FUNDED BY NIHR | National Institute for Health Research

FULL TITLE:

Increasing engagement and improving patient experience of **c**ervica**l** scr**e**ening in prim**ar**y care: Implementing the left lateral test position. A realist evaluation and implementation study.

SHORT TITLE/ACRONYM:

The CLEAR Study

PROTOCOL VERSION NUMBER AND DATE

VERSION	DETAILS	ETHICS APPROVAL DATE
V1 (12.06.24)	Original protocol	25.07.24 (WP 1 and 2)

Keywords: Cervical screening; left lateral; realist; co-design; engagement

UWE Bristol University of the West of England | University of BRISTOL | Wolstanton Medical Centre | Queen Mary University of London

Contents

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's Standard Operating Procedures, and other regulatory requirement.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: O Doran Date: 17/06/24

Name: OLENA DORAN

Position: DEAN IN RESEARCH & ENTERPRISE, PROFESSOR IN BIOMEDICAL RESEARCH

Chief Investigator:

Signature: N Walsh Date: 17/06/24

Name: NICOLA WALSH

Position: PROFESSOR OF KNOWLEDGE MOBILISATION & MUSCULOSKELETAL HEALTH

Key Study Contacts

Chief Investigator	Professor Nicola Walsh UWE Bristol Nicola.walsh@uwe.ac.uk 0117 328 8801
Project Manager	Rachel Thomas UWE Bristol Rachel4.thomas@uwe.ac.uk 0117 328 8790
Sponsor representative	Professor Olena Doran UWE Bristol Olena.doran@uwe.ac.uk 0117 328 2475
Host representative	Paul Roy BNSSG ICB Associate Director for Research Paul.roy@nhs.net 0117 984 1673
Funder representative	University of Southampton, Alpha House, Enterprise Road, Southampton SO16 7NS
Co-applicants and Study Management Group	Professor Katrina Turner (Alternate Lead) Dr Zoe Anchors Dr Ilhem Berrou Dr Issy Bray Dr Lizzie Cottrell Dr Justin Jagosh Bridgette Love Rachel Thomas Professor Jo Waller

Research Reference Numbers

IRAS Reference:	327564
UWE REC REF:	CHSS.24.05.209
Sponsors Reference:	PIMS11024739
Funders Reference:	NIHR155323
Research Registry:	researchregistry10385

Funding and Support

Funder	This project is funded by the National Institute for Health and Care Research (NIHR): Health and Care Service and Research Delivery Programme (NIHR155323). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.
Funding amount	£810,627.80
NHS Support Costs	£2847.00
NHS Excess Treatment Costs	£4200.00
Host	NHS Bristol North Somerset and South Gloucestershire (BNSSG) Integrated care Board (ICB)

Study Summary

Study title	Increasing engagement and improving patient experience of cervical screening in primary care: Implementing the left lateral test position. A realist evaluation and implementation study.
Short title	The CLEAR Study
Study design	Realist evaluation and Implementation study
Study period	August 1st 2024 – July 31st 2027 (36 months)
Study Aim	To support implementation of the Left Lateral Test Position screening option in primary care. Investigating challenges and facilitators to implementation; and the impact of offering choice on patient experience, acceptability, inclusivity and engagement with the cervical screening programme
Study Participants	1. People eligible for cervical screening 2. General practice staff and cervical screening training staff

Study Steering Committee

Name	Role	Institution
Prof Gretl McHugh	Health Service Research (Chair)	University of Leeds
Dr Glenda Beard	GP with Special Interest in Women's Health	Whiteladies Medical Group
Soumeya Bouacida	Patient and Public Contributor	Independent
Dr Karen Campbell	Nurse Cancer Specialist	Edinburgh Napier
Alex Humphrey	Women's Health Programme Manager	BNSSG ICB
Dr Fiona Moffatt	Realist Methodology Expert	Nottingham University
Dr Theresa Redaniel	Epidemiologist (Independent statistician)	National Cancer Registry Ireland
Louise Ting	Patient and Public Contributor	Independent

Roles and Responsibilities

Study Sponsor

The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. The sponsor will ensure that: all necessary approvals from an NHS research ethics committee are obtained before undertaking or permitting another party to undertake any part of the project which requires ethics committee and/or R&D approval; each participating site obtains properly signed ethically approved informed consent and acknowledgement forms from any participants or their legal guardians who will be involved in the project or who will be suppliers of material used in the project; each participating site shall conduct the project in accordance with the approved protocol and all relevant laws.

Study Funder

The funder reserves the right to have access to and to use data compiled during the course of the Research and will respect existing guidance on confidentiality of any data which it obtains. The sponsor shall, at the request of the funder, deposit both qualitative and quantitative data in a relevant data archive subject to any reasonable delay necessary to enable the protection or exploitation of foreground IP.

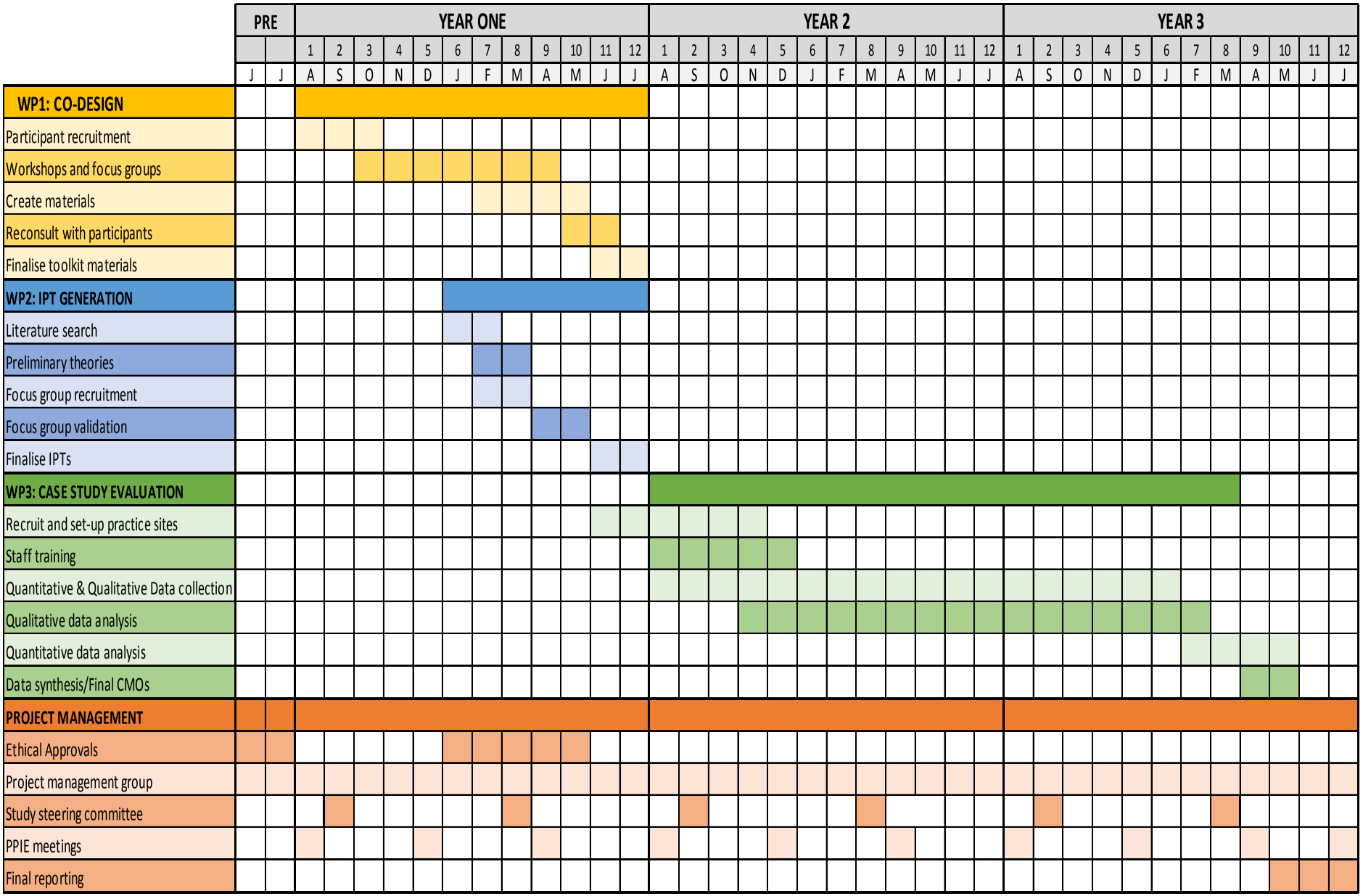
Study Management Group

The study will be managed by a study management group (SMG), which will meet by teleconference approximately monthly. The SMG will be chaired by the Chief Investigator or Project Manager and will include all co-applicants, collaborators and research staff.

Study Steering Committee

The Study Steering Committee (SSC) will provide oversight of the entire study and act as a Data Monitoring Committee if required. They will meet approximately every 6 months, in addition to Extraordinary meetings where deemed necessary.

Gantt chart


PRE
YEAR ONE
YEAR 2
YEAR 3
1 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 5 6 7 8 9 10 11 12
J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J
WP1: CO-DESIGN
Participant recruitment
Workshops and focus groups
Create materials
Reconsult with participants
Finalise toolkit materials
WP2: IPT GENERATION
Literature search
Preliminary theories
Focus group recruitment
Focus group validation
Finalise IPTs
WP3: CASE STUDY EVALUATION
Recruit and set-up practice sites
Staff training
Quantitative & Qualitative Data collection
Qualitative data analysis
Quantitative data analysis
Data synthesis/Final CMOs
PROJECT MANAGEMENT
Ethical Approvals
Project management group
Study steering committee
PPIE meetings
Final reporting

Study Protocol

Increasing engagement and improving patient experience of cervical screening in primary care: Implementing the left lateral test position. A realist evaluation and implementation study.

Background

Cervical screening uptake has steadily decreased in all age-groups over the last twenty years, and falls below the NHS 80% target (1) meaning more women and people with a cervix are at risk due to undetected cell changes that could lead to cervical cancer (CC). Reasons for nonattendance include fear of the procedure, lack of knowledge and awareness of the process, embarrassment, previous test discomfort, not feeling in control, cultural beliefs, vulnerability and history of sexual trauma (2). Some of these issues may be addressed with recent developments in self-sampling for those who have the physical and mental capacity, but early data suggest that given the choice, 36.5% of those eligible reported a preference for in-person screening and 10% remained undecided; lack of confidence in ability to self-test, and screening being considered the role of a professional were the commonly cited reasons for in-person screening (3). Furthermore, in-person screening will still be required in cases of positive human papillomavirus (HPV) test results and inconclusive test results; and there are also the additional benefits of in-person screening including detection of non-malignant cervical changes and discussions around contraception, sexual health and menopause. It should also be noted that trans-women, whose cervix is created from penile tissue could be susceptible to HPV genital infection, so examination for HPV related lesions are recommended (4).

Traditionally in-person cervical screening requires the individual to lie on their back (dorsal position) with their knees bent and apart to expose the vagina for speculum insertion and cervix inspection (5). Public Health England (now OHID) cervical screening guidelines published in 2020 (5) acknowledge an alternative test procedure – the left lateral test position (LLTP), whereby the individual lies on their left side with their legs very slightly apart (similar to the recovery position). This provides an alternative, less exposing position for those who are uncomfortable or in pain in the dorsal position (e.g. musculoskeletal conditions); have a tilted cervix, as it makes the cervix more accessible (6); avoids full exposure of the genital area and associated embarrassment, including cases of dysmorphia (7); assists with cervix visualisation in people who are severely obese (8); and may reduce feelings of vulnerability in individuals who have experienced sexual trauma (2,4). The new guidelines state that all women and people with a cervix should be informed of and offered both test positions to allow an informed choice (5).

In other parts of the world the LLTP is routinely offered and included in information materials (e.g. Republic of Ireland, New Zealand), and screening rates are high (without any self-sampling options at present) (9). Whilst causal links are impossible to prove from this quantitative data alone, offering choice is likely to be a contributing factor to higher levels of engagement. In the UK however, clinicians report a lack of LLTP awareness, understanding and confidence, all of which will impact promotion and implementation of the LLTP in routine practice. Our preparatory work for this application highlighted that whilst clinicians who had undergone recent training reported the LLTP had been briefly mentioned, they received no explanation regarding the procedure, no opportunity to practice the skill, or provided with information regarding clinical scenarios when it may be preferred (10). Furthermore, it is not mentioned as an alternative choice in information provided to people in the UK when invited for screening (e.g. 'Helping You Decide' in England) (11).

Rationale

CC accounts for 2% of all new cancers in those with a cervix, is most common in people aged 25-39, although can affect all ages (12). Mortality rises with age, increasing steeply from 65 years (13); deaths are more common in those living in deprived areas (12). One-year survival is over 80%; reducing to ~50% for 10-year survival (14). Uptake of HPV vaccination is approximately 84% in young girls (other than the COVID hit 2020/21 program), but is starting to show a decline in uptake generally (15). Screening, however, is still necessary for those who have been vaccinated, those who abstain from vaccination, and older unvaccinated

generations. Recent data suggest the benefits of the HPV vaccination programme in girls aged 12-13 are starting to emerge in England, as the first vaccinated cohorts reach their thirties, with incidence of CC significantly reduced in those born after September 1995 (16).

Each year there are still ~3200 new diagnoses of CC in the UK, and almost 900 die from the disease (13), despite CC being one of the few cancers that is almost entirely preventable through engagement with vaccination and regular cervical screening (13). The average cost of treating CC is calculated at £9233 per person (17), whereas the cost of in-person screening is approximately £56.81 and £40.37 for self-sampling (18), so any increases in attendance could have a significant impact at personal, healthcare and societal levels (17,18). Beyond these benefits, this research also addresses the important issues of patient choice (19) and personalised care via shared decision-making (20), and may address inclusivity by investigating some of the gender orientation (e.g. transgender) and cultural (e.g. female genital mutilation (FGM)) barriers to screening in those individuals who prefer professional screening, require follow-up screening, or have disabilities that preclude self-screening (21-23).

People eligible for testing present differing views on screening. Whilst some consider it a simple health check (24), others report significant negative experiences including pain and bleeding (25). Research also suggests that the test evokes extreme negative emotional responses such as embarrassment, anxiety and vulnerability, and can feel degrading (2). Issues associated with nudity, virginity, exposing genitalia and previous adverse sexual experiences are all cited as reasons for in-person screening avoidance (2). Negative previous experiences also affect decisions to re-engage; people report feeling 'de-individualised', ill-informed or uninvolved in screening decisions (26) – this is particularly noted in women with disabilities and of ethnic minority heritage, who also report a preference for in-person screening over self-sampling (3, 21). Somali women who have undergone FGM report being afraid of pain associated with screening (22) and aware that the dorsal position exposes their genitalia, which may cause feelings of awkwardness for the sample-taker and themselves (2). For transgender men, intersex or non-binary people, additional challenges were associated with dysmorphia and reluctance to expose genitalia (23). A recent survey commissioned by the Department of Health and Social Care showed that individuals who do attend cervical screening report embarrassment as the key reason for delayed testing (27), yet as far back as 2006, research showed that people who attend screening do not find the examination comfortable, both physically and psychologically, highlighting that little has changed to address this in nearly twenty years (28).

This is a critical time to address cervical screening options. Recent data show a decline in HPV vaccination uptake (15); at the same time screening rates are at a ten-year low, with approximately 30% of those eligible having either not been screened at all or not reattended for scheduled checks (29). Furthermore, there remains uncertainty regarding both the relative sensitivity and specificity (compared to in-person screening) of self-screening; how acceptable it will be amongst those eligible; and to whom it will be offered in the future – it is suggested that self-sampling will be offered to people who do not respond to in-person appointment invitations (30). Irrespective of if, when and how self-sampling is implemented, it is critical that people are offered choice to ensure maximum engagement across all screening formats.

Our recent national survey (10) to determine awareness and use of the LLTP amongst clinicians, completed by n=188 primary care screeners, demonstrated that whilst over 90% were aware of the LLTP, fewer than 5% always offered both test positions. This sample included n=111 clinicians who had received training since the 2020 guidelines, and whilst this group reported a very slight increased knowledge of the procedure (LLTP), this did not translate into confidence or clinical competence using it. Qualitative interviews held with a sub-group of purposefully sampled survey participants found that clinicians felt familiar with the dorsal position, and more confident using it, having not received adequate training in the LLTP. Lack of use appeared to be due to clinician preference and their perception that patients would not want it e.g. "I think that for me, that position (dorsal) achieves what I've got to achieve" and "I think it (LLTP) seems a bit more undignified for the woman, though they've never expressed that, I just kind of feel it". One GP however expressed "Last week I had a lady who has cerebral palsy...I've found that a lot of people who can't lie very still, left lateral's better."

We also conducted a single practice audit of n=202 consecutive patients who had experienced both test positions from an expert clinician; there was no difference between the positions in terms of sample validity. When asked to complete an anonymous survey about their experiences, patients overwhelmingly reported reduced invasiveness and discomfort with the LLTP, and 78% of the cohort reported a preference for the LLTP in the future. Patients also noted more comfort and dignity, reduced anxiety, and feeling less exposed and vulnerable in the LLTP. One stated: "I cannot really put in to words how different the experience was having my smear done by (practice nurse (PN)). I have been a victim of rape and so find smear tests or anything dealing with my nether regions very traumatic... not only is this humiliating and emotionally difficult, it has been extremely painful. When (PN) performed the smear, I felt almost no discomfort and I felt a lot less vulnerable in the left lateral position. Unless someone can perform the smear test in the left lateral position, I don't want it done."

The World Health Organisation global strategy 2020 aims to accelerate the elimination of CC highlighting the need for increasing accessibility of testing in all formats, and 'leaving no one behind' (31); yet a 2023 report by Jo's Trust showed that only 17% of healthcare professionals thought enough was being done in the UK to work towards this goal (32).

Elimination of CC requires a multifaceted approach including adequate patient information, vaccination, self-screening, in-person screening positional choice and treatment. This research addresses the critical aspect of making the in-person screening test procedure more accessible, comfortable and acceptable by improving patient information and choice; and understanding perceived barriers to implementation from a staff and practice perspective so appropriate support can be put in place to implement alternative test procedures.

Theoretical framework

Realist Evaluation (RE) is a theory-driven approach to understanding complex interventions (cervical screening programme) in complex environments (primary care). Conducted in a systematic and robust methodological way, RE is concerned with understanding the interaction between contextual elements and underlying mechanisms that influence outcomes of interventions (34). It borrows from constructivist (theory building) and positivist (theory testing) paradigms in an analytic process termed as 'retroduction'. Retroduction offers causal explanations about generative forces that underpin intended as well as unintended outcomes (34,36). Central to the realist approach is the concept of determining 'What works, for whom, in what circumstances, how and why?'

RE has been selected for this study as it is a recognised, valuable method for investigating complexity in health and care sectors, and has the ability to assess evolving models of service delivery (36). In relation to this study, RE will address how key components (e.g. previous screening experience or gender identification) may work in a variety of ways in different contexts (e.g. practice socio-demographics) to impact outcomes (e.g. patient experience or decision to attend).

We will align our IPTs and subsequent Context-Mechanism-Outcome configurations to Normalisation Process Theory constructs (NPT). NPT is a middle range theory, that provides a framework to understand the factors that support and challenge implementation, embedding and sustainability of an intervention (i.e. LLTP screening) in practice (i.e. primary care) (35). Aligned to four constructs: coherence (sense-making); cognitive participation (relational work); collective action (operational work); and reflexive monitoring (appraisal work), NPT provides a robust theoretical basis to understanding the human processes (what happens at patient and staff level) that are in play when new practices are introduced and embed over time (35). Integrating RE and NPT allows us to provide a detailed understanding of the organisational and individual level contextual elements that impact successful implementation, and is a well-documented approach to understanding implementation in context (37).

Study Aim

To implement a cervical screening programme that provides patient choice of test positions, to identify individual and system level challenges and facilitators to implementation; and to assess impact on patient uptake, inclusivity and acceptability.

Objectives and Research Questions

Work-package (WP) 1a: Co-design workshops

Using the Generative Co-design Framework for Healthcare Innovation (33), co-design with a diverse group of patients, patient facing multimedia materials to inform and educate people on the positional options (LLTP and Dorsal) available for cervical screening.

Research Question (RQ): What needs to be included in patient facing materials to ensure people's understanding of their positional choices (Dorsal and LLTP), and how should these be presented to make them accessible and acceptable?

WP1b: Healthcare professional (including screening trainers) and practice staff focus groups

Focus groups to determine screening healthcare professional views of offering and implementing LLTP in practice, and how to support its use.

RQ: What are the challenges and facilitators to implementing LLTP in practice, and what needs to be put in place to support its implementation?

WP2: Programme theory generation

Based on realist principles, create Initial Programme Theories (IPTs) on LLTP in the form of 'if…then' statements (34). Align the IPTs to Normalisation Process Theory (35) constructs to facilitate understanding of implementation (e.g. **If** the practice team note reduced patient anxiety when using the LLTP, **then** they are more likely to offer and advocate for the position – *Reflexive Monitoring Construct in NPT).*

RQ: What are the hypothetical explanations as to how the availability of LLTP as an alternative position to dorsal screening may lead to increased screening uptake and satisfaction in practice, and how do they align to implementation theory?

WP3: Mixed methods realist evaluation implementation study

Using realist methods, empirically test the IPTs developed in WP2, and aligned to NPT constructs, in a series of nationwide case studies within GP practices. A combination of quantitative data regarding attendance and attendees, and qualitative data from interviews with key stakeholders, will provide insight in to how offering positional choice and the implementation of LLTP impacts practice, and how staff and practice level challenges can be addressed to support implementation.

RQ: Implementing the LLTP into practice: what works, for whom, how and why?

WP1a: Co-design workshops (Months 0-9)

Theoretical Approach: Generative Co-design Framework for Healthcare Innovation (GCFHI) (33).

The GCFHI provides a structured approach to co-design, and it specifically supports partnership working with end-users who are 'experts of their experiences'. It utilises generative techniques, whereby end-users (in this case people eligible for

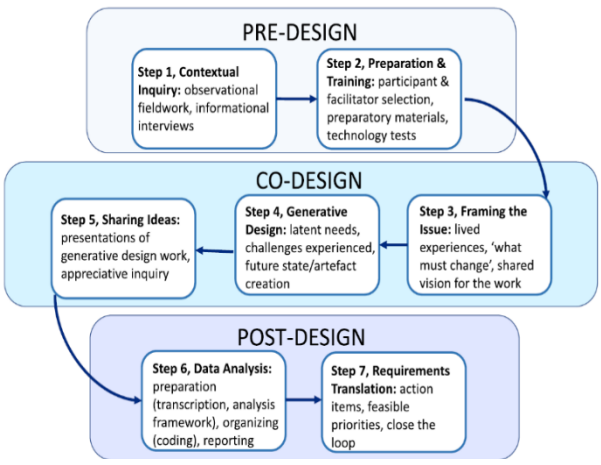


Fig 1: Generative co-design framework (33)

screening) explore the challenges in a process (in this case the cervical screening position) and create an alternative future that idealises how these may be addressed. Through their experiences, feelings, preferences and creative thinking, participants imagine ideal future processes that are then worked into pragmatic solutions.

The process consists of three major stages, pre-design, co-design and post-design, which are then sub-divided into seven steps (Figure 1).

Method

We have already completed step 1 of the pre-design phase in our preparatory work, which included a survey and interviews with clinicians and a practice audit using a satisfaction survey and free text responses.

Participant recruitment and selection (step 2): People who are eligible for cervical screening will be invited to participate. We will seek to recruit those with lived experience of screening covering a range of characteristics including age, gender identification, sexual orientation, disability and ethnicity. We will also actively seek individuals who have not been screened either through choice (non-attenders) or because they are under 24.5 years of age (when cervical screening is initially offered). Recruitment will be targeted through social media, charitable organisations, and our established networks including Caafi Health (a community organisation that works with diverse populations to address health inequality). We aim to recruit 30-35 participants who, once consented, will be sent preparatory information regarding the design workshops.

Workshops (steps 3-5): We will facilitate 4-5 co-design, in-person half-day workshops, aiming for approximately 5-6 participants in each. We aim to have inclusive workshops but will also be responsive to the needs of those who wish to participate in a targeted workshop, for example people who are non-English speaking, or those that have experienced sexual trauma to ensure all voices have equal prominence, and that all participants feel comfortable sharing their experiences and ideas. We will also consider the needs of people who identify as male, but born as female who still have a cervix and determine with them the most appropriate format for data collection – likely to be a targeted focus group or individual consultation as per the person's preference. The workshops will seek to conceptualise a 'future state of care' and will begin with developing a group understanding of the current issues regarding screening position, its impact on decision to attend, challenges, comfort and satisfaction, including impact of current national programme supporting materials. Once the issues have been identified, the group will be invited to suggest what the future state could look like. This will be done creatively by introducing 'personas' typical of the end users (relative to their group characteristics), and what their journey through the screening process could look like in relation to information about screening position and patient choice to address the pre-identified challenges. These 'personas' will be created by the research team in advance of the workshop, and in discussion with our PPIE groups. Participants can represent their ideas in multiple ways including verbal, pictorial or dramatic. Sessions will be audio or audio-visually recorded (depending on participant preference) for analysis alongside material outputs (e.g. drawings).

Analysis (step 6): The recordings of the discussions and material outputs will be themed by the research team (including PPIE representatives) according to participant identified priorities, those that are logistically feasible to address, and information that is considered a clinical priority according to our expert team (including cervical screeners, GP and cancer behaviour specialist). Divergent views will be addressed at an individual level. For example, if participants state a preference for different media (e.g. written versus pictorial) both aspects will be retained as these are likely to represent widespread preferences, and can be readily addressed. In cases where views are divergent and not easily addressed to meet all requirements, we will consult with our PPIE contributors and Study Steering Committee (as required) to inform the final decisions. We will then feedback to participants the outcome of the workshops, explaining decisions and asking for feedback.

Design materials (step 7): We will work with our design company and University Science Communication Unit to create materials that meet the requirements of our participants and are achievable within logistical

constraints (time and budget). Materials will be distributed to workshop participants for comment and amendments made as required. All materials will be reviewed by our PPIE group in advance of dissemination.

WP1b Healthcare professional (including trainers) and practice staff focus groups (Months 3-9)

Method

We will conduct three focus groups (n=5-6 participants per group) with healthcare professionals who regularly perform cervical screening in primary care and practice staff who may be involved in the process (e.g. administrative staff who contact patients).

Process

Via social media and our existing networks, we will recruit n=15-18 healthcare professionals and practice staff. We will aim to recruit from different regions and practice socio-demographic profiles. In advance of the focus groups, participants will be sent details of the LLTP and the NoMAD questionnaire for completion (38). The NoMAD tool consists of 23 items that align to the NPT constructs, posing questions regarding the implementation process. The tool can be edited to be completed in advance of implementation without impacting validity (38). We will therefore ask respondents to comment on their expectations of implementation processes. For example, the question "I can easily integrate LLTP into my existing work" would be amended to "I can easily see how LLTP could be integrated into my existing work". We will use the responses to guide the interview schedule, with particular focus on the statements that identify challenges to implementation (e.g. "I lack confidence in performing the test correctly as I haven't practiced this in training") which we will address in the implementation phase. The Focus groups will be held online and facilitated by a team member, and will last approximately 60-90 minutes. If there are apparent gaps in the data following consultation (i.e. issues have been raised that require input from a different stakeholder not represented in our consultation, (e.g. policy-maker)), we will directly contact specific individuals and request a short telephone interview).

Analysis

Focus groups will be audio-visually recorded and transcribed. Transcriptions will be used to contribute to IPT creation in WP2.

WP1a and b Output: (WP1a) Patient facing information materials regarding position options and the importance of patient choice for cervical screening; and academic paper on the co-design process. (WP1b) IPT theory generation, developed further in WP2.

WP2 Programme theory generation (months 6-12)

The preliminary phase of the realist approach requires Initial Programme Theories (IPTs) to be developed. These are hypothetical explanations in the form of If…then statements regarding how LLTP may work in practice. For example, "**If** the patient is particularly anxious exposing their genitalia, **then** they are more likely to tolerate the LLTP which is less exposing" or "**If** the healthcare professional feels adequately trained to perform the procedure, **then** they are more likely to promote its use practice".

Method

If…then statements will be generated from: the information derived from our preparatory work including healthcare professional interviews; preliminary practice audit data; our diverse PPIE work to date; and insights from WP1a and b. We will also identify any empirical sources that may inform our thinking along with grey literature. To date we have not identified any empirical literature that directly relates to the use of the LLTP for cervical screening but there is literature on reasons for non-engagement and screening experiences that will inform our thinking. We have identified some grey literature sources, including information on Jo's Cervical Cancer Trust website and some training resources from the Republic of Ireland and New Zealand that may provide useful information at this stage.

On commencement of WP2, we will rerun the search to include academic and grey literature sourced from a variety of Medical databases, including: Allied and Complementary Medicine (AMED), British Nursing Index (BNI), Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CCRCT), CINAHL, MEDLINE, PsycINFO, SCOPUS, EMBASE and Web of Knowledge. Given the likelihood of grey literature in this area, we anticipate the necessity to search a variety of websites, for example the Jo's Cervical Cancer Trust, and the Royal College of Nursing website.

IPT validation

We will conduct two, 60-90 minute online focus groups to validate and supplement our preliminary IPTs.

Focus group 1 people eligible for screening: Via social media and our existing networks, we will recruit another n=8-10 participants with diverse characteristics to participate in an online focus group. Participants will be asked to discuss the IPTs and provide their opinions on the validity of the statements, and to propose any further ideas for IPT generation. Given the sensitive nature of this topic for some, we will also offer one-to-one interviews for those who do not wish to engage in a group discussion and/or for those who are unable to engage digitally or are non-English speaking. Our team are experienced in managing interviews in-person with those who are unable to engage digitally or in English language.

Focus group 2 healthcare professionals and other relevant staff: Via social media and our existing networks, we will recruit another n=8-10 healthcare professionals who regularly perform cervical screening in primary care. We will aim to recruit professionals from different regions and practice socio-demographic profiles. Participants will be asked to discuss the IPTs and provide their opinions on the validity of the statements, and to propose and further ideas for IPT generation.

From the focus group and interview data we will further refine our IPTs and identify rival theories (hypothetical statements describing how the same programme resources may lead to different responses and outcomes, or divergent opinions regarding the potential outcome). Through validation and refinement, we will hypothesise Context-Mechanism-Outcome configurations (CMOCs). CMOCs will unpack the IPTs further, to explain contextual factors and the mechanisms through which changes (or outcomes) occur (34, 36-37). An explanatory set of definitions for context, mechanism, and outcome is presented here:

- **Context** pertains to the backdrop of the programme and variations of this across sites. Elements of context include that which existed before the implementation of LLTP screening and are outside of the mandate of service redesign (e.g., rural vs. urban, caseload socio-demographic, current uptake).
- **Mechanism** is defined as the 'reasoning of stakeholders in response to resources offered' (36). Identified stakeholders are practice nurses who perform screening, people eligible for cervical screening and training providers. Mechanisms in terms of how each of these stakeholder groups respond to new resources stemming from the LLTP provision will be investigated. Elements of the mechanisms will include resources offered through the intervention components (e.g., patient facing materials, practice nurse training) and the attitudes and feelings of the stakeholders in response. Responses by practice nurses may include feelings of confidence or greater opportunity to engage in shared decision making; responses by patients may include feelings of reduced anxiety or feeling empowered. In line with RE literatures' interpretation of mechanism (34,36), these responses and feelings will be captured in terms of how they may facilitate or impede the implementation and operationalisation of the LLTP in practice.
- **Outcomes** will include intended outcomes and other outcomes of interest, as well as unintended or unexpected outcomes, and potential negative outcomes in terms of practitioner and patient satisfaction, test validity and uptake.

NPT constructs (coherence, cognitive participation, collective action and reflexive monitoring) will be used to code any mechanisms that may challenge or facilitate embedding LLTP in practice based on the perceptions of all key stakeholders.

We will discuss our proposed theories with our PPIE group for further validation before we test our hypothesised CMOCs in case study sites in WP3.

WP2 Output: Set of CMOCs that have been aligned to NPT constructs and validated by stakeholders for testing in case study evaluation.

WP3 Mixed methods realist case study evaluation (months 13-30)

Study design

Mixed methods case study realist evaluation of implementation of the LLTP in primary care, testing the hypothesised CMOCs derived from WP2. Each case study site will combine patient satisfaction data, screening rates and position choice, with qualitative interviews with key stakeholders guided by pre-determined IPTs and hypothesised CMOCs. In advance of all study procedures, we will consult with our PPIE group to determine whether any amendments to processes or recruitment materials are required. We will also work with this group to develop the survey to ensure the questions are acceptable, appropriate and the demands on study patient participants are not over-burdensome.

Case study sample and recruitment

Sample: We aim to recruit 13 case study sites across England (10 intervention and 3 control) representing key sampling criteria documented below:

- Geographical location
- Practice deprivation index (based on postcode)
- Practice size
- Urban/rural
- Current screening uptake
- Population demographics (ethnicity and age)

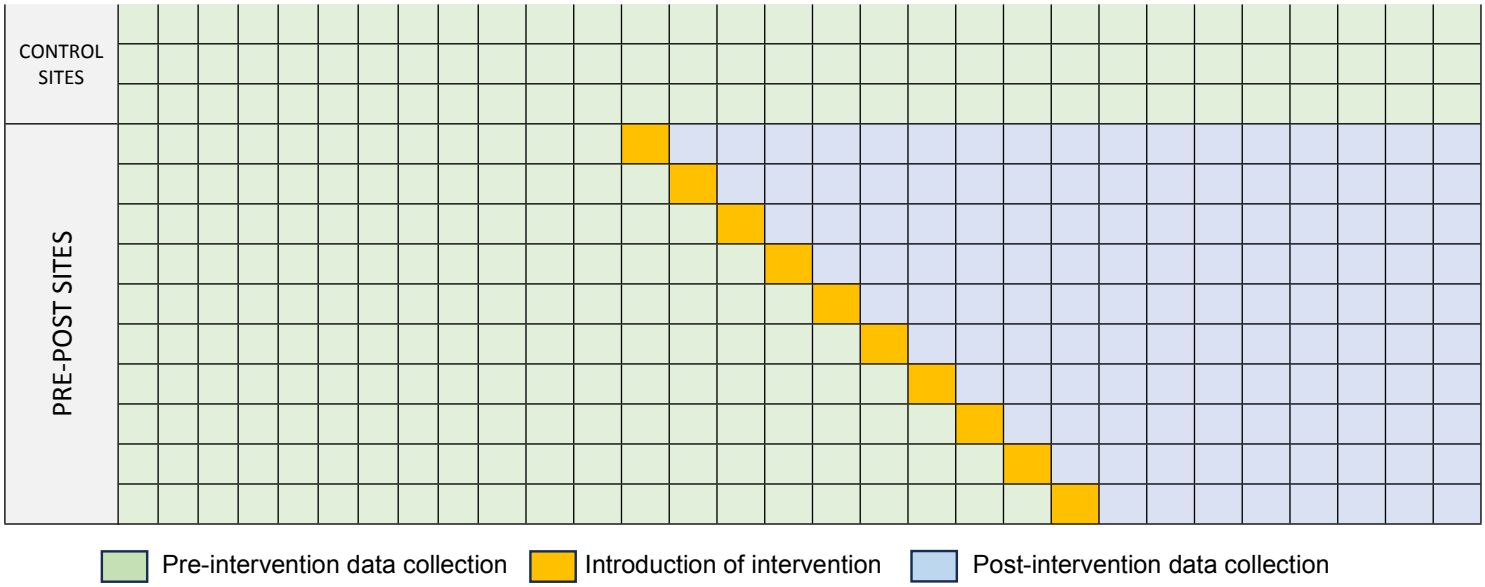
Recruitment: We will recruit practices through the Clinical Research Network (CRN). We will work with the CRN as soon as all appropriate governance is in place to identify other potential practices to ensure recruitment remains within designated target milestones.

Quantitative study design

We will conduct a before and after study in n=10 GP practices, recruited in a staggered way (see figure 2) between month 13 and month 22, alongside 3 control sites. The study design is a variation of the stepped wedge design in which a number of sites (n=3) remain unexposed to the intervention throughout the study period (42). The benefit of this is to monitor current practice and how this may change over time depending on national directives etc, without impacting the validity of the study data. The same participant process will apply to all study sites. At each site, the entire practice cohort eligible for cervical screening over a 30-month period will be included in the study on an anonymous basis. Data on screening outcomes will be collected for all 13 sites throughout the months 0-30. Each intervention site contributes observations under both control and intervention periods (at least 12 months of pre-intervention data from each site, and at least 9 months post-intervention data from each site), while control sites contribute additional control data throughout the whole study period. Analysis will determine the impact of introducing LLTP and patient position choice, on uptake, test position, satisfaction, engagement and test validity. We will recruit sites ensuring there is a geographical spread and diversity in socio-economic factors that may impact screening uptake.

Figure 2: Practice recruitment timings

MONTH	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30



Study Process

On receipt of all governance approvals and study documentation. The practice and participant processes are as follows:

Staff screening training

Intervention sites: In order to participate in the study, all healthcare professional screening staff must have a valid cervical screening accreditation and regularly undertake cervical screen within their routine practice. All staff must undergo a training update at least every three years, therefore by the time staff participate in this study ALL would have received mandatory training since the 2020 updated guidelines and should therefore be aware of the LLTP as a positional choice alongside the dorsal position. We will however provide supplementary training to all staff. This will be provided by co-applicant Love, a practice nurse cervical screening sampler expert in LLTP. We have existing training materials but will supplement these with additional videos. Love will also provide mentoring support for practice staff to undertake LLTP screening throughout the study intervention implementation period. Trained staff will be interviewed later in the study, which will include questions regarding the training they received as part of the national programme and the training and support received within this study, and how prepared they felt for offering and undertaking position choice.

Control sites: To participate in the study, all healthcare professional screening staff must have a valid cervical screening accreditation and regularly screen within their routine practice.

Staff survey (intervention sites)

Healthcare screening staff in all practices will be sent an e-copy of the NoMAD questionnaire (38) and asked to complete this in advance of implementation of LLTP as a positional option, but after training has taken place (baseline). This will be used to understand how individuals feel about implementing LLTP and positional choice, their understanding of the programme (LLTP) and their role and that of others within the implementation process. We will repeat this at four monthly intervals to monitor changes over time as LLTP as an option becomes embedded (or not) within standard provision.

Retrospective practice database search

This will be identified via the practice system database for at least 12 months in the previous year. It is important that the data includes the corresponding period in the previous calendar year as Quality and Outcomes Framework (QOF) (39) returns may impact prioritisation of screening. We appreciate that the

COVID-19 pandemic severely disrupted the screening programme. However, we believe our practice data collection, that will commence in mid-2025, will be representative of the current state of the screening offer and response following COVID 'recovery'.

Data will be anonymised but will show: numbers eligible for screening; numbers screened; screening format (self-screen or in-person); patient demographics of attenders, self-screeners (awaiting OHID policy decision on who is offered this option) and non-attenders; patient response period (response to national screening invitation or to follow-up from practice); test validity (numbers returned from microbiology due to inadequate sample); and where available, in-person screening position choice. Our preparatory work demonstrated an overwhelming use of the dorsal position (lying on back, as documented in current training and patient invitation literature), but we will investigate free text responses to determine if any alternative positions were adopted.

Prospective patient attendance survey

On completion of their screening with the practice healthcare professional, all attendees will be provided with a link to a post-test survey via their practice. We intend to offer multiple completion options including a scanned site specific QR code; site specific e-survey link; and paper options; and we will provide each site with a tablet for those individuals who would prefer to complete the survey on site. The anonymised survey will include questions regarding respondent demographics, their experience, satisfaction, decision making (including response to screening materials), positional choice and preference for future tests. We will provide respondents with the option to include an email address, or a telephone number to contact if they are interested or willing to take part in a follow-up interview regarding their experiences.

Prospective practice database search

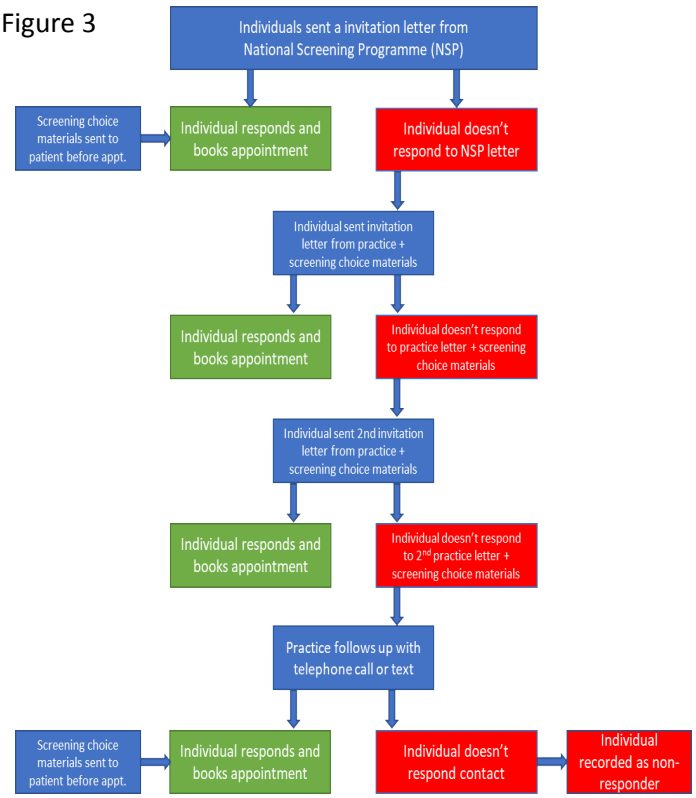
Intervention sites: Via the practice database we will collect screening data for at least 9 -months including month of intervention introduction) (see figure 2). As per the retrospective search (detailed in 6.3.4.2), all data will be anonymised but will show: numbers eligible for screening; numbers screened; patient demographics of attenders and non-attenders (non-attendance based on the QOF requirement of a national invitation, two practice invitations plus 6-weeks to respond to the second practice invitation which should also include a telephone follow-up and likely to be the offer of a self-screen once OHID policy is determined); patient response period (response to national screening invitation or to follow-up from practice); test validity (numbers returned from microbiology due to inadequate sample); and position used. As part of the prospective data collection phase, we will work with the CRN database team to insert a simple tick-box into the patient screening record (e.g. EMIS, Vision etc) to collect the test position.

Control sites: Data from these sites will be collected for the duration of the study.

Patient process

When eligible for screening, patients are sent an invitation from the National Screening Service to contact their practice to make an appointment. Those who are registered as male are not centrally identified, so

Figure 3



individual practice-based systems will be followed to identify these individuals. *Individuals <u>who respond</u> to the National Screening invitation* will be sent a link to the LLTP information materials developed in WP1 (intervention sites only) either through an SMS platform (e.g. AccuRx) if they self-book; or via SMS, email or post depending on their preference if they book on the telephone or in-person. We will work with each practice to ensure we align to their preferred option for forwarding patient screening information. In our qualitative interviews with attendees, we will explore whether delivery route and format impacted outcomes of interest.

Individuals <u>who do not respond</u> to the National Screening invitation will be sent a follow-up letter/postcard from their GP practice, in line with Cervical screening QOF requirements (39). This invitation will include materials regarding the LLTP as a screening option (in addition to the dorsal position) produced in WP1 (intervention sites only). At this point patients will either respond to the letter and book an appointment OR they will not respond to this letter.

Individuals who do not respond to the first practice follow-up letter will be sent another invitation letter (QOF requirement) again including the materials created in WP1 (intervention sites only). *At this point patients will either respond to the second practice letter and book an appointment OR they will not respond to this letter*. For those who do not respond, the practice will adopt their standard approach to following these people up – for many practices this include a telephone contact by a member of the practice healthcare staff or a reminder text. If individuals do not respond at this point they will be registered as non-responders. Figure 3 demonstrates the patient course through the screening invitation process.

At present there are no confirmed details on how (or if) self-screening will be implemented into practice. It is however likely that self-sampling kits will be offered to individuals who do not respond to in-person screening invitations (personal correspondence). Whether or how self-sampling is implemented will not impact the delivery of the current study but self-sampling implementation would provide us with an opportunity to record who opts for which method, and to determine patient and healthcare professional views on how the suite of screening approaches is managed.

<u>Anticipated patient numbers</u>

Based on 13 medium size practices, and data collection over a 18-month period, we anticipate that approximately 13500 people will be eligible for screening (retrospective and prospective timepoints). Assuming a 70% uptake (realistic target given QOF upper threshold is 80% for 2023/24 (39)), we anticipate screening data will be available for at least 9450 people (retrospective and prospective timepoints). This is based on current data, but this research seeks to enhance these numbers, so this figure is likely to increase. Of those who attend, we anticipate approximately 35% will record a survey response (40), resulting in a survey response sample of approximately 3300. We are aware that whilst screening is currently every three years for under 50s, and every 5 years for over 50s in England, there is a likelihood that by the time this study commences, all people eligible for screening will be invited every five years and continue this trajectory if tests are normal (41). We do not anticipate this having any significant impact on our available sample.

Quantitative Data analysis

The proportion of people invited who attend will be calculated for the pre-intervention period and post-intervention period for each intervention site. For each site, these can be compared using Fisher's exact test for a difference in proportions. With at least 12 months of pre-intervention data and at least 9 months of post-intervention data at each site, this will allow for statistically robust comparisons. Where differences in effectiveness are apparent, knowledge of contextual factors at each site will be used to explain why the intervention works or does not work in each case. This analysis will be repeated for secondary outcomes (test position, satisfaction, engagement and test validity). It will also be repeated for subgroups to compare outcomes (pre- and post-intervention) according to the following individual characteristics – age group, ethnicity, first-time attenders (compared to previous attenders), previously inconsistent attenders (compared to previously consistent attenders).

To account for trends over time and site-specific factors, a generalised linear mixed model will be used to estimate the overall effect size (with 95% confidence interval) of the intervention on uptake rates as the primary outcome, controlling for these factors (42-43). Controlling for calendar year allows for changes over time that were not associated with the intervention (e.g. national trends). Controlling for site allows for differences between practices in terms of size of practice and socio-demographics of patients. Individual characteristics of the patient such (age group, ethnicity and attendance history) will also be included as covariates. Similar models will be fitted for secondary outcomes (test position, satisfaction, engagement and test validity). This multivariate analysis will incorporate data from the 10 intervention sites and the three control sites in the stepped wedge design (Figure 2).

Whilst we will consider the whole patient cohort, we will also investigate the effect of the intervention on sub-groups to align with QOF returns (39). These groups are 24.5-49 years and 50-64 years. Within the younger sub-group, we will also consider the sample of 24.5-29-year olds separately as this group have a very low uptake (1) and have been identified as an important group to engage in other studies (44). Additional models including interaction terms will therefore be fitted to test whether the effect of the intervention differs for these age groups (24.5-29 years, 30-49 years, and 50-64 years). Similarly, we will include interaction terms for reported ethnicity, first-time attenders and previously inconsistent attenders, to see whether offering LLTP improves uptake for different groups.

While we will not have complete data on position for the pre-intervention period, because it is not recorded, we will be able to estimate the proportion of tests carried out in LLTP position as it may be recorded as a deviation from standard practice – this will therefore be a lower bound, and likely an under-estimate. We will also ask survey respondents to report their previous test position. We will be able to calculate the proportion of tests carried out in the LLTP position during the post-intervention period (after the offer of LLTP is introduced) from patient responses.

For the post-intervention period we will use survey data to summarise patient satisfaction according to test position (median and range satisfaction scores for dorsal and LLTP groups), and to test for an association between patient satisfaction and test position (Mann-Whitney U test). This will also be repeated for the three ages groups described above and by ethnicity.

Qualitative study design

Semi-structured realist interviews will be conducted with patients (see below for detail) and case study site screening staff. Topic guides will be based on the IPTs/hypothesised CMOCs. They will be designed to elicit information about how the offer of LLTP is integrated into practice, for whom and under which circumstances. The focus of the interview data is to understand the mechanisms through which the intervention, in a given context, results in intended and unintended outcomes. We will identify mechanisms that are put in place to facilitate implementation and align these to NPT constructs to help us understand the processes required to support, embed and sustain implementation of the new programme (LLTP).

Interview approach with patients

We are aware that the sensitive nature of the topic area could mean some participants, whilst having made an informed decision to take part in an interview, could find the interview process difficult. For example, some participants may have chosen to not engage with the programme previously because of experiences of previous sexual trauma for which any intimate test is anxiety inducing. Our interview approach, therefore, will be informed by the trauma-informed research guidelines recently developed by Alessi and Kahn (45) to help researchers design and implement qualitative research in a way that ensures participants feel safe and are empowered throughout the research process. We will draw on existing literature, expertise within our PPIE group and research team to consider what personal, historical, and structural trauma individuals approached for interview may have experienced and use this to inform how individuals are approach for interview, the wording and structure of patient facing documents and the interview topic guide, and how the interviews are conducted and what post interview support or information should be given.

The researcher conducting the interviews will be experienced in sensitive interviewing and will state at the start of each interview that the participant is not responsible for appeasing her, can ask the researcher questions if they want, and can refuse to answer a question or stop the interview at any time, without giving reason. The researcher will be aware that questions can be triggering (e.g. how do you feel when you are asked to undress?), and will therefore think carefully about how they are worded and structured. In addition, throughout each interview, the researcher will pay attention to individual's body language (where in-person or on-camera) and be alert to comments made (for all interview formats) that might indicate the participant is reliving an experience (rather than recounting it) and/or feeling distressed. In such situations, the researcher will redirect the questioning to a less potentially sensitive area or to more resilience-based questions (e.g. what helped you cope?) and, if necessary, pause or stop the interview. Once the interview has ended and before leaving the participant, the researcher will check in with the individual about how they are feeling and help them access information or support if the research has resulted in any distress or re-traumatising. Lastly, throughout data collection and analysis the researcher will be encouraged to debrief with members of the research team. They will also be able to contact the CI (NW) or clinician on the research team (EC), if they need advice or support following an interview.

Beyond the qualitative interviews, other phases of the study will also be designed and delivered in a trauma-informed, sensitive manner using Alessi and Khan's guidelines (45), and with input from our diverse PPIE advisory group and expert PPIE facilitators.

Patient participants – attenders

We will select a diverse sample from those who provided contact details in the survey expressing a willingness to be interviewed. Sampling criteria will include personal demographics, and screening status (i.e. first-time attenders, returners, previous non-attenders). We anticipate that approximately 20% of survey respondents may express an interest in being interviewed, providing a sample of approximately 660. We will purposively sample a diverse group of approximately n=40 interviewees to achieve maximum variation in relation to location, deprivation and protected characteristics. Interviews will last up to one hour.

Patient participants – non-attenders

We will work with practice sites to identify people who, despite multiple invitations (which may include self-sampling, depending on future Cervical Screening Programme guidelines), choose not to engage in the screening process. Via the practice sites, we will distribute an e-survey (with the opportunity to enter a draw for a £50 voucher (46)) to those people to better understand their reasoning, and to determine why the introduction of the offer of LLTP and supporting materials had no impact on their decision-making. We will also provide those people with the opportunity to provide contact details if they wish to be involved in a follow-up interview. We do not anticipate a significant response to either the survey or the invitation to

interview, but will use any data we do capture to inform our thinking. Interviews will last approximately 15 minutes.

Healthcare professionals

We will interview all screening clinicians who participated at each case study site on completion of the six-month study period to further test our IPTs regarding the integration of the LLTP alternative in practice. We will also use individual longitudinal responses to the NoMAD questionnaire to tailor the interview schedule to understand how perceptions of the programme (LLTP) and its implementation change (or not) as it becomes routinely offered within practice (normalised).

We anticipate that each practice study site will have 2-3 staff participating in the study. Therefore, we will interview approximately n=25-30 practice screening staff, interviews lasting up to 30 minutes and conducted remotely either by telephone or video link.

Qualitative data analysis

Data collection and analysis will proceed in parallel, so that early data collection can inform the focus of the later interviews. Transcripts will be imported into NVivo for analysis. Two researchers will independently review transcripts, and a sample (20%) will be double coded to ensure consistency in interpretation and coding allocation. Data will be analysed in relation to IPTs/preliminary CMOCs, and evidence gathered that either confirms or refutes these statements. Analysis may identify theories that were not explicit in WP2; these theories will be reported. We will also code the stated mechanisms of action to NPT constructs to provide an explanatory model of how the LLTP alternative becomes normalised in practice. Alongside the realist methods, this will allow us to address the complexity of implementing and normalising LLTP, and provide an explanation of what works, for whom, in what circumstances, how and why?

Data synthesis

The realist approach embraces mixed methods and it would be an expectation that the qualitative and quantitative data would be incorporated into the realist analysis using CMOCs, to produce the final evidence-informed theories about how the service design (LLTP choice) works, for whom and across variations in context. We will work with our PPIE advisory group to assist us in the interpretation and wording of our evidence-informed theories. This will assist us in producing implementation guidance and materials for supported roll-out.

WP3 Output: Validated programme theories, aligned to NPT, regarding how the LLTP choice works in practice; including clinical data on uptake, satisfaction and engagement. Academic papers of evaluation findings.

Ethical Considerations

All appropriate ethics and governance requirements will be in place in advance of recruiting study sites or participants. All participants will be volunteers and will provide informed consent and will not be required to reveal any information they wish to withhold (e.g. biological sex). Participants will have the right to withdraw at any time until their data is analysed.

Participants will include NHS staff and patient participants and an HRA application to obtain NHS ethics approval will be made. No research activities will begin until all research approvals are obtained.

Regulatory Review and Compliance

Before any site can enrol participants into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations will be obtained and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment and confirm their support for the study as amended.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments will also be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

Equality, Diversity and Inclusion

As a team we are committed to ensuring that everyone (public contributors via PPIE and research participants) has an equal opportunity to participate in the study, contribute to its design, feel equally supported to engage with all work-packages, have acceptable and accessible study materials, and be made aware of study findings, and where possible participate in dissemination. We have incorporated a strong EDI approach in the development of our work to date, particularly with our engagement work with people from African, South Asian and Arabic heritage communities. We have strong links with 'grass-root' community organisations, and through our multilingual co-applicant Berrou, will continue to work with people from these communities throughout the study within our PPIE advisory group. To allow us to include individuals from diverse backgrounds in this implementation study, we have a considerable budget to include: translators and translation costs; production of culturally acceptable and accessible materials; hire of community-based facilities to support engagement; reimbursement payments; and data-use payments.

In addition to ethnic diversity, we also plan an inclusive approach to gender identification, as this is an important area of research for many of the LGBTQI+ community. We will work with the University "LGBT+ Network Committee" to facilitate our engagement work with groups, organisations and partner institutions across the region to facilitate us to recruit and support people from these communities to participate in WP1 and to provide representation on our PPIE advisory group.

We will complete an Equality Impact Assessment in advance of commencing the study with our diverse PPIE advisory group and the study team, to ensure all of our processes create equality of opportunity and do not create unintended discrimination or sensitivities (e.g. requirement to reveal biological sex). Where any processes are deemed to create potential inequities, we will take mitigating action to address these issues.

We will provide explicit information on the diversity of all practice sites; individual participants in all phases of the research; and the diversity of our PPIE advisory group.

Patient and Public Involvement

PPIE is a core feature of our research and essential to ensure public accountability and transparency. Through PPIE preparatory meetings, a diverse range of individuals have endorsed our research as important to the needs of people eligible for cervical screening. Further details on PPIE work is interwoven into the research plan and details regarding how they will be involved in the planned research can be found throughout this study.

At the start of the research, we will convene a diverse group of 6-8 individuals who will act as our PPIE advisory group. They will input into each phase of the study, and assist us with the development of all patient facing research materials (e.g. Participant information leaflets and consent forms) and dissemination outputs and activities. We will formally consult our PPIE advisory group every 3-4 months in meetings conducted in a format, language and location that is acceptable. We will also work with our PPIE advisory group on an agile basis when we require immediate input to assist with problem solving. We recognise that there may be a necessity to consult representatives on an individual or sub-group basis given the sensitivity of the topic area, cultural and language considerations to ensure all voices are equally heard and actioned.

PPIE lead Berrou will co-ordinate all PPIE activities and work alongside PPIE facilitators from the University of Bristol to ensure all participants feel supported to engage in the PPIE advisory group, and that all reimbursements are made in a timely manner and meet individual preferences.

Data Protection and Participant Confidentiality

The University of the West of England, Bristol (UWE) is the sponsor for this study based in the United Kingdom. UWE will use information from participants in order to undertake this study and will act as the data controller for this study. This means that UWE is responsible for looking after participants' information and using it properly. UWE will securely erase identifiable information about participants at the conclusion of the study once the final report has been accepted by the funder.

Participants' rights to access, change or move information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. Participants will have the right to withdraw their data up until the point of their data being analysed; this will be made clear on the Participant Information Sheets. To safeguard their rights, we will use the minimum personally-identifiable information possible.

Data Management

All data will be retained in accordance with UWE and Funder (NIHR) policies. In all outputs, reports, publications and other available documents details will be provided of methodology used, analytical and procedural information, definitions of variables, vocabularies, units of measurement etc, so that users are able to make sense of available data. This will be included within above documents, as supplementary data, on our study website, or by other means. Where relevant and permissible, data will be added to the University Research Data Repository.

Data storage and back-up

Data storage and back up procedures follow UWE recommended guidance and procedures. All electronic data generated as part of the project will be stored on UWE OneDrive using password protected, encrypted university computers. All of the immediate study team are University staff and therefore have access to 1TB of OneDrive storage which provides sufficient storage space for study data. OneDrive data can be accessed online through password protected mobile apps and on University issued PCs and/or Laptops. In the event of off-site working or data collection, as per university recommendations, data may be temporarily held on external devices such as pen-drives (USB sticks) and encrypted audio recorders. For safety and security, it will be common practice of the study team that data are uploaded to university systems using a university laptop as soon as possible after collection.

In the case of collection of identifiable research data (e.g. research interviews), audio-recordings will be uploaded to OneDrive immediately and the original recording deleted, before the researcher leaves the external site. If upload is not possible, all files are encrypted, and upload will be undertaken at the earliest possible convenience. The UK Data Service Guidance on data storage will also be consulted for other best practice. Interviews will be recorded on an encrypted device, anonymised and transcribed verbatim. The data will be anonymised using a Participant Identification Number (PIN) generated specifically for this study by the immediate Research team.

Hard-copy data will be stored at the University of the West of England in a fireproof, lockable filing cabinet. Consent forms and identifiable information will be stored separately from study data. Hard copies of identifiable information will be destroyed when no longer required by the research team.

In relation to back up and recovery of data in the event of an incident, OneDrive is not backed up as such but it is resilient as it is cloud based, with the basic protection offered by the "restore previous version" functionality.

Study database and data use

The database will be developed by the study team. No confidential personal data that identifies individual participants will be included in this database apart from the unique participant study ID. This will be linked to a separate database, containing data linking the participant study ID, to the relevant confidential personal data which will be held securely by the immediate study team. All qualitative data will be analysed by the immediate study team. All identifying information will be removed from transcripts and replaced with the allocated PIN. No confidential personal data that identifies individual participants will be included in any of the qualitative analyses (including analysis performed in databases/Excel/NVivo) apart from the PIN. This will be linked to a separate database containing data linking the PIN to the relevant confidential personal data.

Archiving

Personally identifiable information will be securely erased on completion of the study. De-identified study data will be stored for 5 years after the end of the study. Hard-copy data will be stored at UWE in a fireproof, lockable filing cabinet. Electronic participant data will be stored in OneDrive on password protected, encrypted university computers.

Access to the final study dataset

The immediate study team will have access to the final study data set. Additionally, de-identified data may be shared as per license agreements and regulations for relevant study outcome measures.

Outputs and dissemination

Target audiences for dissemination, the outputs tailored for each audience and the mechanisms for mobilising knowledge are listed below. However, it is anticipated that knowledge products will be relevant for multiple audiences and knowledge cross transference will be maximised. To evaluate the effectiveness of the knowledge mobilisation strategy, feedback will be sought from stakeholders throughout, and dissemination events will include an evaluation component. Alternative metrics will be explored to capture/evaluate impact.

For study participants

At the end of the study, a summary of the study findings will be sent to each participating general practice, and to individual participants if requested, via post, or email as preferred. The summary and more detailed findings will also be available on the study website. The details of which will be circulated to all of the study participants.

For patients and members of the public

A wide-reaching approach will be used for the general public, using inclusive communication strategies. Email lists and ‘X’ will be used to publicise and encourage active commentary throughout, with the use of existing social media networks to drive traffic to the study website. Opportunities will be sought for press releases and guest blogs. It will be important to disseminate the findings to communities with lower levels of health literacy, therefore digital stories and animations, video presentations and graphics will be explored with the study PPI group, with a focus on inclusivity. We will also investigate the possibility of creating a HealthTalk module (47).

For commissioners and service providers

We will collaborate with ICB staff and attend commissioning meetings using the mechanisms of knowledge brokering and relationship building. We will also seek opportunities to present our work at relevant commissioning events, including national conferences and through existing links with OHID and NHS England. We anticipate that the main knowledge products of most interest to commissioners and service providers will be the education materials for patients and staff. All developed materials will be made available through Creative Commons, FutureNHS, Ardens and via the main study website.

For general practice teams

Through early engagement with general practice teams as stakeholders, we will create opportunities to influence practice at an early stage. We will also present at general practice educational events to share learning and to maximise opportunities to influence decision making.

For academics

Academic outputs will include papers covering the methodological approach, main findings and evaluation, submitted to high impact, open-access peer-reviewed journals, such as the British Journal of General Practice. In addition, we plan to give presentations or workshops at relevant professional conferences.

Authorship criteria

Authorship credit will be based only on substantial contribution to all the following criteria:

• Conception and design; or the acquisition, analysis or interpretation of data

• Drafting or critically revising the article for important intellectual content

• Final approval of the version to be published

• Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The level and order of authorship is the responsibility of the CI and will be determined on commencement of each work-package

References

1. NHS Digital (2023) Cervical Screening programme – Coverage Statistics https://digital.nhs.uk/data-and-information/publications/statistical/cervical-screening-programme/cervical-screening-programme-coverage-statistics-management-information [Accessed August 2023]
2. Chorley AJ, Marlow LA, Forster AS et al (2017) Experiences of cervical screening and barriers to participation in the context of an organised programme: a systematic review and thematic synthesis. Psycho-oncology. 2017 Feb;26(2):161-172. doi: 10.1002/pon.4126
3. Drysdale H, Marlow LA, Lim A, Sasieni P, Waller J. Self-sampling for cervical screening offered at the point of invitation: A cross-sectional study of preferences in England. Journal of Medical Screening. 2022;29(3):194-202. doi:10.1177/09691413221092246
4. Carroll, R., Tan, K.K.H., Ker, A., Byrne, J.L. and Veale, J.F. (2023), Uptake, experiences and barriers to cervical screening for trans and non-binary people in Aotearoa New Zealand. Aust N Z J Obstet Gynaecol, 63: 448-453. https://doi.org/10.1111/ajo.13674
5. Public Health England (2020) Guidance: Topics 7 and 8: anatomy, physiology, and taking cervical samples. https://www.gov.uk/government/publications/cervical-screening-cervical-sample-taker-training/topics-7-and-8-anatomy-physiology-and-taking-cervical-samples
6. Bates CK, Carroll N, Potter J (2011) The challenging pelvic examination. J Gen Intern Med. 2011 Jun;26(6):651-7. doi: 10.1007/s11606-010-1610-8.
7. Cadman L, Ashdown-Barr L, Waller J, Szarewski A (2015) Attitudes towards cytology and human papillomavirus self-sample collection for cervical screening among Hindu women in London, UK: a mixed methods study. J Fam Plann Reprod Health Care 2015; 41(1): 38– 47. DOI:10.1136/jfprhc-2013-100705
8. Breitkopf DM. Lateral decubitus position to facilitate pelvic examination of the patient with severe obesity. BMC Womens Health. 2021 Apr 7;21(1):143. doi: 10.1186/s12905-021-01289-2. PMID: 33827544; PMCID: PMC8028184
9. Bruni L, Serrano B, Roura E, Alemany L, Cowan M, Herrero R, Poljak M, Murillo R, Broutet N, Riley LM, de Sanjose S. Cervical cancer screening programmes and age-specific coverage estimates for 202 countries and territories worldwide: a review and synthetic analysis. Lancet Glob Health. 2022 Aug;10(8):e1115-e1127. doi: 10.1016/S2214-109X(22)00241-8.
10. Liddiard C, Turner KM, Love B, Walsh N. Primary care practitioners' views and use of the left lateral cervical screening position: a mixed method study. In Preparation for the Journal of General Practice Nursing
11. Public Health England (2021) Cervical screening: Helping you decide. https://www.gov.uk/government/publications/cervical-screeningdescription-in-brief/cervical-screening-helping-you-decide—2
12. Cancer Research UK (2022) Cervical cancer incidence statistics https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/cervical-cancer/incidence#heading-One
13. Cancer Research UK (2022) Cervical cancer mortality statistics https://www.cancerresearchuk.org/health-professional/cancerstatistics/statistics-by-cancer-type/cervical-cancer/mortality
14. Office for National Statistics (2019) Cancer survival in England: national estimates for patients followed up to 2017 https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/cancersurvivalinengland/nationalestimatesforpatientsfollowedupto2017
15. UKHSA (2022) Human papillomavirus (HPV) vaccination coverage in adolescents in England: 2021 to 2022. Health Protection Report Volume 16 number 13 20 December 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1126762/hpr1322-HPV2.pdf
16. Falcaro M, Castañon A, Ndlela B et al (2021) The effects of the national HPV vaccination programme in England, UK, on cervical cancer and grade 3 cervical intraepithelial neoplasia incidence: a register-based observational study. Lancet. 2021 Dec 4;398(10316):2084-2092. doi:10.1016/S0140-6736(21)02178-4
17. Wordsworth S, Ryan M, Waugh N. Costs and benefits of cervical screening IV: valuation by women of the cervical screening programme. Cytopathology. 2001 Dec;12(6):367-76. doi: 10.1046/j.1365-2303.2001.00358.x. PMID: 11843938.
18. Huntington S, Puri Sudhir K, Schneider V, et alTwo self-sampling strategies for HPV primary cervical cancer screening compared with clinician-collected sampling: an economic evaluationBMJ Open 2023;13:e068940. doi: 10.1136/bmjopen-2022-068940BMJ14.
19. NHS England (2020) The NHS choice framework: What choices are available to me in the NHS. https://www.gov.uk/government/ publications/the-nhs-choice-framework/the-nhs-choice-framework-what-choices-are-available-to-me-in-thenhs
20. NICE (2021) Shared decision making NICE guideline [NG197] Published: 17 June 2021 https://www.nice.org.uk/guidance/ng197
21. Ogunsiji O, Wilkes L, Peters K, Jackson D (2013) Knowledge, attitudes and usage of cancer screening among West African migrant women. J Clin Nurs 2013; 22(7–8): 1026– 1033. DOI:10.1111/jocn.12063
22. Abdullahi A, Copping J, Kessel A, Luck M, Bonell C (2009). Cervical screening: Perceptions and barriers to uptake among Somali women in Camden. Public Health. 2009 Oct;123(10):680-5. doi: 10.1016/j.puhe.2009.09.011.
23. Berner AM, Connolly DJ, Pinnell I, Wolton A, et al (2021) Attitudes of transgender men and non-binary people to cervical screening: a cross sectional mixed-methods study in the UK. Br J Gen Pract. 2021 Jul 29;71(709):e614-e625. doi:
24. Forss A, Tishelman C, Widmark C et al (2001) 'I got a letter …' a qualitative study of women's reasoning about attendance in a cervical cancer screening programme in urban Sweden. Psycho-oncology 2001; 10(1): 76– 87.
25. Chiu LF, Heywood P, Jordan J et al (1999) Balancing the equation: the significance of professional and lay perceptions in the promotion of cervical screening amongst minority ethnic women. Crit Publ Health 1999; 9(1): 5– 22.
26. Wood B, Russell VL, El-Khatib Z, et al. "They Should Be Asking Us": A Qualitative Decisional Needs Assessment for Women Considering Cervical Cancer Screening. Global Qualitative Nursing Research. 2018;5. doi:10.1177/2333393618783632

10.3399/BJGP.2020.0905.
27. OHID (2022) Department of Health and Social Care: Help Us Help You – Cervical Screening campaign. https://www.gov.uk/government/news/new-national-cervical-screening-campaign-launches-as-nearly-1-in-3-dont-take-up-screening-offer
28. Seehusen D A, Johnson D R, Earwood J S, Sethuraman S N, Cornali J, Gillespie K et al. Improving women's experience during speculum examinations at routine gynaecological visits: randomised clinical trial BMJ 2006; 333 :171 doi:10.1136/bmj.38888.588519.55
29. NHSE (2023) https://www.england.nhs.uk/2023/01/nhs-urges-women-to-book-a-cervical-screening-as-a-third-dont-take-up-vital-offer/
30. King's College London News Centre (2021 At home kits to check for early cervical cancer launches in London. https://www.kcl.ac.uk/news/at-home-smear-tests-launch-london
31. World Health Organisation (2020) Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.
32. Jo's Cervical Cancer Trust (2023) We can cervical cancer. The opportunities and challenges to eliminating cervical cancer in the UK. https://www.jostrust.org.uk/about-us/our-research-and-policy-work/our-research/we_can_end_cervical_cancer_report
33. Bird, M., McGillion, M., Chambers, E.M. et al. A generative co-design framework for healthcare innovation: development and application of an end-user engagement framework. Res Involv Engagem 7, 12 (2021). https://doi.org/10.1186/s40900-021-00252-7
34. Pawson R, Tilley N (2004). Realist evaluation. http://www.communitymatters.com.au/RE_chapter.pdf
35. Murray, E., Treweek, S., Pope, C. et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med 8, 63 (2010). https://doi.org/10.1186/1741-7015-8-63
36. Jagosh J, Stott H, Halls S, et al Benefits of realist evaluation for rapidly changing health service delivery BMJ Open 2022;12:e060347. doi: 10.1136/bmjopen-2021-060347
37. Dalkin, S.M., Hardwick, R.J.L., Haighton, C.A. *et al.* Combining Realist approaches and Normalization Process Theory to understand implementation: a systematic review. *Implement Sci Commun* **2**, 68 (2021). https://doi.org/10.1186/s43058-021-00172-3
38. Finch, T.L., Girling, M., May, C.R. et al. Improving the normalization of complex interventions: part 2 - validation of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). BMC Med Res Methodol 18, 135 (2018). https://doi.org/10.1186/s12874-018-0591-x
39. QOF 23/24 https://www.england.nhs.uk/wp-content/uploads/2023/03/PRN00289-quality-and-outcomes-framework-guidance-for-2023-24.pdf
40. IPSOS MORI (2021) GP Patient Survey 2021 https://www.gp-patient.co.uk/Downloads/2021/GPPS_2021_Technical_Annex_PUBLIC.pdf
41. 34. Rebolj M, Cuschieri K, Mathews C S, Pesola F, Denton K, Kitchener H et al. Extension of cervical screening intervals with primary human papillomavirus testing: observational study of English screening pilot data BMJ 2022;377 :e068776 doi:10.1136/bmj-2021-068776
42. Hemming K, Haines T P, Chilton P J, Girling A J, Lilford R J. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting BMJ 2015; 350 :h391 doi:10.1136/bmj.h391
43. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemp Clin Trials. 2007 Feb;28(2):182-91. doi: 10.1016/j.cct.2006.05.007. Epub 2006 Jul 7. PMID: 16829207.
44. Wilding S, Wighton S, Halligan D, West R, Conner M, O'Connor DB. What factors are most influential in increasing cervical cancer screening attendance? An online study of UK-based women. Health Psychol Behav Med. 2020 Aug 7;8(1):314-328. doi: 10.1080/21642850.2020.1798239. PMID: 34040874; PMCID: PMC8114340.
45. Alessi, E. J. and S. Kahn (2023). "Toward a trauma-informed qualitative research approach: Guidelines for ensuring the safety and promoting the resilience of research participants." Qualitative Research in Psychology 20(1): 121-154
46. Lauren Rockliffe, Amanda J. Chorley, Laura A. V. Marlow & Alice S. Forster (2018) It's hard to reach the "hard-to-reach": the challenges of recruiting people who do not access preventative healthcare services into interview studies, International Journal of Qualitative Studies on Health and Well-being, 13:1, DOI: 10.1080/17482631.2018.1479582
47. Real People. Real life experiences. https://healthtalk.org/