and supervision needed for those involved in the delivery of the intervention, assessed through qualitative interviews and feedback sessions

Overall study start date
01/04/2017

Completion date
31/10/2018

Eligibility

Key inclusion criteria
Inclusion criteria for male participants:
1. >21 years of age
2. Using violence/abuse in their relationship to women partner(s) or ex-partner(s) and concerned about that behaviour
3. Ability to read and complete outcome questionnaires

Inclusion criteria for partners/ex-partners:
1. Female partners or ex-partners of men using violence/abuse in their relationships
2. >18 years
3. Ability to read and complete outcome questionnaires

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48 men and their partners or ex-partners

Total final enrolment
51

Key exclusion criteria
Exclusion criteria for male participants:
1. Men who do not have a female partner or ex-partner
2. Court mandated referral to perpetrator programme
3. Men who are high risk perpetrators of DVA as assessed by the intervention group co-ordinator

4. Men who are deemed by the intervention group coordinator not willing to engage with the intervention
5. Participants who cannot understand the English language sufficiently well to give informed consent and to complete the questionnaires
6. Participants with a diagnosis of a mental illness that will prevent them from programme engagement, e.g. active psychosis
7. Participants with current unstable use/misuse of drugs or alcohol

Exclusion criteria for partners/ex-partners:
1. Participants who cannot understand English sufficiently well to give informed consent and to complete the questionnaires
2. Women who are deemed by the DVA support worker to be put at greater risk if they take part in the study
3. Women who are incapacitated by substance abuse or serious mental illness at time of seeking consent

Date of first enrolment
01/05/2017

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House
Tyndall Avenue
Bristol
England
United Kingdom

BS8 1TH
+44 117 928 9000
Anna.brooke@bristol.ac.uk

Sponsor type
University/education

Website
http://www.bristol.ac.uk/primaryhealthcare/researchthemes/reprovide/

ROR
https://ror.org/0524sp257

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
The findings will be disseminated through conventional academic routes: peer-reviewed journal publications and conference presentations. There will be at least three academic outputs (main trial, cost effectiveness analysis, and nested qualitative study), using audience-appropriate open access journals and identifying opportunities to present the findings at national and international conferences (including commissioning, DVA and mental health specific). Given that the findings from the trials will only be produced towards the end of the programme, the final year will focus exclusively on dissemination of findings to academic audiences and implementation into health care services.

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Karen Morgan (karen.morgan@bristol.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	09/02/2018	30/06/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		27/04/2024	02/05/2024	Yes	No