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A trial to expand the IRIS (Identification and Referral to Improve Safety) domestic abuse programme to include men, children and young people

Submission date
14/01/2025

Recruitment status
Recruiting

Registration date
29/04/2025

Overall study status
Ongoing

Last Edited
27/03/2025

Condition category
Other

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

Plain English summary of protocol
Background and study aims
Domestic abuse affects nine million adults in England and Wales. It damages health with societal costs over £66 billion a year. A large minority of adults and children consulting general practice are experiencing domestic abuse. Survivors are more likely to tell GPs than other professionals. Getting specialist domestic abuse support can improve survivors' health, quality of life, and safety. This research aims to assess whether a general practice training and support programme for women, men and children, called IRIS+, works, provides good value for money, and whether it is possible to deliver it at scale. If IRIS+ is effective and cost-effective, the study will inform the commissioning of IRIS+ as a new service. Future implementation of a successful intervention could significantly improve the safety, well-being, and health of domestic abuse survivors and their children. This could create large downstream economic benefits for the NHS and society.

Who can participate?
GP practices participating in the IRIS programme, domestic violence and abuse (DVA) advocacy service users (adults and CYP aged 13-16) referred from these practices, and key professionals involved in the IRIS+ intervention delivery

What does the study involve?
The study will recruit and deliver IRIS+ in many general practices in three areas; Bolton and Bristol/ South Gloucestershire in England and in the Swansea Bay area in Wales. Practices will be assigned by chance to either standard IRIS (focus on women) or IRIS+ (expanded focus on women, men, and children). The study will then test whether IRIS+, compared to IRIS, is effective and cost-effective and whether delivering it on a large scale is possible by investigating the following:
1. Comparing the number of patient referrals to domestic abuse agencies from IRIS+ and IRIS practices to judge effectiveness
2. Exploring the impact of IRIS and IRIS+ support on health and health-related quality of life using routine NHS and domestic abuse agency data and interviews with adults and older children

3. Judging whether IRIS+ is a good use of public funds
4. Studying the process and effects of delivering IRIS+ in different local contexts.

What are the possible benefits and risks of participating?
Benefits and risks not given at publication

Where is the study run from?
The University of Bristol, UK

When is the study starting and how long is it expected to run for?
May 2024 to December 2027. The study is recruiting practices from February to early spring 2025, and patients will be referred to the service for 15 months.

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

Who is the main contact?
Alison Burns, Trial Coordinator, Bristol Trials Unit, University of Bristol, iris-plus-trial@bristol.ac.uk

Study website
https://irisplustrial.bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332585

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58284, NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) Grant Codes: NIHR153788

Study information

Scientific Title
A primary care system-level training and support programme for the secondary prevention of domestic violence and abuse: a multicentre cluster randomised trial with economic and process evaluation.

Acronym
IRIS+ RCT

Study objectives
The study will assess whether a general practice training and support programme for women, men and children, called IRIS+ is effective, whether it provides good value for money compared to IRIS, and whether it is possible to deliver it at scale.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/01/2025, Yorkshire and The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre , Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8021; southyorks.rec@hra.nhs.uk), ref: 24/YH/0253

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Internet/virtual, Medical and other records, Telephone

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
Domestic violence and abuse

Interventions
The IRIS+ trial will test whether the IRIS+ programme, compared to the IRIS programme, is effective and cost-effective, and whether delivering it on a large scale is possible. This will be done by delivering IRIS+ in many general practices in three areas in England and Wales. In both areas, practices will be assigned by chance to either take part in IRIS+ or standard IRIS. Using the randomised controlled trial design and mixed methods, the trial will then test whether IRIS+, compared to IRIS, is effective and cost-effective for men and children and whether delivering it on a large scale is possible.

All eligible and consenting GP practices will be randomised using a 1:1 allocation ratio to the intervention or usual care group based on the randomisation procedure. The randomisation procedure will be:
1. Stratified by centre (Bolton, South Gloucestershire/Bristol, Swansea Bay)
2. Within centre, further stratified by level of prior engagement with IRIS (more recent and no prior engagement with IRIS)
3. Minimised on the number of whole-time equivalent doctors in practice at randomisation (small: < 6500, medium: 6501 to 9999, large: 10,000 or more).
Randomisation will be carried out through an online randomisation system designed and administered by a third-party secure internet-based randomisation system (Sealed Envelope Ltd; www.sealedenvelope.com). Randomisation will be carried out by unblinded members of the research team (e.g. Trial Coordinator, Trial Statistician) as it will not be possible to maintain blinding for those team members as they will be involved in arranging the training for the intervention sites. It will also not be possible for the GP practices to be blinded to group allocation for the same reason.

Recruited GP practices in the three areas (two in England and one in Wales) will be randomised to either continue with/start the usual care IRIS Programme or receive the IRIS+ intervention. DVA agencies (Fortalice and Next Link in England and Calan in Wales), already delivering the IRIS Programme in the three areas will host and deliver the IRIS+ Programme. IRIS+, similarly to IRIS, will have two components: clinical training for GP staff on how to ask all affected patients (women, men, children) about DVA and how to refer them for specialist support; and specialist advocacy service support delivered by DVA organisations to referred patients.

Below, the data groups to be collected, the methods of assessment, and relevant consent procedures are described:

De-identified routinely collected referral, client support, health-related quality of life and service monitoring DVA agency data on women, men and children of any age.

Method of assessment: Referrals to specialist DVA agencies will be collected from DVA agency data systems for up to 15 months before and following the clinical training session in intervention practices and a matched date for control practices. Individual-level self-reported DVA advocacy service user data on adult and CYP health- and service support outcomes will be collected by DVA agencies as part of routine service monitoring between baseline and last meeting/session (case closure, circa 3 months). Data will be extracted from the DVA agency data systems' routine data at baseline, during and post-intervention by DVA agency staff. DVA agencies routinely seek consent from all individuals entering the service from participating practices, including seeking consent for sharing any personal data, such as NHS numbers. Consent is obtained by the Advocate Educator during their initial meeting(s) with the service user. Personal data (including NHS numbers) will only be shared by the DVA agencies with the unblinded members of the research team if the service user has provided consent.

Consent procedure: Use of routine non-identifiable DVA agency data does not require consent. A service level agreement will be in place with the DVA agencies.

De-identified GP practice-level health outcomes and resource use digital data on women, men and children of any age.

Method of assessment: Individual-level healthcare systems female, male and CYP data on healthcare use, and physical and mental health will be collected for 12 months before, and 12 months after referral using digital NHS data platforms. Data will be extracted from SAIL Databank and Graphnet Care Centric system (data agreements will be in place). Data collection will be facilitated by service users' NHS numbers (provided to DVA agencies by GP practices at the time of referral), who will routinely match the NHS numbers to their service user IDs. The unblinded members of the research team will then merge matched NHS and DVA agency datasets using NHS numbers.

Consent procedure: Use of routine non-identifiable digital health data does not require consent. In addition, individual-level GP-recorded DVA identification data will be extracted from a small subsample of GP practices (control and intervention), as part of the process evaluation. This will be subject to securing extra funding/capacity for this work. Non-identifiable data will be extracted from the GP electronic medical records for a period of 12 months after the delivery of the IRIS+ training intervention (matched date for control practices) to measure clinical DVA identifications during the study period. Specific codes relating to DVA victimisation or perpetration event or disclosure will be searched for. Cases identified will be checked by a practice team member (assisted by a researcher blinded to data) for DVA relevance and for the action taken by the clinician.

Consent procedure: Use of non-identifiable digital health data does not require consent. No identifiable information on-(or off-) site will be accessed by the research team.

Post-intervention interview data with IRIS+ service users (women, men and children 13+).

Method of assessment: Service users supported by the DVA agency will be given information about the study by advocate educators. A small sub-sample of IRIS+ advocacy support service users who consented to be contacted at exit from the service will be invited and recruited by a researcher to participate in an in-depth semi-structured post-intervention interview. Data will be collected in post-intervention interviews in a safe clinical or community setting by an experienced researcher face-to-face, or by telephone/online (researcher calling from a private office).

Consent procedure: Consent will be written consent. If written consent is not possible (for remote/telephone interviews) audio-recorded verbal consent will be taken. For CYP, both parental and CYP (in their own right) consent will be sought.

Post-intervention interview data with IRIS+ clinical leads/service providers/commissioners (key professionals involved with the delivery and facilitation of the IRIS+ intervention).

Method of assessment: Key professionals involved with the delivery and facilitation of the IRIS+ intervention will be identified throughout the intervention set-up and delivery by the research team, in collaboration with partner organisations delivering the intervention. Potential participants will be invited and recruited by a researcher to participate in an in-depth semi-structured interview. Data will be collected in post-intervention interviews in a safe institutional or clinical setting by an experienced researcher, face-to-face, or by telephone/online (researcher calling from a private office).

Consent procedure: Consent will be written consent. If written consent is not possible (for remote/telephone interviews) audio-recorded verbal consent will be taken.

Intervention Type
Behavioural

Primary outcome measure
Co-primary outcome measures
Referral rate, per general practice, of adult males, children and young people, to DVA agencies, measured using data extracted from the DVA agencies' data systems, for up to 15 months before and following the clinical training session in intervention practices, and a matched date for control practices.

Secondary outcome measures
1. Referral rate, per general practice, of females to DVA agencies, measured using data extracted from the DVA agencies' data systems, for up to 15 months before and following the clinical training session in intervention practices, and a matched date for control practices
2. Cost-effectiveness of IRIS+ measured using individual-level healthcare systems digital data extracted from the DVA agencies, including the EQ-5D, randomisation data, GP practice demographics, service user demographics and referral data. Digital data providers [SAIL Databank, Wales and Graphnet CareCentric, England] will merge data with data held on healthcare use, and physical and mental health (diagnosis, prescribing). Collected for 12 months before and 12 months after referral. Individual-level self-reported DVA advocacy service user data on adult and CYP health and service support outcomes will be extracted from DVA agency data systems' routine data and collected at baseline, during the advocacy service intervention, and at case closure (circa 3 months after referral).
3. Physical health and mental health (diagnosis, prescribing) measured using individual-level healthcare systems' digital data will be collected on healthcare use, and physical and mental

health (diagnosis, prescribing). Held by data providers [SAIL Databank, Wales and Graphnet CareCentric, England]. Collected for 12 months before and 12 months after referral.
4. Adult and CYP self-reported health-outcomes, HRQoL for service-user participants supported by DVA agencies, and adult DVA exposure measured using individual-level self-reported DVA advocacy service user data on adult and CYP health and service support outcomes extracted from DVA agency data systems. Health outcomes collected at baseline and at case closure (circa 3 months after referral). Service support outcomes collected at baseline, during the advocacy service intervention, and at case closure (circa 3 months after referral). Data collected by a researcher in post-intervention in-depth semi-structured face-to-face or phone/online interviews. Collected post-intervention (within 3 months after case closure)
5. Implementation scalability, mechanism of impact and reach measured using data collected by a researcher in post-intervention in-depth semi-structured face-to-face or phone/online interviews. Collected post-intervention (within 3 months after case closure). Post-intervention semi-structured in-depth interviews with adults and CYP as specified above (4.), and routine training, service monitoring and evaluation data, as specified below (6.) – data will be collected by a researcher in semi-structured face-to-face or phone/online interviews with key professionals involved with the delivery and facilitation of the IRIS+ intervention (between 12-23 months post clinical training/first referral).
6. Service delivery measured using extracted DVA agency data systems' routine data at post-intervention (18 months post-clinical training/first referral).

Overall study start date
01/05/2024

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Inclusion criteria for GP practices:
General practices participating (or eligible to participate) in the IRIS programme (commissioned in the local authority/health board area) at the time of recruitment.

Inclusion criteria for post-intervention interview participants:
1. DVA advocacy service users: female and male adults referred or self-referred from GP practices participating and supported by the IRIS+ service at the DVA agencies. CYP between the ages of 13-16 referred or self-referred from GP practices participating and supported by the DVA agencies (who have been in direct contact with the IRIS+ CYP worker) and whose non-perpetrating parent or carer agrees for the child to take part and who consent in their own right
2. Key professionals involved with the delivery and facilitation of the IRIS+ intervention

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
84 GP practices; Post-intervention interview study: approx. 45 IRIS+ service users and approx. 30 key professionals

Key exclusion criteria
Exclusion criteria for GP practices: General practices not participating (or not eligible to participate) in the IRIS programme at the time of recruitment.

Exclusion criteria for post-intervention interview participants:
Adults (> 16 years of age):
1. Deemed by the advocate educator or researcher to be put at greater risk if they participate
2. With mental health symptoms that will prevent them from research engagement
3. Adult safeguarding concerns that may compromise the safety of the child/adult participants
4. Incapacitated at the time of seeking consent
5. Unable to understand written information in English to be able to give informed consent and undergo an interview if approached

Children:
1. Children under 13
2. Parent or carer or advocate educator/CYP worker or researcher believes that a child's involvement is likely to cause distress or upset, increase the risk of DVA, or any form of child maltreatment
3. Child or adult safeguarding concerns that may compromise the safety of the child/adult participants
4. Unable to understand written information in English to be able to give informed consent and undergo an interview if approached
(v) CYP who do not have capacity to understand or consent to the research process.

Date of first enrolment
01/02/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Bristol Trials Unit
Bristol Medical School, 1-5 Whiteladies Road
Bristol
United Kingdom
BS8 1NU

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House, Tyndall Avenue
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United Kingdom
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not@available.com

Sponsor type
University/education

Website
https://bristol.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

We plan to produce two types of outputs: academic and public outputs on effectiveness, cost-effectiveness and reach, and guidance about the implementation of the IRIS+ intervention and intellectual property of the IRIS+ model. Academic outputs will include high-impact peer-reviewed journals and intend to publish around one year after the trial end date; presentations at meetings and conferences, including at DVA conferences and national primary care conferences; webinars with policymakers and practitioners in areas local to participating general practices; policy briefings for local and national policymakers; Public-facing outputs will include blog posts, news stories and accessible digital summaries of findings co-produced with our PPI groups; webinars/presentations (developed with our PPI groups) for the public including survivors of DVA.
If the trial shows effectiveness and cost-effectiveness, we will work with IRISi to scale up the intervention and develop evidence-based commissioning guidance which will be a vehicle for intervention scaling-up. We will collaborate with our partners with commissioning expertise and the ICB to enable regional commissioning. We will work with the University of Bristol Research Development and contracts team in consultation with IRISi on the IRIS+ intellectual property. The IRIS+ training materials will be part of a commissionable program.
We will disseminate our findings through existing IRISi networks of individuals and organisations implementing and commissioning IRIS and through our existing networks in the DVA sector. In collaboration with our PPI groups and the University of Bristol's communication team, we will create a user-friendly study website [https://irisplustrial.bristol.ac.uk/] hosted at the University of Bristol, to publicise blogposts, public-facing news stories, and webinars. We will develop blogs and news stories on other websites including IRISi. We will use Bluesky, LinkedIn and X (formally Twitter) to share outputs. Our Communication Officer in the Centre for Academic Primary Care and colleagues at PolicyBristol, a University of Bristol team that aims to enhance the influence and impact of research on policy and practice at the local, national and international levels, will support this work.

Intention to publish date

31/12/2028

Individual participant data (IPD) sharing plan

Domestic Violence Agency data.
All study data will be stored in compliance with the 2018 General Data Protection Regulation (GDPR) and the 2018 Data Protection Act. Data storage will be overseen by and conform to the Bristol Trials Centre's (BTC) standard operating procedures. Routinely collected raw data will be transferred every 3 months, electronically from the DVA agency (service data on health outcomes) to the Trial team at the Bristol Trials Centre (BTC) at the University of Bristol (UoB). The pseudonymised data (i.e. with NHS number) transfer will be via a secure NHS email and/or CJSM (Criminal Justice Secure Email) and stored in a secure location on the Bristol Medical School (BRMS) secure drive at the UoB. A specific folder location will be created for the raw transferred data to be stored in. Only the BTC Systems Team, Trial Statistician and Trial coordinator will have permission to access this folder.

NHS data on health outcomes will be collected from SAIL Databank Wales and Graphnet CareCentric, England. Resource use within healthcare settings for DVA-referred patients will be measured using GP-recorded digital data and will include community-based NHS visits, including

GP and nurse visits; inpatient and day-case hospital admissions, A&E and outpatient visits and medication prescribing. These data will be analysed within each data provider's Trusted Research Environment (TREs), and will only be extracted in summary reports. These data cannot be combined across TREs, and therefore, only aggregated results by sites (Swansea, Bolton, Bristol) will be combined and reported. The use of SAIL Databank and Graphnet CareCentric will enable the costing of secondary and tertiary healthcare services, as well as primary care services. Medical notes review files, reflective notes and all audio-recording files of the qualitative interviews will be stored in a secure location at the University of Bristol (UoB). All hard copies of participants' contact details and transcripts will be stored securely. Transcripts will be stored separately from participants' contact/personal details. This will all comply with BTC SOPs. For the post-intervention interview study, we will use encrypted, University-owned audio recording devices to collect interview data. Participants will be asked to consent to this prior to participating. The research team will hold a list of the identities and unique identifying codes for each of the interview participants, names and addresses etc will be removed from electronic records except where identifiable details are essential. This list will be held on a password-protected server and kept securely by the research team and will be accessible only by named research staff using a secure login and password. Hard copies of records containing personal data (eg consent forms) will be kept in locked filing cabinets in locked offices at university premises and separate from interview data. Any data that is used for analysis will be anonymised appropriately. Interview participants will be consented to any anonymised direct quotations to be used for publication and presentations. The University of Bristol's current guidance on the storage of data recommends that data including children should be kept securely for twenty-five years following completion of the research.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	13/02/2025	27/03/2025	No	No