Article

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Feeley, Claire, Crossland, Nicola, Balaam, Marie-Clare, Powney, Deborah, Topalidou, Anastasia, Smith, Eleanor and Downe, Soo

Feeley, Claire ORCID: 0000-0002-8013-0352, Crossland, Nicola ORCID: 0000-0003-1063-8123, Balaam, Marie-Clare ORCID: 0000-0003-4511-7352, Powney, Deborah, Topalidou, Anastasia ORCID: 0000-0003-0280-6801, Smith, Eleanor ORCID: 0000-0001-5746-0815 and Downe, Soo ORCID: 0000-0003-2848-2550 (2021) The ASPIRE study: A midwifery-led research response to COVID-19 and beyond. Practising Midwife, 24 (9). pp. 23-29. ISSN 1461-3123

The ASPIRE study: A midwifery-led research response to COVID-19 and beyond

Carol Kingdon, Nicola Crossland, Claire Feeley, Marie-Clare Balaam, Deborah Powney, Anastasia Topalidou, Eleanor Smith, and Soo Downe

Summary

This is the first article in a series reflecting on the role of research midwives in the ASPIRE study (Achieving Safe and Personalised maternity care In Response to Epidemics). In this article we introduce ASPIRE and provide an overview of the study. We also reflect on what makes ASPIRE uniquely midwifery-led within the National Institute for Health Research (NIHR) portfolio and the role of research midwives within recruitment sites. We hope this article, and those that follow in the series, written by ASPIRE research midwives, will serve as a roadmap to inspire the next chapter of midwifery research in England.

Background

The health and social care research landscape is changing. In June 2021, the National Institute for Health Research (NIHR) published *Best Research for Health: The next Chapter*.[1] In the coming years the NIHR is seeking to become much more integrated across disciplines to better serve holistic research questions of the kind midwives may ask or contribute to. Earlier this year, Professor Jane Sandall was appointed as the first-ever Head of Midwifery Research at National Health Service (NHS) England. She will design and lead the midwifery research strategy for NHS England and Improvement on behalf of the Chief Midwifery Officer for England. Clinical Research Networks (CRNs) are an established part of the NIHR infrastructure. They help to deliver high quality research across England. These CRNs are also now active in strategic health partnerships that value midwives as critical to effective health and social care research. Launched in May 2021, the *North West England Nursing, Midwifery & Allied Health Professionals (NMAHP) Research Capacity & Capability Strategy 2021-24*[2] provides a regional roadmap to promote and support Nursing, Midwifery and Allied Health Professional Research. ASPIRE provides a thread to begin to weave these developments together and consider the potential of midwifery research's contribution to the next chapter. *Best Research for Health* demands that we build on the learnings from the research response to COVID-19. Studies funded or supported by the NIHR in partnership with the NHS have put the United Kingdom (UK) at the forefront of international efforts to find new ways to diagnose, treat and prevent the spread of COVID-19. These studies include trials of vaccine efficacy that midwives have recruited to and/or participated in.[3] Other studies have investigated the operation of the NHS during the pandemic, with the knowledge these studies generate seeking to restore service, and design and deliver them in a way that builds future resilience. ASPIRE is one of these studies.

Overview of the ASPIRE-COVID-19 study

UK policy is for safe, personalised maternity care.[4] However, during COVID-19 face to face provision of antenatal and postnatal tests and visits have been reduced in some places, and some women with worrying symptoms are not going to hospital. Many organisations are trying new solutions, including remote access technologies. Some Trusts have reduced community maternity services, including home and birth centre births; barred birth companions from accompanying their partners during ultrasound scans and in early labour; and reduced or stopped visiting to postnatal and neonatal wards. There have been media reports of women giving birth at home without professional help, either because midwives are unavailable, or for fear of being infected with COVID19 if they go to hospital. Other Trusts have been able to keep all or most of their services going and have rapidly developed innovative solutions to the issues raised by the pandemic. Reports from various professional and policy organisations suggest that these issues have had an effect on service users, their families, and maternity care staff.

In contrast to increased centralisation of maternity care in the UK, some parts of the Netherlands have focused on maintaining community maternity services during COVID-19 as far as possible. Building on experiences in the UK and the Netherlands, ASPIRE aims to find out how best to provide care for mothers, babies, and partners during and after a pandemic. We will look at what documents and national leads say about service organisation in both countries, and at women's experiences. We will also look in detail at eight NHS Trusts. We will find out how their services have been organised during COVID-19, the experiences and feelings of parents and staff, and what the outcomes have been, including infections. Throughout the study, we will work with key stakeholders. Finally, we will agree on an organisational model that can be used across the UK to ensure safe, personalised routine maternity and neonatal care, both during pandemics and other similar crises, and for routine care into the future.

ASPIRE is funded by the Economic and Social Research Council (ESRC), as part of the UK Research and Innovation's (UKRI) rapid response to COVID-19. Funding was awarded in June 2020 for 18 months. As shown in Box 1, the ASPIRE study has five distinct Work-Packages. The principal focus of this article is Work Package 3, which is using an organisational case-study design to investigate the pandemic response in eight NHS Trusts providing maternity and neonatal services in England. This component of ASPIRE is known as ASPIRE-COVID-19-CENTRE (CasE Studies of NHS TRusts in England).

Box 1: Overview of ASPIRE-COVID-19 study

ASPIRE-COVID-19 comprises five overlapping work packages (WP) as outlined below. For further information please see the study website https://aspire-covid19.com/

Work Package 1 (months 1-18): Project Governance

Work Package 2 (months 2-8): International comparison, UK/Netherlands
I. *Documentary review* COVID-19 guidelines/advice/reports/ from governmental, professional and service user sources (internal, and staff and public facing).
II. *Women's views/experiences* of maternity care provision before, during, and after COVID-19 through the B3 survey.
III. *Interviews* with leads in relevant national governmental, professional, and service user organisations (n≤ 40 – n≤20 in the UK and n≤20 in The Netherlands).

Work Package 3 (months 3-12): National in-depth case studies of eight NHS Trusts in England. There are three components to the case-study design:
I. *Documentary analysis;* websites, social media, policies, minutes
II. *Semi-structured Interviews*: heads of service (n≤ 80 – 10 in each Trust), health professionals and service user representatives (n≤ 200 – 25 in each Trust), and service users (n≤ 160 – 20 in each Trust)
III. *Clinical data*: routinely collected data, key maternal and neonatal outcomes

Work Package 4 (months 11-16): Clinical data analysis and modelling
I. Data modelling, using causal inference techniques and multi-level modelling to draw comparisons within and between case study sites (WP3 data).
II. A two-day consensus event with key stakeholders to share insights from data collected, to assess and refine the model, and prototype a toolkit to inform crisis and routine organisation of maternity care
III. Further development and beta testing of the toolkit with the stakeholder group, to include algorithms, videos, podcasts, hints and tips.

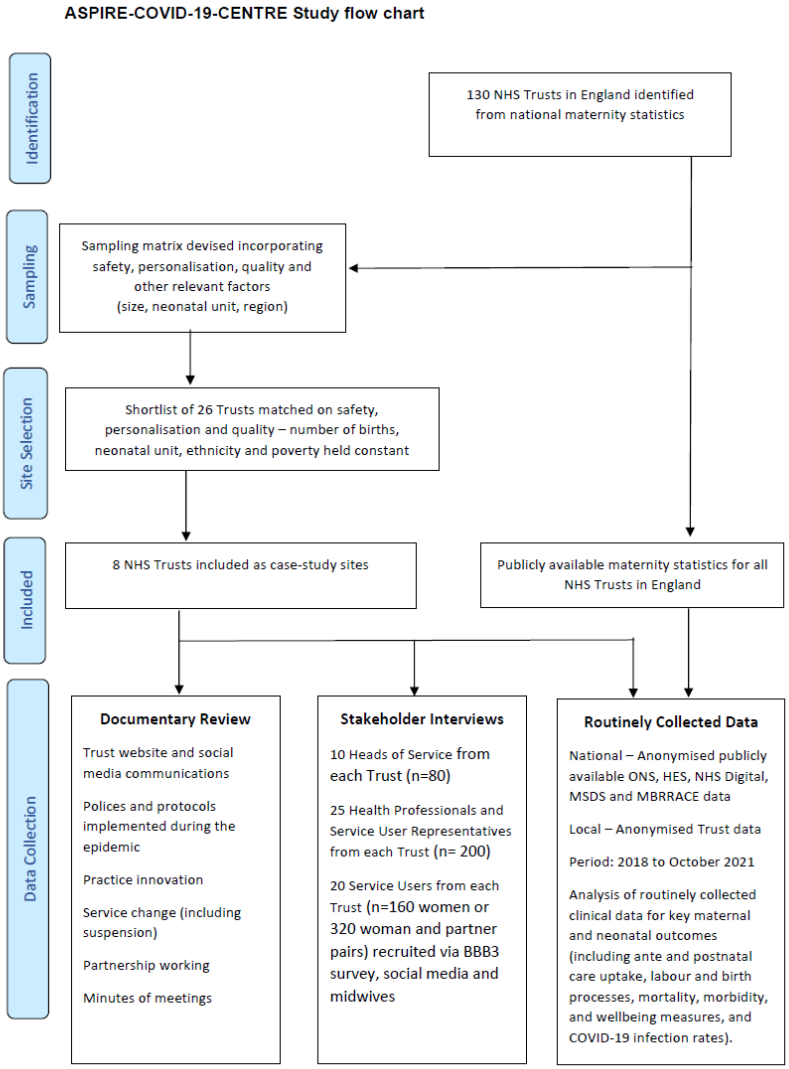
Work Package 5 (months 15-18): Synthesis, tool kit development and testing, dissemination, implementation and project close.

Work package 3: ASPIRE-COVID-19-CENTRE

ASPIRE-COVID-19-CENTRE aims to describe the processes, outcomes, and staff and service user experiences of varying responses to the COVID-19 pandemic in NHS Trusts selected for maximum variation. In other words, we wanted sites that were different. Different in terms of population served, location and response to the pandemic. A 'site' comprised all the maternity services provided by a selected Trust (including hospital, birth centre and home settings). We used three routes to identify which sites to approach: best practice reported by national stakeholders interviewed in Work Package 2; a systematic sampling matrix; and via CRNs. Maternity statistics for England[5] were used to compare 130 Trusts and shortlist 26 based on personalisation (i.e. retained homebirth service), safety (stillbirths), quality (Care Quality Commission rating), COVID-19 infection level, and local community factors (area level deprivation, child poverty and ethnicity).[6] Box 2 provides an overview of

the study design reproduced from the study protocol and provides more detail about the proposed data sources listed in Box 1 (documentary review, stakeholder interviews, routinely collected data). Using our case study approach, data from each site will be examined both individually and across sites to reveal patterns of organisational responses and determine 'best practice' across the maternity and neonatal care system.

Box 2



Research Governance

Regulatory approvals for the study were rapid with ethics approval fast-tracked via the Integrated Research Application System (IRAS). This expedited process of research approval was a direct response to the pandemic by the Health Research Authority (HRA). The opportunity for expedited research delivery was enhanced by the support of local CRNs. The NIHR Portfolio of studies consists of 6,000 quality studies eligible for support from the CRNs. The kinds of support we were able to access included regional CRN teams (who

invited Expressions of Interest from potential sites) and Reproductive Health and Childbirth Research champions (who provided key midwifery contacts within Trusts approached directly). There were financial benefits for Trusts, enhanced study credibility and portfolio adoption entitled it to an assessment to proceed at a time when most studies were paused indefinitely. Between March 2020 and March 2021, the NIHR's priority focus was Urgent Public Health (UPH) COVID-19 studies with all other Portfolio studies categorised according to the RESTART Framework.[8] ASPIRE-COVID-19 CENTRE received HRA and IRAS approval on the 23rd of October 2020.

Listening to stakeholders

Semi-structured interviews are a method of qualitative widely used in research in midwifery to elicit views and experiences of professionals, women, and childbearing people.[7] For ASPIRE, we designed three interview schedules. Heads of Service interviewees include Chief Executives, Directors of Nursing and Midwifery, Obstetric and Neonatal Clinical Directors. In the health professionals and service user representative's participant group, we sought interviewees working in a range of midwifery roles (newly qualified, specialist, community), alongside neonatal staff, obstetric staff, general practitioners, health visitors, and maternity voices partnership leads amongst others. In the service user's participant group, up to 20 service users (women), or service user pairs (women and partners) are purposively sampled to take part in semi-structured interviews. Inclusion criteria for service users is that they have become parents with a first or subsequent baby during the COVID-19 pandemic in England. We have not excluded women who experienced the death of their baby before, during or soon after birth. We are trying to ensure the views and experiences of women of different parity, ages, ethnicities, and COVID-19 status are included.

Moving research forward remotely

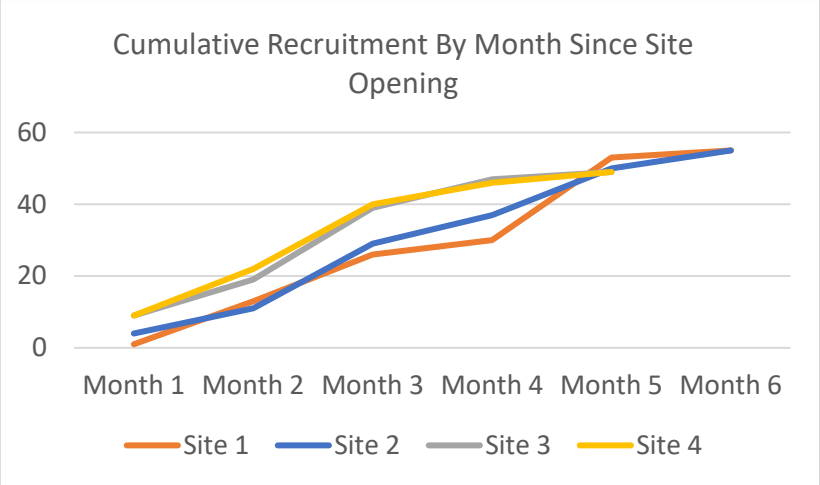
As a university-based research team we had to find new ways of working to deliver the study during the pandemic. All interviews must be conducted remotely rather than face-to-face. We knew the NHS was investing heavily in digital capabilities during the pandemic, including the use of Microsoft (MS) Teams for its collaboration functionality and security features. For these reasons we chose MS Teams as the platform by which to run the study. MS Teams enabled us to devise systems that were both regulatory compliant and could be scaled up as new recruitment (Trust) sites came on board. Using MS Teams we created a digital space for each site where documents could be stored, stakeholder interviews could be scheduled, conducted, digitally recorded and logged simultaneously by university and Trust-based research teams. Research Midwives were provided with university contractor accounts. By accessing TEAMS using their university account they had access to the secure University

Network. Localised information sheets, consent forms and interview schedules were saved in the TEAMS space. Consent and interview recordings appeared in the posts. As soon as they were downloaded recordings were removed from MS Teams In accordance with our ethics approval all participant data had to be stored within the secure MS Teams sites that sat within the University Network. We also used digital enablers to enhance recruitment to stakeholder interviews via Twitter and Facebook Groups.

Widening participation in research

We sought patient and public involvement in the design of our study adverts, information sheets, consent forms and interview questions for service users. The wording on the consent form was simplified in response to feedback to try and widen participation from all sectors of the community. Despite our best efforts one social media advert targeting women from black and brown communities was responded to by white women, adding insights to the multifactorial issues of underrepresentation of some communities in research. Learning from this, we advised later sites to purposefully seek out participants from ethnically diverse communities earlier on in the recruitment phase to ensure we met our commitments to inclusivity. Another unintended consequence of our sampling approach was that actual sites are a mixture of Trusts that are more established research centres and those that are not. While our approach to conducting the study was the same for each site, the incidence of COVID-19 cases was a bigger impediment to recruitment accruals than research experience in the organisation. Therefore, as a combined team (UCLan researchers and research midwives) we learned to pivot and adapt to the changing landscapes across the sites. Good and close communication with supportive processes meant we were able to successfully recruit, albeit on a different timescale than originally planned. The recruitment trajectories for the first four sites are shown in Figure 1 with all sites taking six months to meet the recruitment targets In some sites managers took a personal interest in the success of ASPIRE, which had a positive effect on recruitment.

Figure 1



Role of research midwives within recruitment sites

ASPIRE-COVID-19-CENTRE is unusual in the NIHR Portfolio because it has a strong qualitative component and Research Midwives within Trusts undertake interviews. The ESRC grant included funding for a Research Midwife in each Trust to champion the project, recruit participants for interview and conduct interviews. Typically, these funds have been spent on a shared post with a team of part-time research midwives recruiting and/or conducting interviews. A maximum of 55 interviews per site were specified in the study protocol with 20 interviews conducted by the university-based team and the remainder by the Research Midwives in Trusts. Qualitative interview training was provided alongside practice sessions for conducting the interviews remotely. These sessions helped to foster productive working relationships between the Trust and university teams. Initial challenges with the technology were shared and communication was regular. The first site opened on the 17th of November 2020. The team there comprised of three Research Midwives, the most senior of whom was also the local principal investigator (PI). During December recruitment to the study gained momentum with the Research Midwives and interviewees championing the study within the organisation and on social media. Feedback from participants was incredibly positive with many suggesting it was cathartic, particularly for staff, to participate in interviews.

What makes ASPIRE midwifery-led research?

It is rare, but not unheard of for Research Midwives to be local PIs in NIHR Portfolio studies. In ASPIRE, the first four sites to open all had midwives as PIs. The grant holder and Chief Investigator, Professor Soo Downe, is also midwife. However, it is the midwifery philosophy of care that underpins ASPIRE that fundamentally makes it midwifery led research. ASPIRE

was conceived from a background of international evidence of safe and personalised care that predates the COVID-19 pandemic. Much of that evidence comes from midwifery.[9] This evidence has not changed. Nor has England's national policy ambition for Better Births.[10] The optimum organisational solutions to ensuring protection from COVID-19 infection (for staff and service users) at the same time as attaining high quality, safe and personalised maternity care are unknown. The ASPIRE study seeks to contribute to this evidence gap using a midwifery lens that centres women. At the study outset we used NHS England's March 2020 definition of safe and personalised care.[11] The study findings will report best practice for maintaining what stakeholders perceived as key to delivering safe and personalised care in a pandemic. The formulation of ASPIRE's research questions is what makes it quintessentially midwifery research.

Co-creation and collaboration

ASPIRE's research questions were informed by service user organisation concerns early in the pandemic, when contrary to available evidence, in some Trusts choice of place of birth was suspended and labour companionship restricted. Representatives from these organisations sit on the ASPIRE Advisory Committee. They have been involved in the research design and conduct and will inform the dissemination and implementation of the study's findings. Advisory Committee membership includes representatives from the Stillbirth and Neonatal Death Society (SANDS), the human rights organisation BIRTHRIGHTS, the Royal Colleges (RCM, RCOG) and the International Confederation of Midwives. Collaboration is as pivotal to research in midwifery as it is to midwifery in practice.

The next chapter: Towards a roadmap for midwifery-led research in the NIHR Portfolio

Research in midwifery has a rich history of collaborations with obstetricians and social scientists, like those we have in the ASPIRE team. Opportunities for midwives to pursue research have been available since the 1970's and they gained momentum during the 1980's when research expertise was established in quantitative and qualitative methods.[12,13] Writing in 2000, Renfrew and Proctor acknowledged that while research in midwifery had come far in the preceding 20 years, it remained patchy and of inconsistent quality. This observation led them to make the following recommendation: *We need to increase the numbers of midwives involved in generating knowledge, so that knowledge is appropriate to the needs of midwives, women and babies. This will require investment in research training and a career structure which enables midwives to develop in research, as well as stay in the clinical context (p.201).*[14] Since 2006 the NIHR has changed the landscape of research in the NHS and enabled more and more midwives to be involved in generating knowledge from

research by undertaking a variety of roles. Research Midwives may develop specialist expertise by involvement in recruitment to clinical trials of specific conditions or treatments; or they may develop research skills by undertaking a local PI role in midwifery-led research. There is also the NIHR 70@70 NMAHP Research Leaders Programme that is strengthening the research-led care environment. All Trusts are now encouraged to work closely with CRNs to ensure their workforce can fulfil its research potential. The *North West England NMAHP Strategy*[2] includes a training pathway of the kind Renfrew and Proctor recommended. This pathway illustrates the opportunities for personal transformation by becoming involved in research (figure 2).

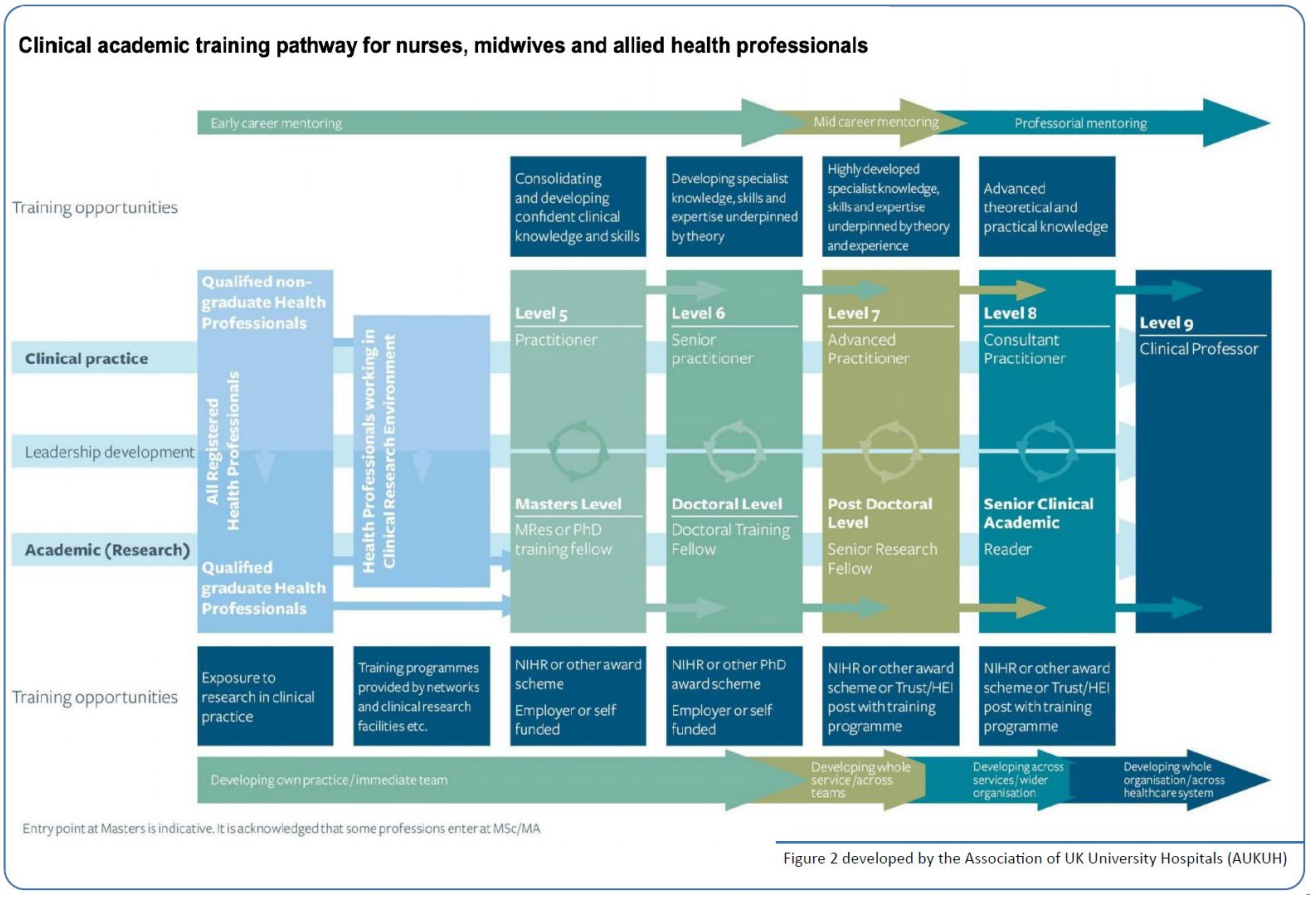


Figure 2 developed by the Association of UK University Hospitals (AUKUH)

Concluding remarks: role of research midwives

The COVID-19 pandemic led the NHS to suspend many routine clinical services and the NIHR to target support towards priority Urgent Public Health COVID-19 studies, which have generated evidence that has underpinned the government response to the pandemic. Work is now underway to support the recovery and increase the UK's research base. These developments include the vision set out by the Department of Health and Social Care in the

national documents (the NHS Long Term Plan[15]: the future of UK clinical research delivery[16], Best Research for Health[1] , UK Policy Framework for Health and Social Care Research Framework[17]), regional and Trust strategies. These strategies come at the same time as the new midwifery research strategy for NHS England and Improvement. The NIHR is now focused on RECOVERY and restoration of a fully active portfolio of NIHR research.[18] Midwives have a vital role to play in this recovery as consumers, champions, investigators, and leaders of research. We hope that this article and those that follow in the series (written by ASPIRE research midwives) will contribute to inspiring the next chapter of midwifery research in the UK.

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Further information

Full details of the ASPIRE study are available ResearchResistry (ID: researchregistry5911) https://www.researchregistry.com/browse-the-registry#home/registrationdetails/5f36aaf27a896d0015764485/ and UKRI Gateway (https://gtr.ukri.org/projects?ref=ES%2FV004581%2F1)

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