STUDY PROTOCOL

SERB reference number	13101949
Full title of study	Experiences and perCeptions among Healthcare professionals and wOmen of NIPT in Scotland
Acronym (if applicable)	**ECHO-S NIPT**
Protocol version number and date	Version 2, 28/07/2026
Sponsor	University of Aberdeen
Funder	University of Aberdeen Roy Weir Fellowship
Has protocol been registered? If yes, give details	No

All projects must have a Chief Investigator (CI) who is ultimately responsible for the delivery of the project. The CI must be an employee of, or have an honorary contract with, the University of Aberdeen. For student projects, the student can be listed as Principal Investigator (i.e., the lead researcher).

Chief Investigator (CI)

Name	Dr Rute Vieira
Employer	University of Aberdeen

Principal Investigator (PI)

Name		
Is the PI a student?		No
PI's supervisor	Name Employer	

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Protocol approval

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The chief investigator must be:

- An employee of the University of Aberdeen;
- An employee of NHS Grampian, with an honorary appointment at the University of Aberdeen; or
- A Postgraduate Research Student (PGR) at the University of Aberdeen.

Where the chief investigator is a PGR student, it also needs to be approved by the student's main supervisor.

By signing this document I confirm that:

- I have read, understood and approve the protocol for the above study.
- I have in-date GCP / GRP / Research Integrity training, as required by Research Governance (including training on informed consent, if applicable) and will keep this up-to-date for the duration of the study.

Rute Vieira		Click or tap to enter a date.
Chief investigator	Signature	Date 13/08/2026

		Click or tap to enter a date.
Supervisor (if applicable)	Signature	Date

List of investigators / other research staff

NAME	UoA RESEARCH GROUP (OR OTHER AFFILIATION)	ROLE IN STUDY
Rute Vieira	Biostatistics and Health Data Science, School of Medicine, Medical Sciences and Nutrition	Chief investigator and Principal Investigator
Elinor Sebire	Biostatistics and Health Data Science, School of Medicine, Medical Sciences and Nutrition	Research Fellow
Andrea Woolner	Aberdeen Centre for Women's Health Research, School of Medicine, Medical Sciences and Nutrition	Co-investigator
Amudha Poobalan	School of Medicine, Medical Sciences and Nutrition	Co-Investigator
Rodolfo Hernández	Health Economics Research Unit, School of Medicine, Medical Sciences and Nutrition	Co-Investigator

List of abbreviations

ABBREVIATION	EXPLANATION
ARC	Antenatal Results and Choices
CI	Chief investigator
PI	Principal investigator
GCP	Good Clinical Practice
GRP	Good Research Practice
SERB	School Ethics Review Board
NIPT	Non-invasive prenatal testing
NHS	National Health Service
DS	Down's syndrome
ES	Edwards' syndrome
PS	Patau's syndrome
HCP	Healthcare professional
IPD	Invasive prenatal diagnosis
CVS	Chorionic villus sampling
Cf-DNA	Cell-free DNA
ECHO-S NIPT	Experiences and perceptions among healthcare professionals and women of NIPT in Scotland
UoA	University of Aberdeen

In this protocol and associated documents, we use the terms 'woman' and 'women' to refer to all individuals who have experienced pregnancy and were eligible for prenatal screening. We recognise that some pregnant individuals may identify as a different gender.

Protocol-associated documents

DOCUMENT	VERSION NUMBER AND DATE
ECHO-S NIPT Study Advert 1 – Women	v2 (28/07/2026)
ECHO-S NIPT Study Advert 2 – Healthcare professionals	v2 (28/07/2026)
ECHO-S NIPT Study Advert Email 1 - Women	V1 (13/05/2026)
ECHO-S NIPT Study Advert Email 2 – Healthcare professionals	V1 (13/05/2026)
ECHO-S NIPT Study Text only advert 1 - Women	V2 (28/07/2026)
ECHO-S NIPT Study Text only advert 2 – Healthcare professionals	V2 (128/07/2026)
ECHO-S NIPT social media text (advert)	V2 (28/07/2026)
ECHO-S NIPT Study Research Webpage Additions Text	V1 (13/05/2026)
ECHO-S NIPT Study – Recruitment Flow Chart: Identifying, Screening and Inviting Participants	v1 (13/05/2026)
ECHO-S NIPT Study – Participant Information Sheet 1 - Women	v2 (28/07/2026)
ECHO-S NIPT Study – Participant Information Sheet 2 – Healthcare professionals	v2 (28/07/2026)
ECHO-S NIPT Study – Consent Form	v2 (28/07/2026)
ECHO-S NIPT Study – Participant Invitation e-mail	v1 (13/05/2026)
ECHO-S NIPT Study – Participant Invitation Reminder e-mail	v1 (13/05/2026)
ECHO-S NIPT Study – Microsoft Form, Participant Recruitment 1 – Women (PDF version)	v2 (28/07/2026)
ECHO-S NIPT Study - Microsoft Form, Participant Recruitment 2 – Healthcare professionals (PDF version)	V2 (28/07/2026)
ECHO-S NIPT Study - Interview Topic Guide 1 - Women	V2 (28/07/2026)
ECHO-S NIPT Study - Interview Topic Guide 2 – Healthcare professionals	V2 (28/07/2026)

Lay summary

During pregnancy in Scotland, women are offered screening tests to check if there is a chance of their baby having certain conditions, including Down's syndrome (DS), Edwards' syndrome (ES) and Patau's syndrome (PS). These tests are optional and are usually offered early in pregnancy.

Since 2020, a newer test called non-invasive prenatal testing (NIPT) has been introduced. This test is more exact than earlier screening tests and can lower the need for more intrusive procedures, which carry a small risk of pregnancy loss.

However, adding this test into the screening process may make decisions harder for both women and the medical team. It may also affect how information is understood and how people feel during the process, particularly the high levels of upset at different stages of these decisions being made. This study will involve online interviews with women who were offered NIPT and the medical team involved in delivering it in Scotland. We will chat about their experiences of screening, understanding of the information, and decision-making. Participation is voluntary and involves a one-hour online interview.

The findings will help identify ways to improve how screening is offered and communicated.

1. Introduction

Pregnancy screening for Down's syndrome (DS), Edwards' syndrome (ES) and Patau's syndrome (PS) is routinely offered in the UK through the NHS. These programmes aim to identify pregnancies with a higher likelihood of these conditions, being nationally coordinated since the early 2000s.[1] In January 2016, the UK National Screening Committee (UK NSC) recommended an evaluative roll-out of non-invasive prenatal screening (NIPT) into the existing antenatal screening programmes for these conditions.2,3 NIPT was recommended as a second-line screening test, offered to pregnant women after the original combined or quadruple screening test (known as first-line screening). Consequently, women who receive a 'higher chance' result from first-line screening are able to have an option of no further testing, NIPT as a secondary screening test, or an invasive prenatal diagnosis (IPD). IPD consists of an amniocentesis or chorionic villus sampling (CVS) and comes with a small procedural related risk of miscarriage. Figure 1 shows the current screening pathway for these conditions in Scotland.

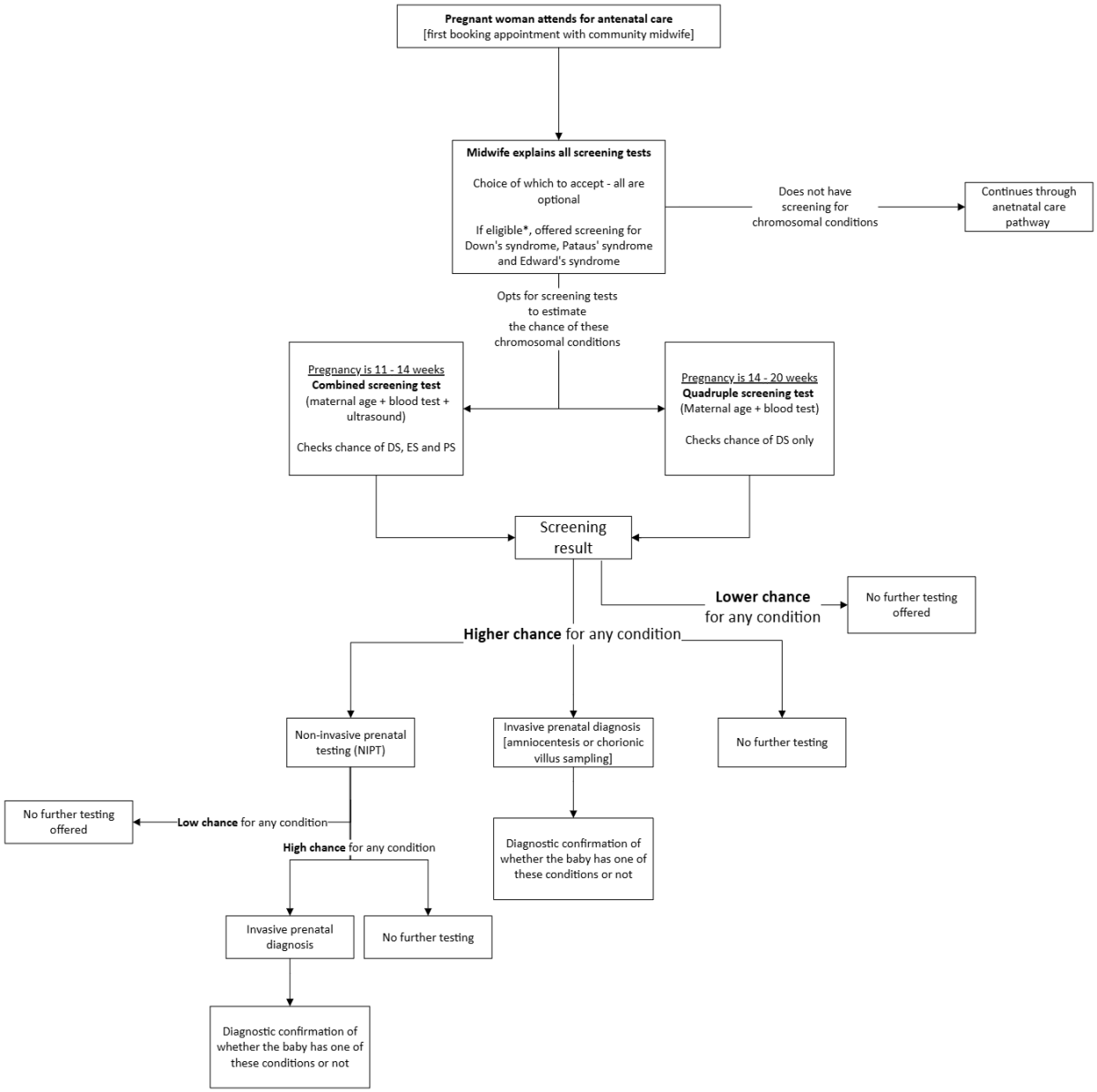

Figure 1: Screening pathway for congenital chromosomal conditions (Down's syndrome, Edwards' syndrome and Patau's syndrome) as offered in the NHS in Scotland since September 2020. pregnancies are eligible for first-line screening if they were booked for initial antenatal care before 20 weeks gestation, and they had an ongoing pregnancy at the time of screening).*

NIPT is a much more accurate screening test than current first-line screening methods and has the potential to reduce the number of women offered IPD within the screening pathway. The decision to implement NIPT as a secondary screening test was taken by the UK NSC, in part to reduce the number of women unnecessarily undergoing IPD and, therefore, to reduce the number of pregnancies at risk of a miscarriage from these procedures.[3]

A systematic review and cost-consequence assessment of NIPT for DS, ES and PS in the UK provided the evidence base for recommending the evaluative roll-out of NIPT in 2016.[4] The evidence suggested that implementing NIPT as a secondary screening test was also the most cost-effective approach, particularly given that the technology would be introduced across the UK and funded by the NHS.

NIPT was implemented into the Scottish antenatal screening programme for DS, ES and PS, for singleton and twin pregnancies, in September 2020. It was implemented in Wales in 2018 and England in 2021, and there is currently no national screening programme for these conditions in Northern Ireland.

While NIPT offers improved accuracy and may reduce the need for invasive testing, its introduction also changes how screening is experienced and delivered. It adds an additional step to the screening pathway, which may influence how information is communicated and understood, as well as how decisions are made. Previous research in other populations has found that NIPT implementation can affect how Healthcare Professionals (HCPs) communicate screening options and how women interpret the risk and test results.[5]

Understanding the impact of this implementation is important, and there is an ongoing quantitative evaluation by Public Health Scotland (PHS) to understand how NIPT implementation in Scotland may have impacted the numbers of tests received and pregnancy outcomes. However, there is a lack of qualitative research within this Scottish context. Stakeholders of the PHS-led NIPT evaluation have called for qualitative research to understand the impact of NIPT implementation on decision-making during pregnancy, and to gather in-depth understanding of experiences of prenatal screening and care.

Previous qualitative work using publicly available online forum data (Mumsnet.com) has suggested that waiting for NIPT results can be associated with anxiety and uncertainty among women, and that understanding of screening information may be limited. It is also acknowledged that such data may not fully reflect the experiences of individuals within the NHS in Scotland (*manuscript under review*).

Moreover, a previous mixed-methods study to understand experiences of and preferences for NIPT prior to its NHS implementation found the test turnaround time to be a key limitation to acceptability, with women reporting elevated and prolonged anxiety during testing.[6] These findings are echoed by international research in England and France that suggested many women experienced stress linked to these screening pathways, and suggested preferences for different ways of offering NIPT, including as a first-line test.[7] Research from other populations also suggests that women feel isolated, anxious and may not always fully understand the tests they are being offered or have undergone during pregnancy.[8,9] Investigating whether these experiences exist within the Scottish population is an important part of evaluating the impact of this new screening test.

Previous research has also highlighted the multi-factorial nature of decision-making during pregnancy, which includes factors such as previous healthcare experiences, perceptions of risk, worry and need for reassurance, and the test characteristics.[6,10]

Despite the available research, there is a lack of understanding of women's experiences of NIPT in the Scottish context, where health system structures, cultural context, and service configuration may shape perceptions and decision-making differently.

The introduction of NIPT has raised a range of ethical and practical considerations.[11] Ensuring informed and autonomous decision making throughout screening delivery, and with NIPT specifically, requires understanding of how women and HCPs experience and communicate the test options and implications, and whether current second-line implementation of this test supports informed choice, timely diagnosis and equitable access.

Despite the introduction of NIPT into the Scottish screening programme, there is limited qualitative research exploring the experiences of women and healthcare professionals within this specific context.

This study aims to explore the experiences and perceptions of NIPT within the NHS in Scotland. It will use in-depth semi-structured interviews with women who were offered or had NIPT and HCPs involved in delivering the test. The study will explore the understanding of screening information, experiences of decision-making, and views on how the current screening pathway operates in practice. This work forms part of a wider programme of research to evaluate the implementation of NIPT in Scotland.

Understanding perceptions of NIPT in this specific population context is important for evaluating the national-level screening test changes and ensuring any recommendations or policy changes are tailored to the population and service providers' needs.

2. Aims and objectives

Research question:

What are the **experiences** and **perceptions** of women offered non-invasive prenatal testing (NIPT), and of healthcare professionals (HCPs) involved in delivering NIPT screening within the National Health Service (NHS) in Scotland?

Aim:

To explore the experiences and perceptions of NIPT among women and HCPs within the NHS antenatal screening pathway in Scotland.

Objectives:

To conduct qualitative, in-depth, semi-structured interviews with women and HCPs to:

1. Explore experiences and perceptions of the antenatal screening pathway, including the role of NIPT, within the Scottish antenatal screening pathway for DS, ES and PS;

2. Explore how screening information about NIPT is communicated and understood;

3. Explore factors that influence decision-making during the pregnancy screening pathway;

4. Explore perspectives on how the current screening pathway operates in practice, including what works well and areas for potential improvement.

Outcomes:

1. Using thematic analysis of interview data, the study will:
    a. Identify key themes relating to experiences of NIPT within the Scottish screening pathway;
    b. Identify factors influencing understanding, communication, and decision-making;
    c. Explore how experiences may vary across different contexts (e.g. rural and urban settings, different population groups, and healthcare roles);
    d. Inform recommendations for improving the delivery and communication of antenatal screening services in Scotland.

3. Overview of study design

This is a qualitative research study using in-depth semi-structured interviews. It has two key groups of participants:

1. Women (and other individuals who have experienced pregnancy) who were offered or had NIPT within the NHS (they do not have to have had the test to take part);

2. HCPs delivering NIPT within the NHS (including all aspects of screening – communicating the offer of screening, undertaking the test, delivering the results/follow-up);

This research will only focus on screening delivered within **Scotland**.

<u>Stages:</u>

1. Purposive and snowball sampling will be utilised for the recruitment of both women and Healthcare Professionals (HCPs). Study adverts for participant recruitment will be sent out to identified organisations*, charities and groups (including professional forums) to be advertised on their platforms and to their members. These organisations (via gatekeepers or directly) will be contacted about the study via email and asked to share the adverts on their public pages/email chains where possible. Researchers will also attend coffee mornings/social events, where invited, to speak about the research to different communities, answer any questions, and invite them to register for the study. Adverts will also be posted by researchers on the study team through social media platforms (Facebook, LinkedIn) and appropriate social media groups will be contacted (e.g. Facebook groups 'Glasgow Mums Group', 'Mums in Aberdeen and Shire') to post adverts and invite participants for the research. The research study webpage, hosted by the University of Aberdeen, will also be edited

to contain information about the current study (lay summary and participant information sheet) and include the study advert (Congenital Conditions in Scotland: Screening, Pregnancy Outcomes and Child Health Research | The Institute of Applied Health Sciences | The University of Aberdeen). Study adverts will be posted within University of Aberdeen buildings (physical posters), and email requests for study recruitment advert posts within the Staff News/newsletters for the university after obtaining ethical approval. There are separate study adverts for each group – women and healthcare professionals which will be shared in separate posts. A small number of local communities will be contacted to facilitate in person recruitment of group 1, using printed versions of the PIS, with the researcher helping participants to register online and answering any questions. For recruitment of HCPs specifically, this will focus on posts within LinkedIn, shared by the research team and related colleagues, and maternity professional organisations based in Scotland will be contacted to ask them to distribute the study advert link with their members. Snowball sampling will be important for recruiting HCPs, who will be asked to share the advert with their relevant colleagues.

2. The study adverts (poster or text-only, depending on formatting needs) will contain a link to a Microsoft Form which will provide the participant information sheet (PIS), and questions for registering interest in participating in the research. There will be two Microsoft forms, one for women and one for HCPs, signposted from the two adverts directed at each group of participants. The forms will also contain a link to the overall research team webpage, hosted on the University of Aberdeen's website. Within the Microsoft Form, after reading the PIS, if they are interested in participating, they will be asked to complete the online form (collecting basic inclusion criteria screening questions, and if eligible, collecting email address/telephone number and optional demographic information). We envisage 20-30 participants from each group (1. Women, 2. HCPs). The final sample size will be determined by the principle of thematic saturation, defined as the point at which no new themes or meaningful insights are identified in consecutive interviews. If data saturation is not obtained within this sample, the sampling frame will be reworked to include more participants.
3. Interested eligible respondents, based on the Microsoft Form response to the initial advert, will be sent an introductory invitation email with another copy of the participant information sheet and a consent form attached. They will be invited to participate in an in-depth semi-structured interview held online and offered the opportunity to discuss the PIS and any other questions with the researcher before signing the consent form and being interviewed. Email communication with the researcher will set up a mutually suitable time and date for the interview. A signed copy of the consent form (signed electronically – initialled and typed signature) will be requested by the researcher and returned via email before the interview if held online, and if the interview is being held in person, then the participant will be able to sign a printed version of the consent form before the interview commences. Contact and interviews will be made by telephone if requested by the participant.

Participants will not receive payment for participation but will be offered a £25 LoveToShop voucher as a token of appreciation for their time and contribution to the study. This amount is intended to compensate for the time required to take part in a one-hour interview and is not considered to be coercive. If the interview is conducted in person (participants local to Aberdeen City and Aberdeenshire only) and the participant needs to travel then their travel costs will be covered by the study. Travels costs for those within this area will be reimbursed for public transport (bus/rail) or personal car travel to/from the interview site. The Car Mileage rate is 55p per mile, with claims being limited to the cost of standard rail travel for the equivalent journey (in line with university travel expenses policy). Journey and mileage details must be provided. We will not refund the cost of motoring offences e.g. speeding tickets and parking fines. Taxis will not be reimbursed unless a reasonable method of public transport is not available. Travel by rail should be in standard class. All tickets and receipts should be retained and a copy provided to the research team for claiming travel expenses.

Each completed interview transcript will be pseudonymised by the researcher (ES), allocating the transcript a unique ID number and any personal information for the participant (including name/contact details) will be deleted from the transcript. The pseudonymised key (relating the transcript's unique ID number and participant personal information) will be kept in a password protected file in the study folder until the end of the study. When the pseudonymisation key is deleted at the end of the study the interview data will become

anonymous. Anonymised interview transcripts (without pseudonymisation key) and associated research data will be securely stored for up to 10 years in line with University of Aberdeen data retention policies. These data will not contain information that could directly identify participants. Publications and lay summaries of the final research findings will be uploaded to the research webpage for participants (and any other members of the public) to access and study updates/findings will be shared with the communities and organisations that were contacted during recruitment, for interested participants to find out about the findings of the study they were involved in. There will be no further direct contact with the participant unless information in the transcript needs to be clarified or to arrange the delivery of the voucher.

*Identified organisations and charities will be contacted by the researcher (ES) via email, briefly explaining the study and asking the organisation to post the study advert on their websites or within newsletters (providing both the study advert and text, to suit different formats). ES will also make contact with leaders of community groups/organisations throughout Scotland to try and engage women from a diverse range of backgrounds and minority ethnic groups. Members of the study advisory group will also be asked to facilitate recruitment by sharing the study advert/text on their organisation's platforms/through their social media pages and with their colleagues. The organisations/charities identified include:

- Charities/organisations will be contacted to help with the recruitment of women and other individuals who have experienced pregnancy:
    - Antenatal Results and Choices (Scottish representative sitting on the study advisory group, provides information for women and partners undergoing screening/diagnosis and baby loss in the UK).
    - Scottish National Childbirth Trust (NCT) groups (through Facebook groups and their official website), including NCT Aberdeen City and Shire.
    - Scottish parenting forums on Facebook – a search of relevant groups will be used to identify Scottish parenting groups. Open groups will be posted in by the researcher (ES) to advertise the study (if it meets the group's rules) and closed/private groups will be contacted through the page admin to request the gatekeeper to post the study advert.
    - Down's Syndrome Scotland charity (representative sitting on advisory group) requested to advertise the study on their webpage.
    - Amma Birth Companions - support women in Glasgow facing barriers like poverty, isolation, or language.
    - Other organisations/charities and community groups for people from minority ethnic backgrounds e.g. Passion4Fusion (Edinburgh-based), Aberdeen Ethnic Minority Women's Group CIC and organisations/charities focussed on support for women and parents.
- Professional organisations (to target recruitment of maternity healthcare professionals in Scotland):
    - Scottish Early Pregnancy Network
    - Royal College of Obstetricians and Gynaecologists, Scottish branch
    - Tommy's the pregnancy and baby charity.

4. Participant identification, selection and recruitment

4.1. Inclusion / Exclusion criteria

1. For women and other individuals who have experienced pregnancy who were offered or had NIPT:
Individuals will be included if they were pregnant and had their first antenatal booking appointment (community midwife appointment) on or after 28th September 2020, in a Scottish NHS health board and were offered or had NIPT. They do not have to have accepted the test to take part.

This means individuals will be included if they:

1. Attended for their first antenatal care appointment on or after the 28th of September 2020 AND
2. Were residents of Scotland at the time of accessing antenatal care (including NIPT) AND
3. Were offered or had NIPT through the NHS (they do not have to have accepted NIPT) AND
4. Adults over 18 years of age

Exclusion Criteria:

1. Individuals who moved out of Scotland during their antenatal care (before screening for the 3 trisomy conditions was finished) OR
2. Individuals who are currently pregnant

For women and individuals who have experienced pregnancy (group 1) we will facilitate interviews in their own language if they wish. Researchers will arrange for an appropriate interpreter from a charity, within the university research staff (an amendment will be made to the SERB application in this case), or from a university approved interpreter service if this is not possible. Healthcare professionals will not be offered interpretation for interviews as they should have a proficient level of English as required within their role.

Individuals who are currently pregnant are excluded to minimise the potential for additional emotional burden or distress during an ongoing pregnancy, particularly when discussing screening decisions and experiences related to non-invasive prenatal testing (NIPT). This approach aims to avoid influencing current decision-making processes and to ensure that participation does not impact ongoing care or wellbeing.

Due to resource constraints, including the lack of funding, this study is limited to mostly conducting online recruitment and interviews and has a low capacity for being able to arrange for translation and interpretation services. Within these constraints, the research team will make an effort to mitigate this limitation by engaging with a wide range of community organisations to support inclusive recruitment, offering a small number of local in person interviews, offering telephone interviews where requested, and arranging for interpretation services to provide interpretation for those who don't have English as a first language.

2. For Healthcare Professionals involved with NIPT screening:

This includes community midwives responsible for delivering the pregnancy booking appointments and screening information, specialist screening midwives, sonographers that undertake ultrasound scans during screening, Consultants in fetal medicine and genetic counsellors.

Specifically, the inclusion criteria include:

1. Maternity healthcare professionals involved in offering or delivering antenatal screening through the NHS in Scotland (including nurses, sonographers, midwives, consultants, genetic counsellors)

Exclusion criteria:

1. Individuals whose work pertains outside of Scotland

4.2. Sample size

Given the qualitative nature of this study, a formal statistical sample size calculation is not required. Instead, a purposive sampling approach will be used, guided by a predefined sampling frame (Appendix, Table 1) to ensure a diverse range of participants and experiences are included. Participants will be recruited from two groups:

1. Women and individuals who have experienced pregnancy who were resident in Scotland, attended antenatal care from 28th September 2020 onwards, AND were offered or had NIPT through the NHS.
2. Healthcare professionals working within the NHS in Scotland with experience of offering or delivering NIPT in antenatal screening.

We will aim to recruit approximately 20-30 participants in each group.[12] The final sample size will be determined by the principle of thematic saturation, defined as the point at which no new themes or meaningful insights are identified in consecutive interviews. [13] Recruitment will continue until thematic saturation is reached or until the end of the data collection period, whichever occurs first. The proposed sample size is consistent with similar qualitative studies exploring experiences of NIPT and antenatal

screening.[5,7,14] For group 1 (women and individuals with experience of pregnancy), the sample size will also be shaped by the ability to recruit sufficient participants across key demographic groups (see Appendix 1 sampling frame) to ensure the sample is broadly representative of the Scottish population. For example, in major cities in Scotland approximately 20% of the population identifies as an ethnic minority.[15] Our sample will aim for at least 20% to be individuals who identify as an ethnic minority (not White British), e.g. 6/30 participants. For group 2 (HCPs) we will aim for at least one representative from each of the key job roles that might be involved with NHS NIPT screening: midwives, sonographers, consultant obstetricians, and genetic counsellors, and across at least 3 different NHS health boards.

Purposive sampling will be used alongside snowball sampling, to select participants from those who express interest, ensuring diversity across key characteristics such as age, ethnicity, geographic location (including rural and island communities), and professional role (for healthcare professionals). The sampling frame will be used iteratively throughout recruitment to guide selection and ensure a broad range of perspectives are represented.

Charity and community groups representing and supporting people that are part of ethnic minority groups in Scotland will be contacted to engage participants from these backgrounds in the study.

4.3. Identifying / screening / inviting potential participants

Participants will be identified and recruited through study adverts and social media posts (see study adverts 1 and 2, study adverts text only 1 and 2, social media post text, and research webpage text documents attached) posted on social media groups, forums and appropriate professional, charity and family representative webpages (detailed in section 3). Snowball sampling from adverts being shared within communities and colleagues will be used. Participants will be purposively selected from those expressing interest, using the sampling frame to ensure a diverse range of participants across key characteristics.

Organisations and community groups will be identified through existing networks, advisory group input, and online searches (examples provided in section 3). Initial contact will be made via email by the research team, providing information about the study and requesting permission to share study advertisements with their members or on their platforms. Permission will be sought from group administrators (gatekeepers) before posting study advertisements in closed or moderated online groups. No direct messaging of potential participants by researchers will take place. No data will be collected from social media platforms or online groups directly. The research team will not access, monitor, or analyse any posts, comments, or user interactions within these platforms. Participation in the study will be entirely voluntary, and individuals will self-identify by choosing to follow the study advert link and register their interest via the secure Microsoft Form. At organisation or community request (following initial researcher email contact), a brief in-person or online presentation about the purpose of the study, eligibility and invitation for registering will be given by the study researchers. This will help recruitment of participants who will not see the advert online/through social media. Advisory group members, representing Antenatal results and Choices, Down's syndrome Scotland and healthcare professionals in NHS Grampian have agreed to help with recruitment through their own organisations/colleague networks. The Down's syndrome Scotland advisory group representative has suggested researchers attend their online coffee morning to present the research and help recruitment from those that are part of this community. Physical study adverts will also be printed and placed in the University of Aberdeen buildings. The research team and study advisory group will also be asked to share the adverts within their own platforms (social media, webpages) and to relevant colleagues for circulation.

Most recruitment and participation will rely of digital access (online sign-up and interview), which may exclude some groups and is a limitation of the study. To help cover a broader spectrum of participants, we will engage with a local women's group/community organisation offer in-person registration (the researcher will fill in the Microsoft Form on behalf of the participant) and interviews. A small number (around 5 participants) will be sought from in-person interviews to improve inclusivity and depth. We will contact local organisations and groups such as NCT Aberdeen City and Shire (offer various social groups for new parents) to offer an information session and Aberdeen Ethnic Minority Women's Group CIC will be contacted to also offer information sessions and in person registration/interviews. Printed study advert posters/leaflets will also be given out to local community groups and organisations to advertise recruitment for the study.

For those participants in group 1 whose first language is not English we will facilitate translation with a University of Aberdeen researcher (amendment submitted to SERB in this case), or with an approved professional translation service during the interview.

The study adverts (attached) will include basic study information and inclusion criteria, and a QR code/URL link to a Microsoft Form (1 and 2 attached) that will ask the potential participant to read the Participant Information Sheet provided as a PDF document (PIS 1 and 2). There are two Microsoft forms, for separately recruiting women and individuals who have experienced pregnancy, and HCPs. In the forms there will also be a link to the University website for more information about the research and research group (see webpage changes text, attached). If the potential participant reads the PIS and wants to participate, the Microsoft Form will collect basic inclusion information and contact details (participants full name and email address) so they can be emailed by the researcher. If the participant prefers to be contacted by telephone, their phone number will be collected, and the researcher will call them to follow up about their involvement in the study. Where more individuals express interest than are required, participants will be selected for interview based on the sampling frame to ensure diversity of experiences and backgrounds.

Once the potential participant has provided their contact details in the form, they will also be asked to provide some basic demographic information within the Microsoft Form (age, ethnicity, religion). This information is optional to provide and will be used along with the sampling frame (appendix 1) to select interview participants from a diverse range of backgrounds. Consent for collecting this information is asked for within the Microsoft Form, detailing why we want to collect the information and where it will be stored. If this information is provided it will be kept, along with the potential participants name and email address, in the secure password protected Excel file only accessible by the study team. This information will be kept for the duration of the study and deleted at the study end. Individuals who are not required for an interview (because the study has reached saturation from their demographic group) will be emailed to thank them for registering and let them know they are not needed in the study and that their details will be deleted. The HCP Microsoft form will ask them to provide their job description and the NHS health board they work in, as well as age, ethnicity and religion. This will also be used to select a range of professionals for interview and will be deleted along with name and contact details following the study end.

After registering their interest in the research using this form, the potential participant will be sent a study invitation email (see study invite email 1 and 2) by the researcher (ES) which will include the PIS (PIS documents 1 and 2 v2) and consent form (Consent Form v2) for their review. The participant will be offered the opportunity to discuss the PIS with the researcher prior to signing the consent form. Potential participants who wish to take part will be asked to confirm that they meet the inclusion criteria when responding to the researcher (ES), and eligibility will be confirmed by the research team prior to interview. If the participant is eligible, then email contact with the researcher will be used to organise a mutually suitable time for interview. This will also be done via phone call if requested by the participant. Participants will be given sufficient time to review the PIS and consider participation before the interview is scheduled, with a minimum of 48 hours between receiving the information and taking part, unless the participant explicitly requests an earlier time.

The researcher (ES) will follow up on the introductory email with up to one additional email if no reply is received within 7 working days (see follow up email document). If there is no response from the follow-up email in 14 working days after this, then the contact information collected from the form will be deleted.

Participants will be given at least 48 hours to consider the participant information sheet and consent forms sent within the invitation email, the invitation email will also explicitly offer the opportunity to discuss the participant information sheet with the researcher to answer any questions before deciding whether to take part in an interview.

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Study recruitment will be conducted during regular business hours, but the data collection team members will determine an appropriate time for interview that is convenient for the study participant and minimise disturbances.

Participants will be asked to sign (by initialling each statement and typing their name) and return the consent form electronically via email in advance of the interview if being held online. For in person interviews, the participant may sign a printed copy of the consent form provided by the researcher before the interview starts. The researcher will confirm consent using the signed consent form at the beginning of the interview (the researcher will also sign the consent form to acknowledge this) or take oral consent if required prior to interview (logged by the researcher in the consent form). A £25 LoveToShop voucher will be sent to the participant (via email or post) following the interview, if the participant withdraws during the interview or they are unable to complete the interview they will still be sent the voucher. For the small number of in-person interviews (participants local to Aberdeen City and Aberdeenshire only), we will reimburse travel costs to/from the interview site.

Travels costs for those within this area will be reimbursed for public transport (bus/rail) or personal car travel. The Car Mileage rate is 55p per mile, with claims being limited to the cost of standard rail travel for the equivalent journey (in line with university travel expenses policy). Journey and mileage details must be provided. We will not refund the cost of motoring offences e.g. speeding tickets and parking fines. Taxis will not be reimbursed unless a reasonable method of public transport is not available. Travel by rail should be in standard class. All tickets and receipts should be retained and a copy provided to the research team for claiming travel expenses.

A study flow chart (attached) also outlines the process described above for identifying and recruiting participants.

4.4. Ineligible and non-recruited participants

Potential participants that are registered with name/email address and basic demographic information through the Microsoft Form will be invited to the study via email and asked to review the participant information sheet and indicate if the criteria apply to them to determine eligibility. Potential participants that have reached out to the researcher but are ineligible will be informed via email. All ineligible and non-recruited participant data held in the secure project folder (names, emails, inclusion/exclusion criteria) will be permanently deleted at the earliest available opportunity.

5. Randomisation and blinding

N/A

6. Withdrawal

Participants who provide their contact details via the initial Microsoft Form may request for these details to be deleted at any time prior to the study end by contacting the research team.

Participants may withdraw from the study at any time without providing a reason. They may withdraw their data up until the point at which the study ends (April 2028). Interview transcripts will be pseudonymised (unique ID number given to each transcript and name/contact details removed), and the pseudonymisation key with ID numbers and corresponding personal details will be kept in a separate secure study folder until the end of the study. Following the study end, the pseudonymisation key will be deleted (deleting all personal information), and it will not be possible to identify or remove individual data from the dataset after this point. Participants will also not be able to withdraw their data if it has been published before the study end date.

To withdraw, participants can contact the research team via email or telephone using the contact details provided in the Participant Information Sheet.

7. Data collection

Recruitment data

The online University of Aberdeen software, Microsoft Forms, will be used to log the details of participants interested in the study. A small number of in-person registrations via local community groups (as described

in section 4) will also be facilitated by the researcher, filling in the Microsoft Form on behalf of the participant. Printed versions of the participant information sheet and consent form will be provided to the participant prior to in person registration. Any questions about eligibility can be discussed with the researcher present. Information sessions with community groups (e.g. with DSS) will be attended by the researchers to explain the study and invite participants for recruitment. If this identifies individuals that want to take part but don't have access to a digital device, then contact details will be taken to provide that individual with the printed participant information sheet and consent form to read, and interviews can then be conducted by telephone. All participants will be offered the opportunity to discuss the PIS with the researcher before signing any consent forms.

The information collected will include:

- Full name
- Email address (or other preferred contact e.g. telephone number)
- Those filling in the HCPs recruitment form will be asked to provide their job title and NHS health board.

Other information will be requested, but is optional to provide in the form:

- Ethnicity
- Religion
- Age (years)

The form will ask the participant to first read the Participant Information Sheet and if they feel they meet the eligibility criteria for the study they will be asked to provide their name and contact information (email address or telephone number if preferred) and the other information detailed above.

Answers received to this form will populate an online Excel file (within the study Teams page, that only researchers on the study team have access to). Once an answer is received, it will be transferred from the online Excel document to a secure password protected Excel file within the university shared folder space only accessible to the study team (held in the UoA secure study file space) – consent to store this information and to contact the potential participant about the research will also be detailed in the Microsoft Form and PIS. Responses to the form stored online will be deleted once transferred to the secure file.

Semi-structured interviews

Study data collection will be in the form of semi-structured interviews. Interviews will follow a topic guide, allowing participants to raise issues that are important to them while ensuring topics are covered across interviews (Topic guides 1 and 2). The interviewer will monitor for signs of distress and respond in accordance with the study distress protocol (see Section 11.1). The lead researcher (ES) will conduct an initial pilot interview with the senior qualitative expertise support and training of co-investigator Amudha Poobalan, to ensure ES is confident to conduct the interviews and the interview topic guide works as intended.

These interviews will be conducted online, and the University of Aberdeen's Microsoft Teams software will be used to record the interview and auto-generate a transcript. Immediately after a Microsoft Teams recording, the researcher will delete the video component of the recording while keeping the audio recording and auto-generated transcript. Recordings will be downloaded from Microsoft Teams and stored securely on the University servers. Recordings will then be deleted from the online platform.

A small number of interviews will be conducted in person, where we have recruited through local women's groups and other organisations. Participants will be met at their preferred meeting place (public place e.g. Union Square Aberdeen or community premises), or the interview will be conducted at the University of Aberdeen Campus, in a booked meeting room. A university of Aberdeen audio recorder will be signed out and used for the audio recording of the interview. This recording will be uploaded to the researcher's

computer and stored securely in the project folder until it has been transcribed by Panopto software, similarly to the Teams recordings. The audio recording will be deleted from the device. If conducted at the university, travel expenses will be reimbursed to the participant, within the limits mentioned in section 4.2.

Among interviews with women and individuals who have experienced pregnancy (group 1), they will be asked about their religion, number of children, age and highest level of education, as beliefs and personal circumstances/context can influence decision making and perspectives around this topic. This information will be recorded within the interview transcript. This will help the researcher to understand the context of their experiences and when analysing the data, but this personal information will be kept confidential and not provided in any published outputs from the study. Online interviews will be conducted with the cameras on (video component to be deleted after the interview), however if the participant would prefer to have the camera off then this will be allowed after the consent process has been completed.

After the interview, all participants will be pseudonymised by assigning a unique ID number which will be used as an identifier on interview transcripts and any field notes associated with specific participants. The information connecting the participants to their ID number will be kept in a separate password protected Excel file (pseudonymisation key) in the secure study folder, whilst their details will be deleted from the initial Excel file used before interview. The study team will ensure that no details are included in the transcript that could identify participants.

Transcription (including cross-checking and clean-up of the auto-generated transcripts) will be conducted by the lead researcher (ES) and/or Panopto software to provide an auto-generated transcript based on the recording, or an approved third-party transcription service by the University of Aberdeen. Audio recordings will be destroyed at the end of the study.

Any handwritten notes made during interviews or other parts of the study, and any other hard copies of study materials, will be stored in the researcher's (ES) locked cabinet in a locked office at the University of Aberdeen. All electronic files, including internal documents, will be stored on a UoA secured shared drive only accessible to the research study team.

General

Audio recordings will be securely stored and transcribed using University-approved software or services. Transcripts will be checked for accuracy by the researcher against the original recording. The Teams recording and the downloaded video will be deleted from the online platform once the audio clip and automatically generated transcripts (which will be reviewed and corrected for accuracy) have been uploaded to the shared drive.

If potential participants provide their contact details via the initial Microsoft Form but at a later date would like these removed, this can be requested, and the research team will delete these.

Once a participant has completed an interview and a unique ID has been assigned to them, their contact details and name (and any other identifiable personal information on file) will be moved to the pseudonymised data key Excel file by the researcher (ES). All personal details within this file will be deleted at the end of the study.

8. Analysis

No quantitative statistical analyses are planned as part of this study.

Interview transcripts will be analysed using reflexive thematic analysis, following the approach described by Virginia Braun and Victoria Clarke.[16,17] This is appropriate for exploring participants' experiences and identifying patterns of meaning across the dataset. Differences between women's (and individuals with experience of pregnancy) and healthcare professionals' accounts during interview will be identified as part of this analysis - highlighting differences as well as similarities in terms of experiences and areas needing improvements. Where accounts contradict or support each other this will be highlighted.

Analysis will be conducted primarily by ES using NVivo software (licensed by the University of Aberdeen), with senior qualitative oversight by co-investigator AP. The analytic process will involve:

- familiarisation with the data through repeated reading of transcripts;
- inductive coding of the data;
- generation of initial themes;
- iterative review and refinement of themes;
- defining and naming themes;
- producing a narrative account of the findings.[16]

Coding will be primarily inductive and data-driven, allowing themes to be developed from participants' accounts rather than being imposed *a priori*. Reflexivity will be an integral part of the analytic process. The lead researcher (ES) will maintain awareness of their assumptions and potential influence on data interpretation, and analytic decisions will be documented throughout. To enhance the rigour of the analysis, emerging codes and themes will be discussed regularly with members of the research team. ES (Research Fellow) has undertaken University of Aberdeen Qualitative Health Research Masters course and has previous experience of thematic analysis in their PhD research. The study is also supported in qualitative methodological expertise by study co-investigator AP, and Advisory Group member Michelle Peter (MP). A subset of transcripts will be reviewed by a second researcher to support the development and refinement of themes. Discrepancies in interpretation will be discussed and resolved through team discussion. Analysis will focus on identifying patterns across participants' experiences, including similarities and differences between groups (women and individuals who have experienced pregnancy, and healthcare professionals), and across different contexts (e.g. geographic location and service delivery settings). Anonymised verbatim quotes will be used in the study output.

To minimise the loss of data, all files and documents relating to the study will be kept within the University of Aberdeen's secure shared drives, which are backed up regularly.

9. Data management

This study will not involve access to medical records. However, it will involve the collection of personal data through interviews about participants' experiences of pregnancy screening, which may include information relating to health and pregnancy. These data will be handled in accordance with data protection regulations and managed as described in this protocol. All electronic data will be stored on secure, password-protected University of Aberdeen servers, accessible only to members of the research team. Data will be handled and stored using University-approved secure systems where applicable.

Once a participant has been interviewed, and a transcript generated, it will be given a unique study ID by the researcher (ES) which will be used on all transcripts and references to this participant (pseudonymisation). Identifiable data relating to each unique ID (e.g. names and contact details) will be stored separately from interview data (pseudonymisation key). The pseudonymisation key will be retained securely for the duration of the study and deleted at study completion. All data for those participants who weren't interviewed or are ineligible will be deleted.

Interviews will be transcribed into Microsoft Word documents and uploaded into university NVivo software to manage qualitative data analysis.

All transcripts created on Teams will be deleted as soon as a copy is saved into the secure computer drive.

All paper files and copies from this study will be locked securely in filing cabinets in the researchers (ES) office at the University of Aberdeen. Anonymised interview transcripts (without pseudonymisation key) and associated research data will be securely stored for up to 10 years in line with University of Aberdeen data retention policies. These data will not contain information that could directly identify participants.

9.1. Transfer of data

There will be no transfer of data between sites or collaborators.

10. Study oversight

10.1. Oversight committees

Oversight of this study will be provided by the Study Management Group. The study will be co-ordinated by a Study Management Group, consisting of the grant holders Dr Rute Vieira (CI, University of Aberdeen), Dr Andrea Woolner (Co-I, University of Aberdeen), Dr Amudha Poobalan (Co-I, University of Aberdeen), Dr Rodolfo Hernández (Co-I, University of Aberdeen), and Dr Elinor Sebire (Research Fellow, University of Aberdeen).

The Research Fellow (ES) will oversee the study and will be accountable to the CI. ES will be responsible for recruiting and liaising with participants, entering data from the recruitment form, storing data according to this protocol, data collection via interviews, transcription and analysing the data. However, this remains the overall responsibility of the CI. Any queries will be resolved by the CI or delegated member of the study team.

An advisory group has been set-up to provide professional and lay advice for the study. It is made up of important representatives of stakeholders in the field.

Advisory group members:

- Jane Fisher – Director of Antenatal Results and Choices (charity supporting parents during pregnancy/pregnancy loss). The Scottish representative for ARC will also join the advisory group once they are in post with the organisation. ARC provides specific information for parents undergoing prenatal testing and has a helpline service for those needing support.
- Michelle Peter – Senior Social Scientist (GOSH NHS hospital trust) and THIS Institute Research Fellow. Qualitative researcher focussing on Black and ethnic minority parent's experiences of prenatal testing in England.
- Lisa Scott – Consultant Obstetrician (NHS Grampian).
- Sarah Campbell - Clinical Midwifery Manager for Outpatients, Rubislaw ward and Specialist Midwives (NHS Grampian).
- Varshali Swadi - Professional Engagement and Development Lead (Down's syndrome Scotland). Down's syndrome Scotland have been involved in the wider NIPT implementation and evaluation, sitting on the Public Health Scotland NIPT evaluation stakeholder group. They support families of children with Down's syndrome, their insight is valuable to ensure we are using considerate and inclusive language and reach a wide range of individuals with different values and beliefs.

Members of the advisory group been asked to help distribute study adverts for recruitment in their respective organisations/communities where possible. Members have agreed to support recruitment and the Down's syndrome Scotland representative has suggested that researchers should attend a virtual coffee morning with the community to present the research and invite potential participants/answer any questions. MP has also provided senior qualitative methodological expertise in regards to the recruitment strategies outlined in the protocol.

The Study Advisory Group – made up of stakeholders in the field – will not have access to any confidential study materials, including participant details. They will be shown carefully selected anonymised extracts of transcripts during interpretation stages of the study to support discussion of emerging codes and themes. These extracts will be reviewed in advance by the research team to remove or minimise any direct or indirect identifiers. No full transcripts or identifiable participant data will be shared with the advisory group. They have reviewed and provided feedback on participant facing materials (study adverts, participant information sheets and interview topic guides) for improvement before SERB ethics submission. This has improved the use of appropriate lay language throughout the participant documents, and has highlighted key areas for improvement in our original recruitment and interview process, particularly for reaching a diverse group of participants and to offer interpretation during interviews if needed.

10.2. Inspection of records

The CI and all investigators and institutions involved in the study shall permit study related monitoring, audits, and research ethics committee review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

10.3. Peer review

This protocol has been peer reviewed in terms of its scientific merit and methods. Evidence of this peer review (and how any changes have been incorporated) will be presented to SERB when submitting the protocol for ethical approval.

11. Research ethics and governance

11.1. Ethical conduct

The study will be conducted in accordance with the principles of Good Clinical Practice (GCP). Prior to commencing any study activities, a favourable ethical opinion will be obtained from the School Ethics Review Board (SERB), School of Medicine, Medical Sciences and Nutrition, University of Aberdeen. SERB reference number: 13101949.

Separate NHS R&D approvals (for study recruitment of women or healthcare professionals working in the NHS) are not required, as confirmed by the Research Governance team.

Participant wellbeing and distress

The topic of pregnancy screening and experiences of non-invasive prenatal testing (NIPT) may be sensitive and could cause emotional discomfort or distress for some participants. Interviews will be conducted by a trained researcher (ES), who will remain attentive to the signs of distress. Participants will be reminded that they do not have to answer any questions they are uncomfortable with and may pause or stop the interview at any time without providing a reason. The participant can skip any questions they are uncomfortable answering. If a participant becomes distressed during the interview, the researcher will offer to pause or stop the interview, check whether the participant wishes to continue and remind the participant of their right to withdraw their data (in line with Section 6). They will be signposted to the support services (stated below) if they become distressed during the interview.

At the end of the interview, participants will be offered the opportunity to discuss any concerns arising from participation. Where appropriate, participants will be signposted to relevant sources of support, such as their General Practitioner (GP), NHS services, or appropriate support organisations (e.g. Antenatal Results and Choices, Down's syndrome Scotland).

For healthcare professional participants, there is a potential risk that individuals may feel concerned about sharing views related to their professional role or workplace practices. To mitigate this, participants will be reassured that all data will be treated confidentially and that no identifiable information about individuals, specific roles, or workplaces will be included in study outputs. Care will be taken during analysis and reporting to ensure that quotes or findings cannot reasonably be attributed to individual participants or specific NHS settings.

Participation in this study is entirely voluntary. Participants may choose not to take part or may withdraw at any time without providing a reason and without any consequences for their care, employment, or relationship with the University or NHS services, which is clearly stated in the PIS. They may withdraw their data up until the point at which the study ends. Interview transcripts will be pseudonymised (unique ID number given to each transcript and name/contact details removed), and the pseudonymisation key with ID numbers and corresponding personal details will be kept in a separate secure study folder until the end of the study. Following the study end, the pseudonymisation key will be deleted (deleting all personal

information), and it will not be possible to identify or remove individual data from the dataset after this point. Participants will also not be able to withdraw their data if it has been published before the study end date.

Participants will be informed of how to raise concerns or complaints about the study through the Participant Information Sheet. This will include contact details for the research team and for the School of Medicine, Medical Sciences and Nutrition Ethics Review Board (SERB) at the University of Aberdeen.

Researcher wellbeing and distress

This research covers topics that might include reference to termination of pregnancy or miscarriage. There is potential for risk to the researchers in terms of emotional distress. Researchers on the team will be referred to support services available e.g. University Metal Health First Aider scheme and University Counselling Service.

For the few local in-person interviews that will take place, the researcher might be lone working. This carries potential risks of physical or verbal threat or abuse towards the researcher from the participant or other members of the public. All colleagues in the team will be advised of the interview schedules, and the researcher will check in with the principal investigator following the interview. They will ensure their mobile phone is fully charges with easy access to emergency call function. The SafeZone app will be installed by the researcher for lone working within campus. No interviews will be conducted in the participant's private home. Any non-public premises e.g. community centre, will be attended by two members of the research team where possible.

11.2. Confidentiality

All participant data will be handled confidentially. Identifiable information will be stored separately from research data and accessible only to authorised members of the research team. Further details on data storage, pseudonymisation and retention are provided in Section 9.

11.3. Data protection

The University of Aberdeen is the data controller for this study. All personal data will be processed in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

The lawful basis for processing personal data is **Article 6(1)(e) – task in the public interest**, as this research is conducted as part of the University's research function. Where the study involves collection of information relating to participants' pregnancy experiences, this may constitute special category data and will be processed under **Article 9(2)(j) – research purposes**, with appropriate safeguards in place.

Personal data collected for recruitment and study administration (e.g. name and contact details) will be used only for these purposes and will be stored securely with access restricted to authorised members of the research team. Research data will be pseudonymised, and identifiable information will be stored separately from interview data.

All data will be handled using secure, University-approved systems. Further details on data collection, storage, pseudonymisation, and retention are provided in Sections 7 and 9.

Participants will be informed of how their data will be used and stored, and of their data protection rights, through the Participant Information Sheet. These rights include the right to access their personal data, request rectification, and request erasure where applicable.

No identifiable personal data will be included in any publications or outputs arising from this study.

11.4. Insurance and indemnity

The University of Aberdeen is the study Sponsor and holds a policy of Public Liability Insurance for legal liabilities arising from the study.

The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above.

12. Study conduct responsibilities

12.1. Protocol amendments, deviations and breaches

The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor (in the first instance), SERB, and if applicable the relevant NHS R&D office(s). Amendments to the protocol or other study documents will not be implemented without these approvals.

In the event that the CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to SERB for review and approval.

In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the GRO 'Breach Report Form'.

12.2. End of study

Project Milestone	**Date**
Anticipated start of data collection	1st August 2026
Anticipated end of data collection	1st March 2028
End of project	14th April 2028

The Sponsor and CI have the right at any time to terminate the study for clinical or administrative reasons.

If the study is terminated early, the CI will notify the Sponsor and SERB within 15 days, with an explanation for the early termination. The CI will also ensure that any appropriate follow up is arranged for all participants.

An End of Study report will be submitted to SERB within six months of the end of the study.

12.3. Study record retention

Physical study documents will be archived according to SOP-QA-32 Archiving. Electronic documentation will be stored on the secure University of Aberdeen R: drive. Only those on the research team will have access. When the study ends, all electronic documentation (interview transcripts, coding summaries) will be archived in the e-archive, according to SOP-QA-32, on a secure University of Aberdeen secure networked server. Personal identifiable information (name, contact details) held within the pseudonymisation key will be destroyed at the conclusion of the study, whilst interview transcripts will be stored for a maximum of 10 years beyond the study end in line with university policy.

To ensure that project data on the University-owned storage device such as servers and laptops is disposed of appropriately at the end of the study and end of retention period, the researcher will contact the IT Service Desk. IT staff will advise, organise destruction and will provide an update when the data is destroyed as a written record of disposal.

13. Reporting, publication and notification of results

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed and tabulated, and a study report will be prepared.

The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Key study updates and lay summaries of the findings will be shared with the organisations and communities that facilitated recruitment and made available through the university-hosted research webpage, for dissemination to a wider lay audience. The intended end-users of findings from this study are HCPs and screening policymakers in Scotland. Recommendations for healthcare practice improvements will be based on the findings of themes around experiences of women and HCPs in this study.

14. References

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15. Appendices

Table 1: Sampling Frame for Women and individuals who have experienced pregnancy Offered NIPT Within the NHS in Scotland since 2020. *In major cities in Scotland, approximately 20% of the population identifies as an ethnic minority.*[15] *Our sample will aim for at least 20% to be individuals who identify as an ethnic minority (not White British), e.g. 6/30 participants.*

Participant characteristics	**Options**	**Number of participants**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Age (years)	<20										
	20-24										
	25-29										
	30-34										
	35-39										
	40+										
Ethnicity	Asian or Asian British										
	Black, Black British, Caribbean or African										
	Mixed or multiple ethnic groups										
	White										
	Other ethnic group (including Arab)										
Religion	None										
	Christian										
	Muslim										
	Hindu										
	Buddhist										
	Sikh										
	Jewish										
	Other										
NHS Health board of residence	Ayrshire and Arran										
	Borders										
	Dumfries and Galloway										
	Fife										
	Forth Valley										
	Grampian										
	Greater Glasgow and Clyde										
	Highland										
	Lanarkshire										
	Lothian										
	Shetland										
	Tayside										
	Western Isles										
	Orkney										
Rurality	Urban										
	Rural										
Education level (highest)	Secondary School										
	College										
	University – Undergraduate										