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Improving the response of general practice to adult patients experiencing and perpetrating domestic violence and to their children

Submission date
11/03/2021

Recruitment status
No longer recruiting

Registration date
16/03/2021

Overall study status
Completed

Last Edited
04/09/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
IRIS+ will expand our previous research showing that general practice staff can respond appropriately to women experiencing domestic abuse. It will assist general practice professionals in identifying, documenting, and referring female and male patients who may have experienced abuse as victims, perpetrators, or both. It will also support children who may have been exposed to abuse to specialist services and offering them appropriate support.

The IRIS+ (Enhanced Identification and Referral to Improve Safety) stage II feasibility study is part of the REPROVIDE (Reaching Everyone Programme of Research on Violence in diverse Domestic Environments) Programme.

Phase I of the IRIS+ study successfully developed and piloted the feasibility of the IRIS+ intervention. IRIS+ Phase I was well received by general practice professionals and patients, but the process evaluation and discussion with stakeholders and our PPI groups has driven the formulation of added elements to the intervention. Our learning from Phase I of the IRIS+ pilot needs to be integrated into the intervention and re-tested for feasibility and acceptability in the next phase of IRIS+ (Stage II).

In Stage II, we propose to test the enhanced model in seven general practices in two sites: Bristol and South Wales. Stage II will include the assessment of the feasibility of the reconfigured IRIS+ model. Stage II will also include an exploratory assessment of cost-effectiveness of the reconfigured intervention with feasibility data and may include a value of information analysis to inform the decision the best course of action at the culmination of stage II (i.e. recommendation for direct NHS implementation or not).

Who can participate?
Seven general practices in Bristol and South Wales.

What does the study involve?
For Health Care Professionals (HPCs), the training provided, along with associated resources,

aims to consolidate and improve their knowledge, enhance their skills and confidence and aims to enable them to identify and record domestic violence and abuse (DVA) and to offer appropriate referral for all family members affected by DVA. The intervention also aims to enable HCP's to manage ongoing relationships with all patients including members of the same family. Following this, interviews will be held with a wide cross section of HCPs participating in the IRIS+ training intervention.

For patients and their children referred to the IRIS+ service/hub by general practice, a first meetings between the IRIS+ support worker and the IRIS+ clients and their children (potential research participants) takes place where the IRIS+ support workers will provide information about participation in the REPROVIDE study and seek the IRIS+ clients' written consent to be contacted by the researcher. In the case of children/young people, parent/carer written consent will be sought for the researcher to make contact to discuss the possible involvement of children in the research. Once informed verbal consent is obtained, the research team arrange a mutually convenient and safe location to meet with a potential study participant who will be asked to complete a questionnaire and possibly have a separate (semi-structured) interview at a time of their choosing. Support will be provided to all family members referred for up to six months [and longer if their case is referred onwards].

What are the possible benefits and risks of participating?
We recognise that both perpetrators and victims may find completing the service users questionnaire and interview distressing. As such, we have ensured that the study will take place in an area where services for victims already exist. Representatives from national organisations representing perpetrators, male victims, and gay male victims are included as collaborators within the project and have assisted in the design of the research materials to ensure that potential risk is minimised. All participants will be given information about available support services. Respondents to the service users (REPROVIDE) questionnaire will be given the option of completing the survey anonymously.

Some respondents will be asked to take part in semi-structured interview which will take the form of a telephone interview or, if safe to do so, a face-to-face interview conducted within a clinical/community setting. A comprehensive safety protocol will ensure that both participants and researchers safety is paramount.

Some general practice clinicians, health professionals or training/service providers may have personal experiences of domestic violence and abuse (DVA), either as a victim or perpetrator, and may find completing the interview/survey distressing. Representatives from nationals organisations representing perpetrators and victims, including male victims are included as collaborators within the project and have assisted with the design of the research materials to ensure that potential risk is minimised. All participants are offered information about available support services.

General practice clinicians and health professionals may feel a pressure to complete the PIM+ survey. Our information sheet for general practice clinicians and health professionals makes it clear that participation is optional and survey data are anonymous. We ask a small number of clinicians and health professionals (2-3 per practice) to volunteer to participate in the interview study. Interview data will be anonymised.

We recognise that children may become distressed during or after the interview if topics of a sensitive nature are discussed. In order to minimise this, researchers will ensure that interviews are paused or stopped if it is felt the subject matter is distressing. Also the interviews will be held in a safe place and a location the child feels comfortable. The child will already have access

to an IRIS+ support worker and their contact details will be confirmed at the end of the interview. children and parent/carers will be encouraged to contact the IRIS+ support worker if they want to talk about any of the issues raised in the interview.

Children may be at risk of being exposed to increased DVA if perpetrators become aware of or are involved with the study. There is always an element of risk in DVA research, particularly with children and their families. Risk to participants is minimised because they will be engaging with, or offered support via the IRIS+ support service.

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

When is the study starting and how long is it expected to run for?
September 2019 to July 2023

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
256321

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 256321, CPMS 41997

Study information

Scientific Title
IRIS+ stage II Feasibility Study

Acronym
IRIS+II

Study objectives
IRIS+ will have expanded previous research showing that general practice staff can respond appropriately to women experiencing domestic abuse by broadening the response of general practices to identify, document and refer men and children also in need of support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2019, London-Surrey Borders Research Ethics Committee (Ground Floor, Skipton House, 80 London Road, London SE1 6LH, Tel: (0)207 1048104; surreyborders.rec@hra.nhs.uk), ref: 19/LO/1132

Study design
Interventional non-randomized trial with qualitative follow-up

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Identification and referral for victims and perpetrators of domestic violence

Interventions
The IRIS+ (Enhanced Identification and Referral to Improve Safety) stage II feasibility study is part of the REPROVIDE (Reaching Everyone Programme of Research on Violence in diverse Domestic Environments) Programme.

IRIS+ will expand our previous research showing that general practice staff can respond appropriately to women experiencing domestic abuse. It will assist general practice professionals in identifying, documenting, and referring female and male patients who may have experienced abuse as victims, perpetrators, or both. It will also support children who may have been exposed to abuse to specialist services and offering them appropriate support.

Phase I of the IRIS+ study successfully developed and piloted the feasibility of the IRIS+ intervention. IRIS+ Phase I was well received by general practice professionals and patients, but the process evaluation and discussion with stakeholders and our PPI groups has driven the formulation of added elements to the intervention. Our learning from Phase I of the IRIS+ pilot needs to be integrated into the intervention and re-tested for feasibility and acceptability in the next phase of IRIS+ (Stage II).

The revised intervention model incorporates enhanced and tailored training about domestic abuse and a referral pathway for survivors and perpetrators and their children. It also includes the release of a medical records prompts system and a dedicated online resource supporting the face to face training.

In Stage II, we propose to test the enhanced model in severn general practices in two sites: Bristol and south Wales. Stage II will include the assessment of the feasibility of the reconfigured IRIS+ model. Stage II will also include an exploratory assessment of cost-effectiveness of the reconfigured intervention with feasibility data and may include a value of information analysis to inform the decision the best course of action at the culmination of stage II (i.e. recommendation for direct NHS implementation or not).

7 general practices will be recruited to the study, 3 practices who are IRIS naive will be trained on an enhanced IRIS+ model to identify and refer men, women and children, perpetrators and victims of domestic violence and abuse (DVA). 4 practices who have had previous IRIS training will be trained on a shortened version of the enhanced IRIS+ model, focusing more on the identification and referral of men and children, female victims being the focus in the original IRIS training.

We will conduct training observations, an online pre-post intervention PIM+ survey and semi-structured phone interviews with Health Care Professionals to assess feasibility and acceptability.

Intervention Type

Behavioural

Primary outcome(s)
1. Professionals' engagement with and experience of the IRIS+ training and support intervention measured using pre/post-training/intervention questionnaire at baseline and follow-up, and interviews at follow-up
2. IRIS+ patients' engagement with and experience of the IRIS+ support intervention measured using pre/post-training/intervention questionnaire at baseline and follow-up
3. Number of patient identifications, referrals and contacts (practice and agency data)
4. IRIS+ patients/HCPs' engagement with research, the value of information and completeness of data measured using pre/post-training/intervention questionnaire at baseline and follow-up, and interviews at follow-up

Key secondary outcome(s))
1. Primary health professionals' perception of changes in knowledge, skills, self-efficacy and preparedness to respond to domestic violence and abuse (DVA) measured usinpre/post-training /intervention questionnaire at baseline and follow-up, and interviews at follow-up
2. IRIS+ patients' and their children's experiences of DVA and physical and mental health and wellbeing measured using/post-intervention questionnaire at baseline and follow-up and interviews at baseline and follow-up for adults and follow-up only for children
3. Cost-effectiveness of the reconfigured IRIS+ model and value of information measured using pre/post-intervention questionnaire at baseline and follow-up

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Inclusion criteria for HCPs (health care professionals) in the PIM+ survey:
All HCPs working at or geographically linked with the pilot clinical settings will be invited to complete the REPROVIDE PIM+ survey before and after attending the IRIS+ training intervention
2. Inclusion criteria for HCPs in the IRIS+ clinician interview study:
All HCPs in the pilot clinical settings who attended at least one session of the IRIS+ training will be invited to take part in a semi-structured interview. Only those who agree will be contacted further
3. Inclusion criteria in the REPROVIDE survey and interview study for adult IRIS+ client participants:
All adult patients (> 16 years of age) who are using or/and experiencing violence/abuse in their relationship to partner(s) or ex-partner(s) and were referred to the IRIS+ service/hub by IRIS+ trained professional as a result will be invited to participate in the REPROVIDE survey and/or interview study. Only those who agree will be contacted further
4. Inclusion criteria in the interview study for IRIS+ child and young people client participants:
All children and young people between the ages of 8-18 who and/or whose parents have been referred to the IRIS+ service/hub by HCPs as a result of abuse/violence taking place in the home, who have been in direct contact with the IRIS+ children's worker, whose non perpetrating (safe) parent/carer agrees for the child to take part and who consents in their own right is eligible to take part
Young people aged 16-18 who and/or whose parents have been referred to the IRIS+ service /hub by HCPs as a result of abuse/violence taking place in the home, who have been in direct contact with the IRIS+ children's worker

Young people aged 16-18 also may be referred due to their own intimate relationships and, in this case, would be treated as adults under the IRIS+ protocol.
5. Inclusion criteria for secondary data:
With regards to the reviews of patient medical and referral data and IRIS+ client contact and referral data, the records of all patients/clients within relevant pilot practices/agency will be searched and the number of records containing identifications and referrals counted in the pilot sites for the 10 months period post-intervention (between post-delivery of first IRIS+ training intervention for HCPs and the end of feasibility phase

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
7

Key exclusion criteria
1. Exclusion criteria for HCPs (health care professionals) in the PIM+ survey:
Primary health care professionals not based at or geographically linked with the pilot clinical site (general practice) will be excluded
2. Exclusion criteria for HCPs in the IRIS+ clinician interview study:
HCPs in the pilot sites who did not attend at least one training session will be excluded
3. Exclusion criteria in the REPROVIDE survey and interview study for adult IRIS+ client participants:
3.1. IRIS+ clients who are deemed by the researcher to be put at greater risk if they take part in the study
3.2. IRIS+ clients who are deemed by the researcher to be high risk perpetrators of DVA
3.3. IRIS+ clients who cannot understand the English language sufficiently well to give informed consent and to complete the questionnaires
3.4. IRIS+ clients with a diagnosis of a mental illness that will prevent them from research engagement, e.g. active psychosis
3.5. IRIS+ clients who are incapacitated by substance abuse or serious mental illness at time of seeking consent
4. Exclusion criteria for the interview study for IRIS+ child and young people client participants:
4.1. Only safe (non-perpetrating) parent/carers will be asked for consent for their child to take part in research. If the advocate educator is in doubt as to whether the parent/carer is a perpetrator or not, then the child would not be eligible for participation. This is in order to prevent any increased control, manipulation or violence that the perpetrating parent/carer may use to influence or coerce the child in relation to the interview
4.2. The parent/carer or researcher believe that a child or young person’s involvement in the research is likely to cause significant distress or upset
4.3. The parent/carer or researcher believe that a child or young person’s involvement in the research is likely to increase the risk of domestic violence or abuse, or any form of child abuse or

neglect within the household
4.4. There are child or adult safeguarding concerns that may compromise the safety of the child or adult participants
4.5. The parent/carer or researcher believe that the child/young person does not have the capacity to understand or consent to the research process

Date of first enrolment
01/10/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Charlotte Keel Medical Practice
Seymour Road
Easton
Bristol
United Kingdom
BS5 0UA

Study participating centre
Greenway Community Practice
Greystoke Avenue
Southmead
Bristol
United Kingdom
BS10 6AF

Study participating centre
Llan Healthcare
Ball Road
Cardiff
United Kingdom
CF3 5NP

Study participating centre
North Road Medical Centre
182, North Road
Gabalfa
Cardiff
United Kingdom
CF14 3XQ

Study participating centre
Pioneer Mecical Group
Ardenton Walk
Brentry
Bristol
United Kingdom
BS10 6SP

Study participating centre
Willowbrook Surgery
5 Strathy Road
St.Mellons
Cardiff
United Kingdom
CF3 0SH

Study participating centre
Brynderwen & Minster Surgeries
Crickhowell Road
St. Mellons
Cardiff
United Kingdom
CF3 0EF

Sponsor information

Organisation
University of Bristol

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (the University of Bristol repository).

Added 04/09/2023:
The name of the repository: Research Data Storage Facility (RDSF) based at the University of Bristol.
Data will fall into two categories:
1. Personal data which will be 'closed': includes participant personal information, consent forms, interviews etc.
2. Open data – non-personal: key documents such as PIS and blank consent form etc; anonymised patient data.
Please note: Given the highly sensitive nature of DVA research, the researchers will adopt trauma-informed data-sharing approaches, still consistent with open science. Anonymised data (Anonymised transcript, as safe and appropriate, and questionnaire data) will be stored at the University of Bristol's Research Data Service Facility. Bona fide researchers will be able to access non-identifiable data upon reasonable request. Access will be subject to a data access agreement and following approval from the Chief Investigator (Prof. Gene Feder, gene.feder@bristol.ac.uk) and the University of Bristol Data Access Committee.
Consent forms were required and will be included in the closed repository and kept for 5 years.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	version v5	29/11/2017	16/03/2021	No	Yes
Participant information sheet	version v5	29/11/2017	16/03/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		01/07/2022	01/09/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes