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Protocol

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Detailed research plan

Full title of project

Supporting the health of women at work: A realist review of pregnancy, postnatal, and menopause workplace interventions and their effectiveness

Background and rationale:

There are currently 15.7 million women in the workforce in the United Kingdom (UK) (ONS, 2022). Women experience several reproductive health inequities across their lifespan, these often converge at key points in careers (i.e., pre-pregnancy, pregnancy and pregnancy-related complications, postnatal return-to-work, and menopause). These experiences have significant impact on women's physical and mental health and, if poorly managed, can pressure women to reduce their working hours or leave the workforce altogether – resulting in social and economic inequalities (Connolly and Regan, 2022). These health-related work inequities are longstanding, on-going, and persistent. For example, an estimated 500 miscarriages occur each day in the UK, with women reporting insufficient support from managers and organisations, despite the Equality Act 2010 (Tommy's, 2023). Approximately 54,000 women want to leave work each year due to pregnancy-related discrimination (Equality and Human Rights Commission, 2015) and many returners-to-work cite inadequate facilities to breastfeed or to pump and store expressed breast milk (Whiley et al., 2022a, Chang et al., 2021). Finally, women over the age of 50 years are one of the quickest growing worker demographic groups in the UK, many of whom will require menopause support (CIPD, 2021). Yet most workplaces still offer little to no support; 21% of women pass on promotions that they would have otherwise considered, 19% reduce their working hours, and 12% resign due to menopause (Newson Health Research and Education, 2022). The resulting inequities are simply not going away and women will continue to fall pregnant, return-to-work postnatally, and experience menopause. Therefore, the resulting inequities will only be mitigated by effective interventions that take account of contextual factors. To-date there have been no syntheses that have enabled such knowledge to be generated.

These important experiences are now being awarded the recognition they deserve. This has been evidenced by the: recently formed Women's Health Strategy for England (DoH&SC, 2022); NIHR Collection about Women's Health and Reproductive Health and Childbirth National Symposium; and media coverage on menopause followed by several leading firms implementing policies (e.g., BBC). It is therefore imperative for managers to have access to evidence regarding good practices on how to best support women's health at work. However, this requires evidence to be reviewed, synthesised, and presented to organisations in a format where they can use it to inform their practice, which does not exist currently. Our work is timely and of great importance, bringing together and synthesising the scientific literature to address the urgent need to support women's health in the workplace. Moreover, we explicitly contribute to the remit of the Public Health Research (PHR) programme by synthesising the current evidence base relating to three critical topics relating to women's health (i.e., pregnancy and related complications, postnatal return-to-work, and menopause). Bringing together this diverse scientific knowledge is crucial to managers, Human Resource Management (HRM) professionals, and anyone with supervisory responsibilities. A particular strength of our project is the decision to employ a realist review methodology which focusses on identifying individual and organisational contextual factors that lead to the effectiveness (or lack thereof) of supportive measures. Realist reviews can thus provide evidence that distinguishes between mechanisms that work for a large

corporation versus a Small-to-Medium Enterprise (SME). These critical insights, typically lost in more traditional literature reviews, can enhance transferability and help managers make complex decisions about which interventions to implement, often with limited budgets.

The following section presents a brief literature review of published evidence identified through initial scoping searches of EMBASE, PROSPERO, and Google up to July 2023. The research was co-designed by the research team including Co-PIs, PPI and stakeholder groups, and our information specialist (JW). We identified a sample of 2,888 records using scoping search words and subject headings for workplace interventions, pregnancy, postnatal, menopause, and 'reproductive health'. Screening 2,000 of these records found no similar realist reviews incorporating all three topics (published or ongoing) and identified sufficient evidence for a meaningful review covering these areas. To our knowledge, this is novel work.

Pregnancy: Women continue to report conflicting and inconsistent guidelines, stress, and complications to their careers due to pregnancy (Al-Hadithy, et al., 2021). Anderson et al. (2022) indicate that pregnancy-related adjustments are often made on a case-by-case basis, reflecting the level of complexity inherent in assessing interventions and evaluating their success rate. A 2018 systematic review by Pedersen et al. explored interventions targeting sickness absence among pregnant women. However, only studies from Sweden and Norway were included, indicating a gap in evidence which our review would address. A recent systematic review undertaken by Goodman et al. (2023) identified prenatal screening practices and interventions in healthcare settings. They explored the risk factors associated with working conditions during pregnancy across eight included articles. Findings from this review indicate that contextual factors associated with work-related risks during pregnancy are not always assessed resulting in a lack of understanding about effectiveness interventions. This is an element our review would explore because of the ability of realist reviews to consider context as key.

Postnatal support: In our research, we have argued that breastmilk pumping rooms are notoriously inadequate (Whiley et al., 2022a). In a recent systematic literature review into breastfeeding at work, Vilar-Compte et al. (2022) found that despite spaces designated for breastfeeding or extraction being commonly provided, neither their effectiveness nor the implications for the mother's wellbeing were investigated. A recently published realist review into workplace breastfeeding interventions suggest that awareness of an intervention, workplace culture, and time and space are important mechanisms for success (Litwan et al., 2021). These authors suggested the need for further research to be carried out across different contexts. Our review will offer this by exploring international literature, across different work settings. In regard to postnatal mental health problems, Ortega and Reio (2016) observed that no reviews existed within the field of human resources relating to interventions in the workplace. Social support can be effective, yet to what extent this could be considered an intervention, and what type of support is of most benefit is unknown (Ortega and Reio, 2016). Therefore, reviewing and synthesising different disciplines, as well as grey literature will yield further insights.

Menopause: Up to a third of women have considered reducing their working hours or leaving work completely because of menopause-related symptoms (Lewis and Newson, 2019). In our own research, we have shown how women are stigmatised at work because of menopause (Whiley et al., 2022b) and are even threatened with negative performance evaluations (Atkinson et al., 2021; Beck et al., 2018). Indeed, 90% report that perimenopausal or menopausal symptoms have a negative impact on work with a staggering 19% taking more than eight weeks off work (Newson Health Research and Education,

2022). Moreover, this often coincides with women reaching leadership positions, further aggravating structural inequities such as the gender pay gap, the glass cliff, and the glass ceiling. Literature on menopause at work is an emerging field. From our scoping search we identify one systematic literature review assessing the effectiveness of interventions amongst menopausal women at work (Rodrigo et al., 2023). Five articles were included for review, however these were all quantitative. This presents a limitation for dynamic organisations when evidence is focussed on specific outcomes because the complexity of how, why and for whom is not accounted for. Findings conclude that self-help cognitive-behavioural therapy (CBT) could be effective psychologically, but authors indicate a need to better understand mechanisms for sustainability, particularly in dynamic workplaces. Taking a realist approach to reviewing literature in this area will specifically facilitate the identification of mechanisms, not only in quantitative trials but also across qualitative studies and grey literature.

The current evidence base straddles many different types of workplaces producing a plethora of guidance for employers on how to support women at work and minimise health inequities. For this reason, organisations provide inconsistent support. Context, which is currently lacking in the guidance, is key to intervention effectiveness. We know, from existing work we have had funded by NIHR (HSDR Project: NIHR131606 (co-ap RA) and HSDR Project NIHR129528 (PI CT)) that underlying principles relating to intervention effectiveness can guide decision-making. For example, this may include addressing broader, systemic issues of inequity that pre-exist within an organisation, establishing trust within management and teams, as well as better understanding the role that sector, industry, and size of organisations play. By reviewing these three critical topics on women's reproductive health in parallel, we will collate and identify underlying mechanisms as to why, how, and for whom, interventions are effective or not. This is a particular strength of a realist review and in doing so we will produce theories and recommendations for each topic, as well as an integrated set of recommendations and overarching theory for organisations more broadly. This approach is likely to generate greater learning across topics than if they were synthesised separately.

Across these three topic areas, there have been no realist reviews of interventions to bring this interdisciplinary bodies of literature together. The evidence currently comprises of individual studies, but as we know, employment setting, occupation, and work conditions are factors that can influence interventions and their implications (Atkinson et al., 2020). Thus, by adopting a realist review approach, we are able to determine what intervention works, for whom, how, and why.

Research questions

Aims: (1) to improve understanding of the effectiveness of workplace interventions to support women's reproductive health in the workplace during pregnancy, postnatal return-to-work, and menopause; and (2) to produce evidence-based and context-specific recommendations to enable organisations to determine which interventions to implement for whom.

Research questions:

1. Which women's reproductive health workplace interventions work, for whom, in which settings?
2. What are the mechanisms that make these workplace interventions effective (or ineffective)?
3. In what contexts are these mechanisms triggered (or not triggered)?

4. What outcomes (both intended and unintended) might help to guide organisational and policy decision-making?
5. What are the resource/cost implications of interventions intended to address women's reproductive health in the workplace?
6. What are the critical gaps in the literature (including the views and experiences of minoritized communities)?

Research plan/methods

Research design and theoretical framework

We will undertake a realist review and in doing so develop programme theories that describe the interventions and conditions for their success (e.g., extracting contextual information on industry, size of organisation, participant demographic etc using NVivo data analysis software). Our resulting evidence-based report will guide organisations including managers, HRM professionals, and other decision makers to make evidence-based decisions about implementation of good practices that support women at work during these three life stages. Realist reviews are theory-driven and synthesise literature about complex social interventions. They focus on understanding the mechanisms by which interventions work (or not) and seek to understand contextual influences on whether, why, how and for whom these might work (Wong et al., 2013). Our broad conceptualisation of the relationship between work and health is underpinned by Sorensen et al.'s (2021) model, updated by Peters et al. (2022) to include gender (Figure 1). We will use this model a-priori both to help classify types of interventions (e.g. targeting individual worker characteristics, workplace policies, or workplace conditions), and as a starting point to identify and describe the potential mechanisms of action (the proximal outcomes resulting from interventions). Other gendered factors that impact women's health such as home-work interface will also be considered inductively as they emerge in the literature.

Evidence corresponding to each area will be explored in parallel, with their own relevant theories. Cross comparisons will also be made across the three areas to explore the possibility of one broader, overarching programme theory (see also HSDR Project: NIHR131606 (co-app RA) and HSDR Project NIHR129528 (PI CT), for approaches that integrate multiple topics/ areas into one review). This project will also include a review of health economics data, led by co-applicant HM. Two members of the team (RA and JW) already have pre-existing experience and expertise in combining realist methods and health economics data (see also ARC KSS Project: NIHR200179, PI RA and HSDR Project: NIHR135102, co-app JW).

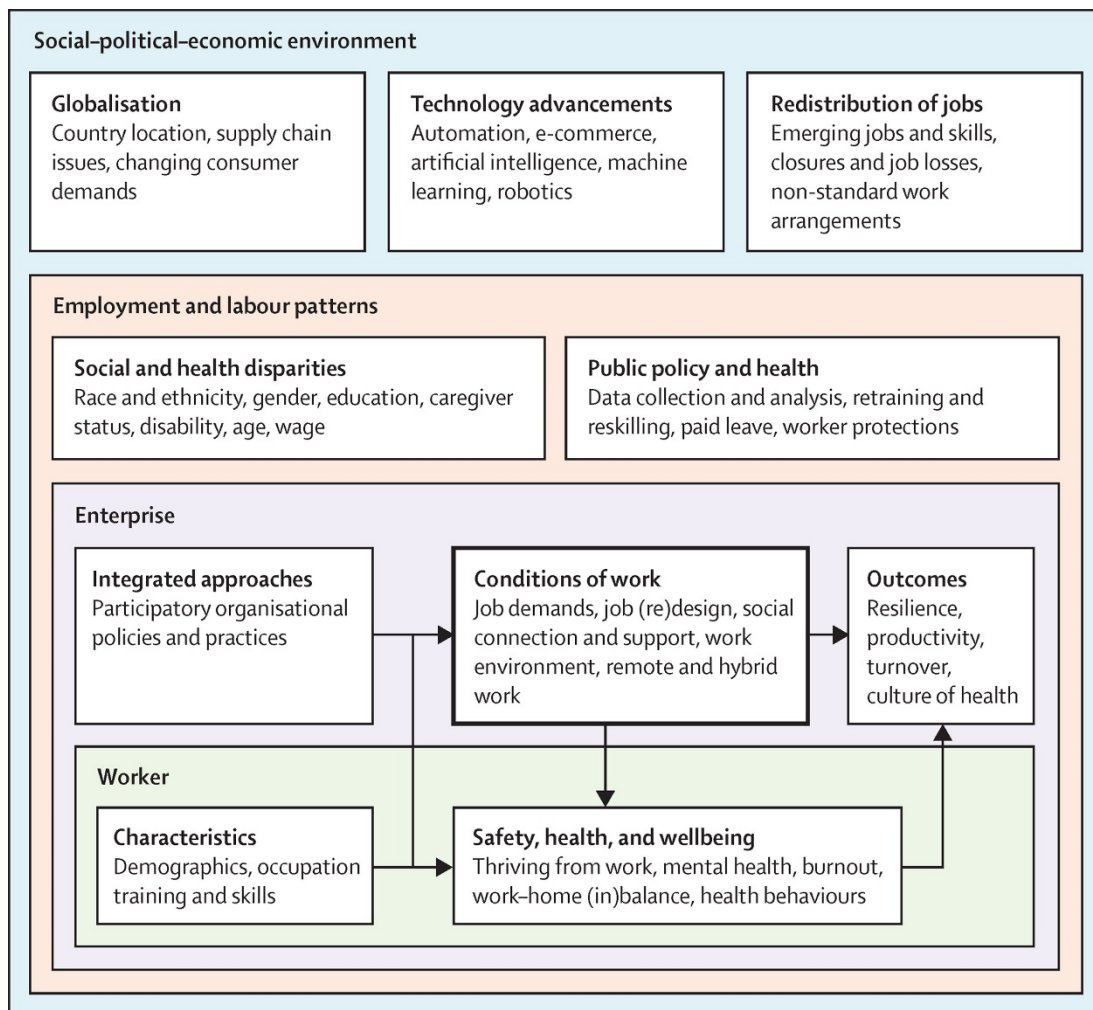


Figure 1. Conceptual model (Peters et al., 2022)

The realist approach to data collection and analysis is driven by retroduction, a form of logical inference, which starts with the empirical and explains outcomes and events by identifying the underlying mechanisms capable of producing them (Sayer, 1992). It is therefore essential that we consider a range of workplace settings. By illuminating these contexts, working practices and organisational cultures, we will also be able to determine how women can be most effectively supported. We are applying the realist review methodology to answer our questions. Our evidence-based recommendations will provide critical guidance on the implementation of appropriate interventions, across a range of settings to support women. The review will be conducted in an integrated way, with emerging ideas and insights from reviewed papers informing further future searching (see figure 1 project flow chart attached).

The realist approach advocates that in order to infer a causal outcome (O) between two events (X and Y), one needs to understand the underlying mechanism (M) that connects them and the context (C) in which the relationship occurs (Pawson et al., 2005). These are represented as heuristic data configurations which include: Context (C) + Mechanism (M) = Outcome (O). For example, to evaluate whether an intervention effectively supports women physically or mentally (O), we will examine its underlying mechanisms (M) (e.g. what are the resources offered and how might these effect changes in participants through reasoning/response), and its contiguous contexts (C). Throughout an entire review, these configurations come under intense scrutiny as more evidence emerges. Configurations

relating to intervention effectiveness are also tested against existing theory (i.e. "middle-range theories", Merton, 1967) and it is these middle-range theories which can support implementation and guide decision making.

The plan of investigation will follow a detailed realist review protocol informed by Pawson's five iterative stages in realist reviews, and the RAMESES realist review quality and publication standards (Wong et al., 2013; Pawson et al., 2005). This realist review protocol has been written by the project team, who have experience and expertise in conducting such reviews (RA, CT, and JW). The review will be registered with PROSPERO, which helps avoid duplication and enhance transparency.

The review process incorporates iterative cycles of engagement with the literature and with our stakeholder group (see below and figure 1). These iterative sense-making cycles of engagement will enable the research team to test out theories with stakeholders to produce action-oriented middle-range theory which can inform decision-making at individual, team, and organisational levels. In the following section we provide further detail on the steps associated with conducting a realist review.

Search strategy

Step 1: Identifying existing theories

The goal of this step is to identify theories that explain how and why a particular job design, work environment, organisational culture or setting may influence the effectiveness of an intervention to support women's reproductive health or not. This step will identify the contexts at individual, team, and organisational levels to demonstrate how, why and for whom, which interventions work or not. This process, of identifying existing theories will inform the construction of our initial programme theories. An initial programme theory (IPT) provides the foundation to a realist review, helping to surface taken for granted assumptions, indicate hunches and draw on existing knowledge (Pawson et al., 2005). The rationale for this step is that for interventions to be successful in supporting the health of women at work, it is necessary to understand existing patterns of behaviour and explore how things have traditionally been 'done'. In this act of surfacing existing knowledge, relevant components and how they might work become apparent, ready to be tested through further data collection. This stage is not intended to be exhaustive. To co-develop initial programme theories, in the first instance we (including Co-PIs, PPI and stakeholder groups, information specialist) will iteratively:

- a) draw on preliminary discussions with our stakeholders which includes: subject matter and lived experience experts including women experiencing pregnancy, postnatal return and menopause and those with Black and Minority ethnic (BAME) perspectives; academics; and employing organisations;
- b) examine literature already known to the research team about supporting women's health at work (namely, the literature identified in our initial scoping review and used to develop this proposal).

This first informal screening of the literature will sensitise the team to the breadth and depth of published and unpublished literature across the review topic areas. By investigating the theoretical underpinnings of programmes, we can map out the conceptual and theoretical landscape of current interventions to explore how they are supposed to work in different settings to develop our initial programme theories. Building these initial programme theories will require iterative discussions within the project team and stakeholder group to make

sense of and synthesise the different assumptions. We will refine the initial programme theories based on their feedback.

Step 2: Specific review - search for evidence

Evidence search

Step 2 is our exhaustive, primary search and takes the 'Exclusive (Realist-only) searches' model (Booth et al., 2020), intended to identify the majority of studies for the review. We have already worked with our Realist information specialist (JW) and to determine the scope of the search strategies. A trial of primary search terms indicates that across three areas and multiple databases including grey literature, we can anticipate approximately 10,000 abstracts. Screening a sample of 2,000 records identified 175 potentially relevant title and abstracts.

Follow-up searches will be conducted to address emerging questions to test and refine theories if necessary (see additional searches section below for further detail). Throughout the review, complementary CLUSTER search techniques (for example citation searching) will be used to ensure closely related studies likely to inform theory development and testing are included (Booth et al., 2013). All search results will be saved in reference management software. A detailed spreadsheet will record all searches conducted, to ensure transparency when reporting the search activities. In this formal, primary search we will:

- a) Search for studies which discuss a workplace intervention in relation to women's health (physical or mental) with regards to pregnancy and related complications (including pre-pregnancy IVF, miscarriage, and stillbirth) OR postnatal support OR menopause. For studies relating to postnatal workplace interventions, our scope is up to 18 months post birth because women are more likely to require support at work during this transitional period (e.g., with breastfeeding, pumping, or postnatal depression). Searches will be run in academic databases including Medline, Embase and PsycInfo. Search strategies will comprise search terms, synonyms and index terms including: Workplace intervention; Employer guide; worker programme; pregnancy; maternity; antenatal; postnatal; breastfeeding; menopause; perimenopause. We will also run searches for resource/ cost implications in order to assess and integrate our health economics component.
- b) Use studies in OECD countries. This is so as to identify evidence that is broadly applicable to the UK and countries with similar workplace environments, labour law protections, and economic background.
- c) Conduct a grey literature search. Grey literature such as trade journals/news, policy and professional reports will be sought from sources including ABI Inform, HMIC, Maternity and Infant Care database, Financial Times, Employee Benefits News, People Management Reward and Employee Benefits Association (REBA) <https://reba.global/>, and Chartered Institute of Personnel and Development <https://www.cipd.org/uk/>. Our stakeholder group will refine our list of grey literature sources to search and contribute relevant documents including signposting us to known initiatives and policies used by employers.

Additional searching

An important process in realist reviews is finding additional data needed to confirm, refine, or refute aspects of developing programme theory throughout the review. If we find that we require more data to develop, confirm, refute, or refine programme theory development, we will conduct additional searches (see Figure 1). For each additional search the project team will meet to discuss and set/review the inclusion and exclusion criteria as appropriate.

Different search terms and databases are likely to be needed for these purposive searches which will be co-developed, piloted, and conducted in conjunction with our information specialist. These searches will greatly increase the amount of relevant data for the realist review. If there is a large volume of literature from additional searching (which we do not anticipate at this stage), we would prioritise including studies based on key criteria such as (1) UK based evidence, and/or (2) organisation wide interventions (not only individual approaches). The screening processes will be as described above.

Strategy for reviewing literature

Step 2 continued- Screening

We will include all empirical and if necessary, non-empirical literature (e.g. additional grey literature) that will help provide causal explanations in relation to our research questions. The following initial inclusion criteria will be applied:

- Study design: all study designs
- Setting/context: all workplace settings but particularly those where there is a high proportion of women employees, such as the health and social care sector. The intention here is to gain a representative range of employment, sectors and job types, and minoritised groups including for example, lower socio-economic groups and minority groups including ethnicities or disabilities.
- Study population: Our study populations comprise those who have experienced one of the following: IVF, miscarriage, stillbirth, pregnancy, postnatal return or peri-menopause/ menopause.
- Interventions: all studies that include any strategies/interventions designed to target women's wellbeing (i.e. psychological and physical) at the individual, team or organisational level. We will seek out process evaluations, and studies exploring experiences, barriers and facilitators.
- Outcome measures: All outcome measures (mental and/or physical) related to women's reproductive health during IVF, miscarriage, stillbirth, pregnancy, postnatal return and menopause, including subjective and objective measures and measures relevant to their impact (e.g., job performance, employee engagement, job satisfaction, stress, intention to leave). Economic outcomes will include direct costs of workplace interventions and any healthcare related costs and indirect costs such as absenteeism and presenteeism (lost productivity at work), time off work, health-related quality of life and any other economic outcomes. As this is a realist review, outcomes will be linked to the intervention via the articulation of causal mechanisms and presented in programme theories.

Screening will be undertaken by the Research Fellow (to be recruited), in collaboration with the Co-PIs (RA and LW). A 10% random sub-sample of the citations retrieved from searching will be reviewed independently for quality control (by a second reviewer, EB or CT). Any disagreements will be resolved by discussion between the RF, the second reviewer and the PIs. If disagreements still remain then a third member of the team will review and any disagreements will be resolved through further review/discussion.

Step 3: Article selection

Documents will be prioritised and selected based on relevance (whether data can contribute to theory building and/or testing) and rigour (whether the methods used to generate the relevant data are credible and trustworthy). Our provisional criteria for classifying the potential contribution of studies are:

Major:

- Peer reviewed studies which contribute to the study aims and are conducted in high income countries; or,

Minor:

- Studies conducted in practice and have not been peer reviewed but where the mechanisms causing or moderating intervention effectiveness could plausibly operate across settings.

Classification decisions will be checked between two reviewers and discussed with the rest of the team. The RF will read all included papers and finalise article selection by including documents or studies that contain data relevant to the realist analysis (i.e. those that could inform some aspect of the programme theory). Decisions will be made regarding whether a paper is to be included in the study or not based on a combination of relevance (based on inclusion criteria above) and rigour (e.g. how trustworthy the study is). This will allow us to determine whether papers make a major or minor contribution. We will use the RAMESES guidelines for reporting realist review (Wong, et al., 2016). Following an initial random sample of documents (10%) being selected, assessed and discussed between two reviewers to ensure that decisions for final inclusion have been made consistently, the remaining 90% of decisions re rigour will be made by the RF.

In the remaining section we provide details on how data will be collected, analysed and synthesised according to realist steps.

Step 4: Extracting and organising data

The full texts of the included papers will be uploaded in a reference manager software tool (i.e. Rayyan). Relevant sections of texts interpreted as related to contexts, mechanisms and/or their relationships to outcomes will be coded and organised in Excel or NVivo. This coding will be both inductive (codes created to categorise data reported in included studies) and deductive (codes created in advance of data extraction and analysis as informed by the initial programme theory). These will be analysed separately and then brought together in further iterative analysis cycles. Each new element of relevant data will be used to refine aspects of the programme theory, and as it is refined, included studies and documents will be re-scrutinised to search for data relevant to the revised programme theory that may have been missed initially. The characteristics of the studies will be extracted separately into an Excel spreadsheet to provide a descriptive overview.

We will start the coding and analysis process by using the literature deemed to make a 'major' contribution to the research questions to start building and refining our programme theory, while progressively focusing the review. Articles categorised as providing 'minor' contributions will be analysed to address particular aspects of the programme theory where necessary. The aim of the review will be to reach theoretical saturation in achieving the objectives, rather than to aggregate every single study that exists in the area. Decisions about whether a study can have a 'major' or 'minor' contribution may change over the course of the project, as the analysis progresses. All changes will be documented and recorded as

part of an audit trail to increase transparency and ensure consistency. Data to support the health economics review will also be extracted at this stage and integrated into the realist review process (see also Health Economics Evaluation section for further details).

Step 5: Synthesising the evidence and drawing conclusions

Our data analysis will use realist logic to make sense of the initial programme theory. Data will be interrogated at individual, team and organisational levels to establish their relationships. This type of analysis will enable us to understand how the most relevant and important mechanisms work in different contexts, thus allowing us to build more transferable CMOCs. During the review, we will move iteratively between the analysis of particular examples from the literature, refinement of programme theory, and further iterative searching for data to test particular subsections of the programme theory.

As outlined above, the realist review will follow current RAMESES quality and publication standards (Wong et al., 2013) and we will use the following analytic processes to make sense of our data (Pearson et al., 2015; Pawson, 2006):

- Compare and contrast sources of evidence – for example, where evidence about strategies in one paper or report allows insights into evidence about outcomes in another paper.
- Reconciling of sources of evidence – where results differ in apparently similar circumstances, further investigation is appropriate to find explanations for why these different results occurred.
- Adjudication of sources of evidence – included papers would be divided into those which can make ‘major’ or ‘minor’ contributions to our research questions and those that are considered ‘thick’ and ‘thin’ conceptually (Pearson et al., 2015).
- Consolidation of sources of evidence – where outcomes differ in particular contexts, an explanation can be constructed of how and why these outcomes occur differently.
- We will also identify a number of middle range theories (e.g. theories around groupthink and psychological safety) to enable us to move beyond description and provide a ‘set of assumptions’ lying behind the observed associations (Merton, 1967).

This process will allow us to explore why some interventions are more or less beneficial for some staff groups and in some contexts but not others. Our output from this final stage will be an evidence informed programme theory to answer our aim to improve understanding of how, why and in what contexts interventions work across pregnancy, postnatal return and menopause including their cost-effectiveness.

Step 6: Testing findings and developing evidence based recommendations

We will then test and refine our emerging evidence informed findings and programme theory with our stakeholder group. Informed by evidence-based implementation theory and stakeholder involvement we will use findings from our realist review to produce actionable theory to inform recommendations to support policy makers, health services, managers/leaders, and local team leaders. We will develop evidence-based recommendations to help guide the selection, tailoring, implementation of contextually-sensitive interventions and indicate gaps in the current evidence base.

We will use our existing relationships with stakeholders as a foundation for building the networks and widely disseminating our findings. To understand what is required in terms of resources to influence change, and the most effective interventions, we will ensure our stakeholder group has the required breadth and depth with membership as outlined above (see PPI section in on-line form) and below (project management section) and in table 1 which will be kept under review. Additional members will be approached and invited as

required. The exact design and components of the recommendations will develop iteratively through the project in collaboration with our stakeholder group (including our PPI members).

The recommendations produced will be pragmatic, actionable and reflect 'real-world' issues facing organisations such as equitable provision of interventions to meet a range of differing needs. We will use the 'Evidence Integration Triangle' (EIT) (Glasgow et al., 2012) as a framework to inform the structure and conduct of our stakeholder meetings. The EIT will support the team to bring together stakeholders around the evidence produced from our realist review in a collaborative, action-oriented way.

We will use the EIT to structure and conduct the stakeholder group enabling us to create a facilitative context in which research can inform practical decision-making, and for experiential knowledge from lived experiences and from professional practice to inform interpretation of that research. We will use the three components of the EIT (see below) to structure and inform the facilitation of the stakeholder group meetings.

Practical evidence-based strategies. The emerging contextualised findings of our realist review will be presented to the stakeholder group and critical discussion of these findings will be facilitated. Insights will be incorporated into programme theory refinement.

Pragmatic, longitudinal measures of progress. The stakeholder group will discuss what is useful and meaningful in the workplace to monitor intervention effectiveness. This will inform our understanding of how our study findings can inform the design of locally-relevant, meaningful, and usable resources within local/regional/national systems.

Participatory implementation process. We expect local understandings of implementation issues to be particularly important in shaping our reviews, but this will work 'both ways' and we will challenge our stakeholders to consider what might be possible in terms of implementation in their workplaces, or what changes would enable adjustments to become possible. This localised understanding, trials, and pilots will serve as a springboard for further participatory actions and co-developments.

Health economic evaluation: As part of this realist review, we will also search for economic studies (i.e. evaluations that look at direct and indirect costs and outcomes). This is not stand-alone – the cost-effectiveness review is part of the full review. For each identified study that meets the selection criteria, we will extract data relating to study design, population, intervention(s), comparator(s), type of economic analysis, perspective, time horizon, resource use and cost data including direct and indirect costs, health-related quality of life and any other economic outcomes. Data on economic costs and outcomes will be synthesised quantitatively, where appropriate, or narratively. These data will then be incorporated into the broader realist review at stage five. The PI RA has experience in incorporating health economic evaluations into realist studies, as does co-app JW, who is part of the REEM Realist Economic Evaluation Project which is ongoing to develop and test realist economic method.

Assessment and follow up: As a realist literature review, there will not be a traditional follow up because there is no direct intervention being implemented. However, in terms of follow up, we will re-run all searches one year after they have been conducted to capture any evidence of further intervention effectiveness documented during this time.

Assessment of efficacy/effectiveness: To determine intervention effectiveness we will extract data on primary and secondary outcomes as well as process evaluations/ studies into experiences, barriers, and facilitators regarding how and why the interventions work in

relation to women's reproductive health. This will be interpreted using the realist logic of causation and inference to determine effectiveness.

Assessment of unanticipated outcomes: Unlike a traditional systematic literature review, a realist review does not require outcomes to be determined a-priori, supporting instead a flexible and iterative approach. Therefore outcomes can and will emerge from the process of analysis and synthesis. In addition, realist methods consider both proximal and distal outcomes, and their relationship to both context and mechanisms, as well as unintended outcomes. The team is primed to identify and describe unintended/ unanticipated outcomes and is committed to discussing these within our project team meetings.

Scalability and translation: Taking a realist approach specifically accommodates the transferability of findings across settings. Unlike a traditional systematic literature review, a realist review considers context, implementation and setting. Much like the CIC Framework (Pfadenhauer et al., 2017), realist reviews take into account socio-cultural, socio-economic, ethical, legal, political, geographical and epidemiological factors, alongside implementation theory, process, agents, strategies and outcomes. Our data extraction will document physical settings (e.g. different working conditions and environments), and through the use of our theoretical and conceptual frameworks, findings will be mapped across micro, meso and macro levels and presented in programme theories capable of scale and translation.

The outputs emerging from our project, namely the evidence synthesis and recommendations, have direct value for decision making. To ensure broad reception, we have developed a clear dissemination strategy to transfer knowledge with our stakeholder group. Additionally, our project opens avenues for further developments by future scholars and practitioners to generate new knowledge, for example, by exploring the intersection of different identities (e.g., the confounded outcomes that women of colour experience vis-à-vis their health, the nuances of gender identity and sexual orientation etc.).

Socioeconomic position and inequalities: This review will draw on a wide range of interdisciplinary sources across the scientific databases using a co-created set of keywords to specifically target our research areas. Socio-economic position and inequalities will likely be important contextual factors and emerge in our analysis as we are not restricting the sectors which we are considering i.e. data across all industries will be collected. By doing so we will capture the full range of evidence including studies which have included participants from different socio-economic backgrounds or lack of. There will likely be differences across industry type and the relationship this may have to socioeconomic backgrounds and inequalities. We will present these nuances in our final report and this is a key advantage of using a realist review approach as it specifically identifies such contextual intricacies. Similar to the process described above, we will code for demographic characteristics in each paper to ascertain whether some practices need to be tailored to the needs of different groups therefore recognising and highlighting the significance of intersectionality. We will code for job type, socioeconomic status, ethnicity, ability and disability, and gender identity where available (including other characteristics that emerge from the literature). We will also make sure these issues are reflected in our stakeholder group. We will also focus on identifying gaps in the evidence, in particular any groups or characteristics where evidence is lacking.

Dissemination, outputs and anticipated impact

What do you intend to produce from your research?

The project will produce three major types of output in collaboration with our stakeholder group including:

1. Evidence-based recommendations. This output, in the form of infographics, will be tailored to audiences including business managers/leaders, HRM departments and Equality, Diversity, and Inclusion (EDI) specialists, and where relevant, policy makers to help guide decision-making about effective intervention implementation. Shorter news bites will also be shared via social media.

2. Academic outputs. An NIHR report for publication will be submitted; an overall findings paper submitted to a high-impact peer-reviewed journal (e.g., *Human Resource Management Journal*); conference presentations (e.g., *Gender, Work and Organization*).

3. Plain English summaries/ newsletters. We will create plain English summaries and study newsletters tailored to different audiences (e.g. healthcare professionals, business managers/ leaders, training providers, policy makers).

How will you inform and engage patients/service users, carers, NHS, social care organisations and the wider population about your work?

Key members of our stakeholder group will help promote and distribute our work. We have budgeted for dissemination costs and intend to produce a range of material designed to target different audiences. Table 1 below identifies the stakeholder groups and mechanisms of engagement through which we intend to reach wider audiences with our work.

Table 1. Stakeholder mapping

Group	Stakeholder	Mechanisms for engagement
1	Policy makers or those capable of influencing policy (e.g. Unions)	Policy briefing notes and fact sheets, created with the support of University of Surrey Communication and Public Affairs Team.
2	HRM/ EDI departments	Stakeholder support (e.g. through organisations such as Affinity health at work, What Works for Wellbeing).
3	Team leaders/ managers	Easy to digest evidence-based recommendations and news bites co-produced in an infographic and distributed via professional networks including CIPD, Affinity health at work evidence-based hub, as well as social media.
4	Patients and the public (i.e. women)	Easy to digest evidence-based recommendations produced in an infographic and distributed via those in contact with women (e.g. midwives, doctors, as well as via social media platforms to maximise reach).

How will your outputs enter our health and care system or society as a whole?

1. Media engagement strategy. We will co-identify various mediums to engage with our non-Academic stakeholder groups. For example, through engagement with relevant professional bodies (e.g CIPD, Trade Unions) and through promoting our findings via alternative publication routes (e.g. practitioner facing journals, The Conversation, Social Media). This will achieve impact through knowledge transfer in the short- to medium-term (1 month-2 years).

2. PPI / Stakeholder Engagement: Our stakeholder representatives will be actively involved in the co-production all outputs. The stakeholder group, including PPI representatives, will be encouraged to think about alternative or additional approaches to dissemination, which will include different approaches or networks. Our research will enter organisations through our strategic partnerships with CIPD, Affinity health at Work, and What works for Wellbeing amongst others.

3. Innovative forms of communication: We have had positive experiences of involving film makers to help with the communication of study outcomes, for example, we work with Studio Lotalica, a feminist and queer specialist organisation, who create user friendly and accessible summary reports to share on social media. We also have expertise in more creative forms of dissemination, for example, using the medium of theatre to perform research findings (Is there a doctor in the house: Evidence Synthesis Working Group: NIHR SPCR Project Number 390). Therefore, depending on the results of the realist review, we will translate some of our outputs into cartoons, videos, animations and/or interactive performances to facilitate wider distribution. This stage will be contingent on access to impact funds that we will seek out.

What further funding or support will be required if this research is successful (e.g. From NIHR, other Government departments, charity or industry)?

We have budgeted for dissemination costs to ensure transfer of knowledge. However, to maximise impact from our findings, we may seek additional impact funds through internal university avenues. For example, PI RA has previously been awarded £8,000, and co-app CT has received £10,000 from Impact Acceleration Account awards (IAA) funds in the past and both applicants have experience in monitoring and evaluating engagement and pathways to impact.

What are the possible barriers for further research, development, adoption and implementation?

Challenges may include the ability of organisations/ employers to implement the evidence-based recommendations. To address this, we will ensure our recommendations are practical and actionable by sense-checking outputs with key stakeholders embedded in practice and by using evidence-based frameworks to guide the development of the resources and their proposed implementation (e.g. the CFIR, Damschroeder et al., 2022). All resources will be designed in a user-friendly way (i.e. accessible for those who are very busy and need access to information to aid decision-making under possible resource or time constrained environments) including PDF and interactive versions. PI contact details will be made available on reports, news bites, and other informative sources so that managers can contact us for further information. Personalised support for implementation can be discussed separately and follow up work explored further. As well as ensuring our findings are disseminated in a variety of ways to maximise adoption and implementation, we will house the evidence-based recommendations on external facing websites (e.g University of Surrey; University of Sussex etc). Lack of resources (funding, personnel) to implement recommendations may be a further barrier. The health economic analysis component of this project as well as the contextual strengths of a realist review will be important to help organisations make decisions about cost/ benefit of investment in implementation.

What do you think the impact of your research will be and for whom?

Anticipated impact includes: (1) improved understanding of effective workplace interventions amongst those implementing workplace interventions; (2) improved wellbeing (physical and/or mental) amongst women experiencing pregnancy, postnatal return, and menopause at work; and (3) future research capable of measuring intervention success.

We anticipate that our evidence-based recommendations for HRM, EDI departments, managers, and policy makers will help to help guide decision-making about whether interventions are needed; and if so, which are most effective, in what circumstances. This will achieve impact over the medium term (1-5 years) once organisations supporting women are able to implement changes and evaluate the impact of those changes. We anticipate a future next step being the evaluation of the implementation of our evidence-based recommendations across a range of case study sites.

We anticipate our academic outputs will achieve impact over the longer-term (3-5 years) through informing the agenda for debate and action in health services, organisational culture, workplace support and in public health policy more widely.

We anticipate that our plain English summaries tailored to different audiences (e.g. healthcare professionals, business managers/ leaders, training providers, policy makers) will achieve impact through knowledge transfer in the short- to medium-term (1 month-2 years) by providing a meaningful summary of findings increasing knowledge and understanding, and will equip different audiences with evidence to support actions they may take.

How will you share with study participants the progress and findings of your research?

As this study is a literature review, it does not include study participants. However, we have four stakeholder group meetings scheduled for the project duration. Ahead of each of these meetings we will share briefing notes, highlighting project progress and key findings to date where relevant and appropriate. We also intend to involve our stakeholders in the co-production of a study newsletter to inform the wider public about our work, co-producing it with our PPI members and done in collaboration with co-app CT who has previous experience of co-producing study newsletters.

Indicative Project/research timetable (see also uploaded project flowchart)

Months	Tasks
1-3	Recruit, brief & train research fellow & Stakeholder Group members Stakeholder Group meeting (1; month 3) Step 1 of realist review (locate existing theories and build initial programme theory); with input from the first Stakeholder Group meeting
4-6	Start Step 2 of realist review (search for evidence and screen results) Iteratively refine initial programme theory based on initial search data and run additional searches as indicated by the emerging programme theory Complete Step 2 of realist review (search for evidence and screen results)
7-18	Start Step 3 (select articles) and Step 4 (extract and organise data) Stakeholder Group meeting (2; month 9) Complete Step 3 and 4 of realist review Start Step 5 of the realist review, refining the programme theory; Stakeholder Group meeting (3; month 15);

19-21	Complete Step 5 of the realist review (synthesising evidence), resulting in both independent partial programme theories, and an overarching programme theory. Start Step 6 including developing evidence-based recommendations and begin draft report
22-24	Stakeholder Group meeting (4; month 22), with draft documents shared for feedback and advice; Complete Step 6; Complete final report and submit; Finalise recommendations and disseminate (post report submission).

Women's health	2024									2025												2026		
	April → Dec									Jan → Dec												Jn	Mar	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Recruit RF & additional stakeholder group members																								
Core Project Team meetings																								
Stakeholder group meetings																								
Realist review: Step 1																								
Realist review: Step 2																								
Realist review: Step 3																								
Realist review: Step 4																								
Realist review: Step 5																								
Draft final report																								
Develop evidence based recommendations																								
Final report submitted																								

RF = Research Fellow

Project management

The project team will be led by RA and LW. Co-app CT will provide ongoing mentorship and guidance throughout this project and has experience of delivering three previous NIHR HSDR grants. RA has substantial project management experience, as well as topic and methodological expertise (see below). The team will take responsibility for outputs and for leading resources production. RA and LW are also supported by the wider team of co-applicants and will chair and lead internal project meetings with co-applicants and collaborators and take overall responsibility for the project and outputs, including:

1. Project management, including budget management (with the support of institutional administrative and research support systems) and day-to-day risks and issues.
2. Project outcomes quality and timely delivery and NIHR reporting requirements.
3. Relationships between researchers, stakeholder group and partners.
4. Data management. The core team will plan and share all elements using appropriate software. Any data held will conform to local and national data protection policies.
5. Guidance and career development support for the recruited Research Fellow.
6. Production of outputs and their dissemination.

The project team will meet every two weeks initially, then monthly and subsequently 2-3 monthly, online, to facilitate maximum attendance. Meeting minutes and action points will be documented by the appointed RF and circulated to all co-applicants. A subset of the project team (RA, LW, CT and the RF) will meet weekly. Additional meetings and email contact between team members will take place as and when needed, and will complement the project meetings. Secure file-sharing will take place using a secure OneDrive site hosted at the University of Surrey which also allows non-Surrey users to access authorised folders. Overall research governance and financial/project management oversight will be provided by University of Surrey; and all data handling will comply with the Data Protection Policies of our respective institutions, and with EU General Data Protection Regulation (GDPR) requirements.

As this is a secondary review, we understand that we do not need a steering group in addition to the above.

Ethics

The University of Surrey's Ethics committee have confirmed that ethics approval is not required for a secondary realist review of the evidence.

Patient and Public Involvement

Nigel Simpson, the National Lead for the NIHR Reproductive Health and Childbirth Speciality said that women "are very open to research [...] to help other women to understand more about the common problems they encounter" (NIHR, 2023). To date we have worked with women experiencing pregnancy, postnatal return, and menopause, along with content matter experts including academics, and employer facing groups to develop this proposal and we wish to continue to work with these people if the project is funded.

The stakeholder group will meet four times during the 24-month project, online, to maximise attendance and accessibility for all. The group will help us to: make sense of the findings from the review; optimise our dissemination plans; and produce feasible and practical recommendations for the key audiences.

We have several members already recruited including: Affinity Health at Work (Dr Jo Yarker); What Works for Wellbeing (Joanne Smithson); CIPD (Rebecca Peters), and content matter experts (Dr Krystal Wilkinson; Ms Jo McCarthy-Holland) who all support this work, seeing it as both timely and necessary. We have also consulted with a group of women at different stages of their reproductive lifecycles as part of this review including individuals at a top film financing and production company; Foreign, commonwealth and development office; Google; and Unilever.

We recognise that not every member will be able to attend every meeting and will encourage non-attenders to contribute their insights by another means (e.g. email and/or telephone conversation). We also recognise that for some group members there may be some inhibition or tension of discussing potentially sensitive topics/views in a larger group, so we will provide opportunities for stakeholders to discuss the topic further with the research team between meetings. For example, we will convene 'briefing meetings' as required before the 'full' stakeholder meeting – to better prepare those who may be inhibited. Finally, we recognise the need to create spaces that are effective of wider diversity and inclusion and this will be a key priority for us.

PPI Lead

Whilst we could have identified a PPI lead from our stakeholder group, we have decided to appoint the three PPI representatives to lead in their respective reproductive life experiences. These PPI representatives will be supported and coordinated by RA, CT, and the appointed RF where appropriate. RA has previous experience of embedding PPI in research more broadly, and specifically in realist reviews. RA and LW will lead on additional PPI recruitment with the support of the wider team; be the point of contact for all PPI and stakeholders including support and facilitation of input and payments during meetings and throughout the project lifecycle; ensuring timely and appropriate communication to PPI including briefing updates, meeting agendas, minutes and summaries of PPI with the support of the appointed RF.

Project/research expertise

Team: The research team includes clinical and academic expertise in research with and for women (RA, LW, CT, EB), women's health (EB), organisational culture (RA, LW, CT), methodological training/experience in realist synthesis (RA, CT, JW), health economics (HM) and experience in creating innovative dissemination resources for health managers/leaders to disseminate research findings and ensure the research has impact (RA, LW, CT). The team also has experience of delivering NIHR grants.

Research Team	Role/expertise
Ruth Abrams (RA) 15%	<i>Lecturer in Health Services Research.</i> Expertise in realist methods; qualitative research; healthcare service design, delivery and evaluation; healthcare workforce; organisational design/ culture. Role: Project lead.
Lilith Whiley (LW) 15%	<i>Senior lecturer in Occupational and Organisational Psychology.</i> Expertise in organisational psychology; HRM; workforce wellbeing; gender; women's health at work. Role: Co project lead.
Cath Taylor (CT) 5%	<i>Professor of Workforce, organisation and wellbeing.</i> Expertise in realist methods; Organisational psychology; workforce wellbeing including psychological and physical health. Role: Mentor; Methodological guidance.
Elizabeth Bailey (EB) 5%	<i>Associate Professor and Director of the Elizabeth Bryan Multiple Births Centre.</i> Expertise in pregnancy (including complex pregnancy), midwifery, the organisation of maternity services. Role: Content matter expertise- Women's health.
Hema Mistry (HM) 10%	<i>Associate Professor in Health Economics.</i> Expertise in economics analysis and modelling. Role: Health Economics lead and supervise RF in HE.
Judy Wright (JW) 10%	<i>Information specialist.</i> Expertise in search methods for realist synthesis, systematic reviews and health services reviews. Role: Responsible for search method design and gathering and managing all review literature sources etc.
HE Research fellow 20%	<i>To be appointed.</i> Post-doctoral fellow with experience of health economics will be appointed for six months.
Research Fellow (RF) (100%)	<i>To be appointed.</i> Post-doctoral fellow with experience of realist synthesis and literature reviewing will be appointed for 24 months.

Success criteria and barriers to proposed work:

Success criteria

- Meeting project milestones as outlined in project timeline and Gantt chart.
- Evidence of building on the existing evidence identified in this proposal, based on our initial scoping review and initial programme theory development.
- Produce a review capable of explaining what interventions works, for whom, and in what circumstances in relation to supporting the health (psychological and physical) of women at work during pregnancy, postnatal, and menopause.
- Evidence of engagement including collaboration and co-production with our stakeholder group to sense-check review findings and co-develop evidence-based recommendations.
- Translating evidence into practice: use of EIT framework will support collaborative, action-oriented stakeholder engagement and guide the translation of findings into practice.
- Production of evidence-based recommendations for organisations and policy makers (where appropriate) to guide decision making around utilising the most effective interventions for different contexts, circumstances and professional groups.

Potential barriers

- Managing the breadth of the synthesis across interdisciplinary literature. We have however set out how we will prioritise evidence (detailed inclusion/ exclusion criteria) and conducted preliminary scoping searches with the help of our information specialist which have reassured us that we will have sufficient evidence to work with.
- Quality of the research on interventions may be limited. For example, we may be able to identify interventions but these may not have been evaluated for effectiveness in their own right. Where possible we will account for evidence demonstrating intervention effectiveness. Additionally, by taking a realist synthesis approach, effectiveness is not defined simply as 'does it work?' but instead uses empirical papers to understand how an intervention works ,by what mechanisms, how these are triggered (or not), and in what contexts, developing evidence informed programme theories and hypotheses.
- There may be limited evidence for some of the staff groups or industries. However, we have planned an iterative approach to searching, including reviewing grey literature and secondary searches, and drawing on our stakeholder group and evidence from their experience to develop, test, and refine theory.