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Family recovery after domestic abuse: testing the feasibility of a group intervention for children

Submission date
14/09/2020

Recruitment status
No longer recruiting

Registration date
27/10/2020

Overall study status
Completed

Last Edited
05/11/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Some 15% of UK children witness at least one form of domestic violence or abuse (DVA) during childhood; many more are exposed in other ways such as seeing the aftermath of abuse. Exposed children are more likely than those who are not, to experience mental health (MH) problems throughout their lives.

There are programmes that try to prevent or reduce the damage that DVA causes to MH, but overall there has been very little research to work out whether these programmes improve outcomes and reduce costs associated with DVA.

Programmes combining education, support and counselling (Psycho-education) are most widely available in the UK, but there is no good quality evidence to show if this type of support is helpful and good value for money.

This study will investigate one particular programme called CODA (Children Overcoming Domestic Abuse), because it has become quite well established in London and parts of Scotland. It was developed in Canada, and has been adapted for use in the UK. It is delivered by different types of professionals in community settings (e.g. children's centres). Children receive a 12-week group intervention, and a group work programme runs at the same time for mothers or female carers. Children are encouraged to recognise, name and explore feelings surrounding DVA, and to develop coping strategies to deal with conflict and other stressful situations. Sessions for mothers help them to support their children to come to terms with their experiences.

The study aims to find out if it is possible to conduct an experimental study, or trial, to compare whether children (aged 7-11 years) who take part in CODA (along with their female caregiver) do any better than similar children who receive the support that would normally be available to them. For this reason it is called a feasibility study. It is needed as a first step because it is not yet clear if families or the people working with them would be willing to support a trial where only some children and mothers are able to access the programme being tested.

At the end of the study it will be clear whether it is possible to proceed to a full scale trial and, if so, about any changes to the study methods or indeed the intervention and the way it is delivered that might be needed. It is hoped that tis study will also provide some insight into the potential of this type of programme in assisting male victims and their children.

Who can participate?
Families with exposed children aged 7-11 years will be identified and referred to the study by community agencies (e.g. housing) as part of their normal work. Families wishing to take part will complete questionnaires about their health and well-being and then be divided into two groups at random using a computerised system that is like flipping a coin.

What does the study involve?
Participating children and their female parent (or carer) will be randomly allocated to either receive standard care or to receive the CODA program.

The CODA program group will attend weekly sessions lasting 1.5 to 2 hours over 12 weeks. The sessions consist of structured activities and free play. The focus and order of each session follows the CODA manual, and activities and resources are suggested, however, it is possible for facilitators to deliver different activities that address the prescribed focus of the session where necessary. The content of each parent session reflects that of the children's sessions.

Groups are delivered in age bands of 7-8 and 9-11 years. Siblings are not permitted to attend the same group, so as to protect each child's confidentiality, and acknowledging that siblings in the same family may experience DVA differently.

The study will use questionnaires to assess how all families are getting on at 4 months, 6 months and 12 months past the date they entered into the study. The study will also explore if the number and strength of links between the host agency and other community services makes a difference to how easy or difficult it is to run the programme; talk to families and professionals to hear what they thought about taking part in the study and in CODA (if they received it), and gather information to inform an analysis of cost vs benefit. Finally, we will undertake a small sub-study to gather thoughts of men who have been victimised to find out whether an intervention such as CODA could be helpful for them, and what adaptions might be needed.

What are the possible benefits and risks of participating?
The nature of DVA means that there are inherent risks to undertaking research with victim /survivors of DVA and their children including: the potential for disempowered parents and children to feel pressured to take part in research; the possibility (due to the overlap between DVA and child maltreatment) that child safeguarding issues will be identified, and the potential for participants to be re-exposed to abuse by the perpetrator. This is in addition to the emotional impact of re-engaging with experiences of and feelings about the abuse in the context of the research (and/or the intervention), and the possibility that support offered in one arm is more effective than the other.

There are no specific benefits to taking part in the study, other than the knowledge that participation may help others in the future. Participants will receive shopping vouchers following each research task (e.g. completion of questionnaire).

Dyads/clusters will be withdrawn from the intervention if the participating parent reconciles with the abusive party. In these cases, it will be possible for families to continue to participate in the study. However, withdrawal from the study will be necessary if it becomes known that participation is placing them or professionals (including researchers) at increased risk of physical

or emotional harm. These decisions will be taken by the Chief Investigator (CI) and programme manager in consultation with the TSC and in collaboration with the intervention co-ordinator and MAFs. These decisions will be documented appropriately.

The risk in this population for adverse events and serious adverse events (as defined in Good Clinical Practice guidance) is high. All SAEs will be recorded on the study database and reported to the CI and chair of the TSC, within 48 hours of receiving the report. The CI who is also the Trial Manager is responsible for reporting to the Chair of the TSC. In the context of this feasibility trial, the TSC will also assume the duties of the DMEC.

The CI and chair of the TSC will consider whether the SAE is: not related to participation, possibly related to participation or related to participation. Judgement will be made on whether to report the possibly related cases on to the Sponsor and ethics committee chair, but all cases of related will be reported onwards.

All SAEs will be followed up where appropriate by the researcher, the intervention coordinator or the host site. If it is felt that a child or adult are at significant risk, then the local area safeguarding procedure will be initiated. All adverse event reporting will be in accordance with HRA guidance.

A cumulative review of all safety information by the TSC will be made on a 6-monthly basis.

Where is the study run from?
The University of East London (UK)

When is the study starting and how long is it expected to run for?
From January 2020 to April 2022

Who is funding the study?
The National Institute for Health Research (NIHR) Public Health Research Programme (project reference: NIHR127793) (UK)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283925

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FReDA protocol v0.2_240820; IRAS 283925

Study information

Scientific Title
Family REcovery after Domestic Abuse (FREDA): A feasibility randomised trial and nested process valuation of a group based psycho-educational intervention for children exposed to domestic violence and abuse

Acronym
FREDA

Study objectives
1. Is CODA (Children Overcoming Domestic Abuse) intervention acceptable and feasible to implement in two community settings?
2. Can the intervention be delivered with fidelity by multiple practitioners?
3. How do socio-demographically diverse populations of women and children engage with the intervention?
4. Is the trial design feasible and acceptable to implement in community-based organisations?
5. What is the in-principle acceptability of CODA for victimised male caregivers and their children?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/07/20, Wales Research Ethics Committee 5 Bangor (Castlebridge 4, 15-19 Cowbridge Road East Cardiff, CF11 9AB; +44 (0)7970 422139; Wales.REC5@wales.nhs.uk), ref: 20/WA/0199

Study design
Two site, interventional, open, pragmatic, parallel group, individually randomised controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See attached files

Health condition(s) or problem(s) studied
Prevention of internalising symptoms and externalising problems in children who have experienced domestic violence and abuse

Interventions
The Children Overcoming Domestic Abuse programme (CODA) is a Canadian founded, manualised, trauma-informed psycho-educational programme. The intervention has been adapted for a UK audience by the third sector organisation Against Violence and Abuse (AVA). The intervention is supported by manuals and tools, as well as an online forum for providers, all of which can be accessed via AVA.

The programme aims to prevent onset or escalation of MH problems following exposure to DVA. It targets children no longer exposed to serious abuse and who live separately from the abusive

party; acknowledging that some forms of abuse, such as coercive control may be ongoing beyond separation. It is offered based on children's known exposure to DVA and perceived need, rather than linked to the presentation of any particular symptom profile.

Children and parents entering the study will be randomised to either: the control arm where they will receive usual care offered by the host organisation, or to the intervention arm where they will receive care as usual plus the CODA intervention. The unit of randomisation will be the mother-child dyad or family cluster (where there is more than one eligible child). Family clusters recruited to the study will be randomised in a 1:1 ratio to the two study arms (intervention + usual care vs. usual care), using a remote telephone randomisation system implemented by the Pragmatic Clinical Trials Unit at Queen Mary University. Randomisation will be stratified by site, age band (seven-eight, nine-11 years, where more than one child, age band will be determined by average age of children), and whether more than one child from the family is participating in the trial (1 vs >1).

Participating children and their female parent (or carer) allocated to the intervention arm will attend a 12-week intervention, participating in parallel groups. Sessions are delivered on a weekly basis (1.5-2 h) and consist of structured activities and free play. The focus and order of each session is manualised and activities and resources are suggested, however, it is possible for facilitators to deliver different activities that address the prescribed focus of the session. The content of each parent session reflects that of the children's sessions.

Key aims of the intervention are to help children break the secret of abuse that has happened in their families, imbue children with knowledge that they are not the only ones to have experienced DVA, equip them with the vocabulary to describe their experiences, understand that use of abusive behaviour is always wrong, to reduce feelings of shame and self-blame, explore constructive means of conflict resolution, to develop peer relationships, to assist mothers in acknowledging and exploring the impact of DVA on children and parenting, equip mothers with the skills and confidence to support their children in talking about DVA and addressing adjustment difficulties associated with exposure, to parent in age appropriate and sensitive ways, to enhance maternal wellbeing and perceptions of social support.

Several etiological process models speak to these aims and inform key intervention activities including: 1. Development of a trauma narrative and focus on children's maladaptive trauma-related appraisals (trauma theory; social-cognitive perspectives)
2. Development of adaptive responses to everyday conflict (social information processing theory)
3. Helping mothers to understand impact of DVA on children, respond to children's distress and develop warm and sensitive parenting (attachment theory, spill-over hypothesis, coercion theory)
4. Enhance maternal mental health, wellbeing and social support (family stress hypothesis)

The programme is expected to improve intermediate outcomes by improving parenting self-efficacy, enhancing child and parent perceptions of social support and addressing maladaptive appraisals and attitudes about abusive behaviour and relationships. Change in children's longer-term MH and wellbeing is expected to be mediated by enhanced maternal MH and parenting practices (increased warm and sensitive parenting and reduced hostility).

It is recommended that groups are delivered in age bands of 7-8 and 9-11 years. Siblings are not permitted to attend the same group, so as to protect each child's confidentiality, and

acknowledging that siblings in the same family may experience DVA differently. If groups run in a serial fashion (i.e. two different groups are not available at the same time) mothers must make a decision regarding which child attends first, although have the option to attend with each child.

Whilst it is desirable for the intervention to be delivered to a child and their female parent or caregiver in parallel, children can participate in the programme without the active involvement of their mother. In instances where the mother does not participate, the intervention co-ordinator is responsible for providing information on the content of weekly group sessions, and assisting mothers to respond to emergent issues (e.g. blame of the non-abusive parent for remaining in the situation).

The intervention includes a complex model for embedding the CODA, focused on harnessing existing relationships and resources between organisations to ensure wide reach and coordinated delivery. It requires coordination by a host agency (e.g. specialist DVA agency; Local Authority early intervention service) and relies upon the support of community agencies and partnerships to maintain the programme, through the provision of suitable community venues and staff to facilitate the groups. Each 12-week cycle requires a minimum of four facilitators (2 per group) and can be delivered by professionals from a range of backgrounds and disciplines.

Care as usual for children experiencing DVA in the UK is in general, unstandardized and poorly defined. This is in large part owing to short term commissioning arrangements and limited funding, which gives rise to a rapidly changing landscape of what is available for children who have experienced DVA. A key purpose of the process evaluation is to characterise care as usual in each local area. Researchers will draw on study questionnaires but also routinely collected data by the organisations to understand which services families are helped to access, and how this may differ across study arms, and sites. On this last point the sites delivering the intervention in the context of this feasibility study have different remits – Cardiff Women's Aid is a DVA focussed organisation whereas services delivered via Family Action in children's centres are targeted more broadly at vulnerable families with a child aged 0-5 (although many of these families have older children).

As CWA is a specialist domestic abuse service, it is commonplace for children referred to the service to receive one to one support from a children and young people's DVA worker. may involve activities with a focus on fun and respite, those that are trauma focus such as working together to construct a trauma narrative, or those that address the mental health difficulties connected to the trauma. The content of support sessions is informed by a risk assessment (focusing on risks associated with DVA) and initial assessment. Assessment may highlight other needs that require referral to other services. Where children are accessing psychological therapy (through CAMHS or other services), it is common place to wait until this has completed, before starting or resuming trauma focussed support. In general, is CWA practice, not to offer multiple forms of support to children in parallel, for example group based and 121 support.

Targeted support for children may be delivered in tandem with practical (advocacy) and or emotional support or psychological therapy for a child's parent within the CWA cluster of services and partner agencies.

The Children's Centres in Southend offer a range of programmes in each centre to support individuals and families within their locality. These range from advice for new and expectant parents, Positive parenting courses, advice regarding a wide range of issues relating to children, parenting and family life, support from health professionals, such as midwives, and a range of parent and child activities to support learning, attachment and interaction. Whilst children's Centres target families with children aged 0-5, many of these families have older children. In

addition to the work of the Children's Centres Family Action also deliver "Stronger Families" a Lottery Funded project for children 5 to 10 and their families, which provides homebased and group work family support.

Further, the Local Authority have a commitment to expanding provision for children affected by DVA and Family Action have a national approach to DVA which covers all aspects of delivery, including direct targeted support to families and partnership with specialist partner agencies. This is to ensure a coordinated community response to DVA can be achieved.

Intervention Type
Behavioural

Primary outcome measure
1. Feasibility to progress to a definitive trial assessed using child report of internalising symptoms (e.g. anxiety, depression, withdrawal) and externalising problems (e.g. acting out, oppositional behaviour) using the Behaviour and Feelings Survey (which would be the indicative proposed primary outcome of a future full-scale trial) at baseline, 6, and 12 months

Secondary outcome measures
1. Caregiver experience of Intimate partner violence measured using the Composite Abuse Scale (Revised)—Short Form (CASR-SF) at baseline, 4, 6, and 12 months
2. Normative beliefs about general aggression and aggressive behaviour, measured using the general beliefs subscale of Normative beliefs about general aggression and aggressive behaviour at baseline, and 4 months
3. Children's appraisals of self-blame about inter-parental conflict, measured using the self-blame subscale of the Children's Perceptions of Interparental Conflict Scale, at baseline, and 4 months
4. Child perceptions of coping efficacy, measured using the Children's Coping Self Efficacy Questionnaire, at baseline, and 4 months
5. Children's emotion regulation, measured using the ERC Q-sort scale, at baseline, and 4 months
6. Children's Internalising/externalising symptoms, measured using the Behavior and feelings survey, at baseline, 4, and 6 months
7. Children's school adjustment, measured using How I feel about my School, at baseline, 6, and 12 months
8. Paediatric health-related quality of life measured using Child Health Utility (CHU9D) measure, at baseline, 6, and 12 months
9. Parent health-related quality of life, measured using EuroQol 5 dimension 5 level (EQ-5D 5L) questionnaire, at baseline, 6, and 12 months
10. Parental symptoms of depression, measured using the Patient Health Questionnaire (PHQ9), at baseline, 6, and 12 months
11. Parental symptoms of anxiety, measured using General Anxiety Disorder (GAD7) questionnaire, at baseline, 6, and 12 months
12. Parenting self-efficacy, measured using Child Adjustment and Parent Efficacy Scale (CAPES-SE), at baseline, 4, 6, and 12 months
13. Parent capacity to mentalize their children, using Parental Reflective Functioning Questionnaire (PRFQ), at baseline, 4, 6, and 12 months
14. Parent and child service usage, using developed measure based on a shortened version of the Client Service Receipt Inventory (CSRI) with the addition of relevant services, at baseline, and 12 months

Overall study start date

01/01/2020

Completion date
30/04/2022

Eligibility

Key inclusion criteria
1. Family identified as having experienced domestic violence and abuse (DVA) during the lifetime of the referred child
2. Children aged 7-11 years exposed to DVA, and their female caregiver
3. Child and female caregiver living separately from the perpetrator of the DVA eliciting referral
4. No significant risk to the physical safety of the child (from either parent) or supporting parent
5. Ability to complete outcome questionnaires (with reading assistance or translation where required)

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
64 child-caregiver pairs or family clusters (if more than one child eligible)

Key exclusion criteria
1. Families in acute crisis, as determined by caregiver, identifying agency, intervention co-ordinator or researcher (e.g. only recently left the abusive situation; immediate risk of harm, lack of stable accommodation, significant substance misuse that would inhibit engagement in study or intervention)
2. Victimised male caregivers and their children (although male caregivers are included in the nested process evaluation)
3. Cannot understand the English language sufficiently well to give informed consent and to complete the questionnaires and where adequate and safe translation services cannot be secured

Date of first enrolment
01/12/2020

Date of final enrolment
30/07/2021

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Cardiff Women's Aid
16 Moira Terrace
Cardiff
United Kingdom
CF24 0EJ

Study participating centre
Southend-on-Sea Borough Council via Family Action (service provider)
Victoria Ave
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SS2 6ER

Sponsor information

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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

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
For academic publications we will follow the Consort Guidelines and appropriate extensions prior to generating any publications for the trial, to ensure they meet the standards required for submission to high quality peer reviewed journals etc. http://www.consort-statement.org/

The University of East London owns the data arising from the trial. Any dissemination of this feasibility trial (either academic or lay) by participating investigators will only be done in

discussion and agreement with other participating investigators. The NIHR require that they have one month to review publications prior to submission. The NIHR require that funding needs to be acknowledged within all publications: Disclaimer/acknowledgement thus:
"This report is independent research funded by the National Institute for Health Research (Programme Grants for Applied Research, REPROVIDE (Reaching Everyone Programme of Research On Violence in diverse Domestic Environments), RP-PG-0614-20012). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health."

Planned publication of the feasibility trial protocol in a peer-reviewed journal.

On completion of the feasibility trial, the data will be analysed and tabulated and a Final Study Report prepared. This will feed into the main trial protocol which will follow this pilot if the intervention and trial methods meet progression criteria.

The full study report, anonymised participant-level dataset, and statistical code for generating the results will be made publicly available via the UEL data repository following the completion of the feasibility trial, estimated to be at the end of 2022 (study end April, 2022)

We will prepare and publish a quarterly newsletter that will be made available via the study website. The target audience for this will be our PPI group members, but trial participants will also be encouraged to access this if they want to know the outcome of the trial. For participants or PPI members who cannot access the internet, a paper copy in the post will be made available if it is safe to send to the given address.

We will present findings at meetings convened by each host site and at a UK practitioner-focused conference. We will disseminate findings via appropriately tailored briefings to all Clinical Commissioning Groups (CCGs) and Local Authorities (LAs) and throughout our extensive practitioner and policy links, already established through earlier NIHR-funded studies and involvement of several members in three NIHR CLAHRCS (EH, GF, VB). Funds to support this activity are built into the proposed budget. We will also use blogs (e.g. the Conversation, The Cost of Living, Mental Elf) and the Twitter accounts of DECIPHer and the forthcoming NIHR Applied Research Centres (ARCs) to increase public awareness of the study.

Intention to publish date
30/04/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the UEL data repository. Available data will include de-identified questionnaire data, interview data (anonymised transcripts, no link to questionnaire data), and service access data, along with meta data (e.g. codebooks). Data will be available 12 months after the close of the study for research purposes only. Informed consent will contain explicit permission for the sharing of anonymised data with other researchers.

Requests for access to the data by external researchers will be reviewed by UEL data archivists on a case by case basis. All reasonable request for access to the data will be met. Anonymised data will be stored for a period of up to 15 years. Archived data will be checked by the CI on a five-yearly basis. If the CI leaves UEL, responsibility for this will be formally handed over to one of UEL’s clinical research leads.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V6.0	17/08/2020	05/11/2020	No	Yes
Participant information sheet	version V4.0	17/08/2020	05/11/2020	No	Yes
Protocol file	version v0.2	24/08/2020	05/11/2020	No	No
HRA research summary			28/06/2023	No	No