CO-LOCATING UNIVERSAL WELFARE ADVICE IN HEALTH SETTINGS FOR MOTHERS AND THEIR FAMILIES

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ABSTRACT

Childhood deprivation is associated with poor health and social outcomes, limiting childhood development with long-lasting effects into adulthood. Welfare advice services improve financial security but access is often unequal for the most vulnerable. Maternity care offers a unique opportunity to access most pregnant women and may provide a suitable setting to host a universal welfare advice service to improve advice uptake. However, little is known on how to effectively design, implement and evaluate these services to reach those most in need.

This thesis aims to understand whether co-location of universal welfare advice in health settings for mothers and their families, as a cost-effective measure to improve health and wellbeing, is acceptable and feasible to deliver and evaluate.

The thesis adopts a complex intervention research framework as a methodological approach to the development, implementation and evaluation of this intervention. First, I conducted a narrative systematic review to explore the effectiveness and implementation of co-located welfare services. Secondly, I conducted an analysis of a longitudinal study to explore how financial security changed and impacted the health, wellbeing and socioeconomic security of mothers in Bradford during the COVID-19 pandemic. Third, I conducted a before and after study, exploring the feasibility of evaluating a co-located welfare service in primary care. Finally, I explored the feasibility of utilising financial data linkage to improve evaluations of co-located welfare services.

This research presents a theory of change model, depicting how universal welfare services co-located in maternity settings improves health and wellbeing and cost savings to the National Health Service, and demonstrates evidence of promise to support this theory of change. I demonstrate the most appropriate effectiveness and implementation outcomes and report the utility of routine financial data linkage for such evaluations. The thesis culminates with a methodological approach to investigate the effectiveness and implementation of a welfare service co-located in maternity settings.

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All errors remain my own.

AUTHOR'S DECLARATION

I confirm that this work is original and that if any passage(s) or diagram(s) have been copied from academic papers, books, the internet or any other sources these are clearly identified by the use of quotation marks and the reference(s) is fully cited. I certify that, other than where indicated, this is my own work and does not breach the regulations of HYMS, the University of Hull or the University of York regarding plagiarism or academic conduct in examinations. I have read the HYMS Code of Practice on Academic Misconduct, and state that this piece of work is my own and does not contain any unacknowledged work from any other sources. I confirm that any participant information obtained to produce this piece of work has been appropriately anonymised.

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CHAPTER 1 INTRODUCTION

This chapter establishes the rationale for establishing universal welfare advice co-located in health settings for mothers and their families. The chapter begins by providing a background to the relationship between financial insecurity and poor health and wellbeing. It goes on to describe the relationship between welfare advice services and health settings in the United Kingdom (UK), and how co-location might be a measure to improve the uptake of welfare rights and benefits advice, improve financial security and thereby improve health and wellbeing. The chapter concludes with the aim and research questions of the thesis.

1.1 FINANCIAL SECURITY

Financial security refers to the state of having sufficient financial resources to cover current and future financial needs.[1] This can relate to individuals, families and households at the micro level to organisations, institutions and countries at the macro level.

Traditionally, financial security for individuals and families has been measured in terms of income and monetary assets.[2] However, whilst income is considered a necessary component of financial security, the literature suggests that financial security is a more complex and multi-faceted concept.[3] Financial security encompasses several components, including but not limited to having a steady and reliable income, having savings and investments to provide for short and long-term financial needs, and managing debt responsibly to avoid straining financial resources.[1-3]

Whilst often considered alongside financial security, financial resilience is conceptually distinct from financial security. Financial resilience refers to the ability of individuals and groups to withstand and recover from financial shocks, economic downturns, or unexpected expenses to continue to meet necessary financial obligations and pursue long-term financial goals.[4]

Financial insecurity and a lack of financial resilience may lead to poverty for individuals and families.[5] Poverty refers to a state of deprivation characterised by a lack of basic necessities required for a minimum standard of living, including social participation.[5] These necessities are typically considered to include adequate food, shelter, clothing, healthcare, and access to education.[6] As such, poverty can be a challenging concept to define and measure. Traditionally, poverty, like financial security, has been measured in monetary teams. In the UK, poverty is defined as living below 60% of the median income of the UK population.[7] However, other measures are sometimes used in conjunction with this, such as use of food banks.[6] Some specific measures of poverty have also been developed, such as the United Nations Development Programme (UNDP) Multidimensional Poverty Index (MPI), that combine various dimensions of poverty, including income, living standards, social inclusion and education.[8]

Financial literacy refers to an individual's ability to process economic information and make informed and effective decisions about their finances.[9] This may include having knowledge and skills, such as budgeting, debt avoidance and management, financial investment, and long-term financial planning and decision making.[10] Financial literacy is an important contributor to an individual and a family's financial security and resilience. According to the Organisation for Economic Co-operation and Development (OECD) international survey of financial literacy, about half of the European Union (EU) adult population does not have a good enough understanding of basic financial concepts, with the most vulnerable affected.[11] Low-income groups, women, young people and older people, were found to have the lowest levels of financial literacy.[11]

For the purposes of this thesis, financial security refers to the ability of individuals and families having sufficient financial resources to cover current and future financial needs[1] and financial resilience is refers to the ability of individuals and families to withstand and recover from financial shocks, economic downturns, or unexpected expenses to continue to meet necessary financial obligations and pursue long-term financial goals.[4] For the purposes of this thesis financial literacy refers to an individual's ability to process economic information and make informed and effective decisions about their finances.[9] Poverty is not explicitly measured for the purposes of this thesis.

1.2 FINANCIAL INSECURITY AND HEALTH

The relationship between financial insecurity and poor health and wellbeing is well established. Childhood deprivation refers to the condition in which a child lacks essential resources and opportunities for a healthy and happy life. This includes sufficient access to material, social, cultural, emotional and environmental resources, opportunities and support.[3] Early childhood material deprivation is associated with poor physical and mental health and negative social outcomes that not only limit a child's development in the short-term but have long lasting effects into adulthood.[12] Areas with high levels of early childhood deprivation are linked with: poorer levels of child development, school readiness and educational attainment; high levels of obesity; more high-risk behaviours; more looked after children; poor performing schools and higher school exclusion rates; higher levels of youth crime; and lower entry into further education, training or employment.[12-16] These wider determinants damage child health, cause clustering of unhealthy behaviours, impair life opportunities and increase longer term non-communicable disease risk.[12]

In adulthood, links between financial difficulties, social deprivation and mental health are also well established.[17] Financial insecurity can precipitate and perpetuate mental health problems[17,18] and has been found to be a predictor of chronic physical illness.[19-21] Furthermore, individuals suffering with poor mental health associated with financial insecurity are more likely to face challenges in accessing the advice and support needed to address such welfare issues.[18,21]

In the public health discourse, these circumstances are understood as social determinants of health, which are major causes of illness and inequality internationally.[22] The World Health Organization estimates that income security and living conditions account for almost two thirds of health inequities between socioeconomic groups within countries of the European region.[23] Poor health can also lead to socioeconomic welfare problems, propagating the cycle of deteriorating health and socioeconomic welfare, and perpetuating inequalities.

1.3 WELFARE BENEFITS AND RIGHTS ADVICE

The adverse effect of financial insecurity on physical and mental health can be obviated if corrected early on. Consequently, the availability and accessibility of welfare benefits and rights advice to improve uptake of the benefits and financial support to which individuals are eligible is crucial to addressing these social determinants of health and to improving health equity.[20]

In the UK, state benefits and financial support are available for people with a low income and for people unable to work, looking for a new job or affected by redundancy. State benefits and financial support are also available for people living with a health condition or disability, for families, and for carers.[24]

Welfare advice services in the UK are provided by different types of organisations, including local authorities, charities, law centres and other pro bono legal services. The National Association of Citizens Advice Bureaux is one the leading providers of welfare rights advice in the UK. It is made up of a network of 258 independent local Citizens Advice charities specialising in the provision of free, confidential specialist advice to assist people with issues relating to welfare benefits, debt, housing, employment, education and immigration, among others.[25] The mechanism of delivery of welfare advice to those who need it varies across the country but is usually offered over the phone, in person and online, including via web chat.

1.4 FINANCIAL INSECURITY IN THE UNITED KINGDOM

For families in the UK, living with financial insecurity has become more commonplace over recent years. Years of austerity following the global economic recession in 2007 caused financial insecurity for many families. More recently, the COVID-19 pandemic has triggered or further exacerbated socioeconomic insecurity, with the largest effects amongst the most vulnerable in society, including ethnic minorities and those living in socioeconomically deprived areas.[15,26,27] For families with children, the closure of educational settings and the need for home-schooling brought with it additional costs for families and increased pressure on the already stretched budgets of low-income households,[28] as well as stress and tension in the home.[29,30]

In the aftermath and recovery from the pandemic, rising inflation, together with tax increases and rising energy and food costs, has created a cost of living crisis meaning that average household take-home pay is falling further, deteriorating living standards and quality of life for many families in the United Kingdom.[31] A recent report from the International Monetary Fund highlights that the energy crisis is currently affecting UK households harder, as a proportion of household spending on energy, than any country in western Europe, with the difference between the cost burden on poor and rich households being far more unequal in the UK compared with other countries.[32] These crises particularly affect those on the lowest incomes and who have already been affected by austerity measures, such as women and women from ethnic minority communities, particularly due to their unpaid caring roles, lower savings levels, and poverty.[33,34]

Since the UK Coalition Government's first Budget in 2010, significant reforms have been made to the UK's social security system. The introduction of the Welfare Reform Act 2012 legislated for Universal Credit and Personal Independence Payment and led to one of the most radical transformations of the UK welfare system.[35] The introduction of Universal Credit has since been the subject of a great deal of controversy in the UK.[33,34,36-38] There are concerns that the policy led to several negative impacts for individuals dependent on welfare payments, increasing the risk of poverty disproportionately for the poorest and widening inequalities. Several studies report worsening financial security, increased food insecurity and worsening poverty.[36-38] Furthermore, the policy has been linked with poor mental health, with participants of some studies having considered suicide,[36] and exacerbation of long-term health conditions.[37] From 2015, further austerity measures and policy changes were made, including the introduction of the benefit cap, bedroom tax, and restriction of Housing Benefit and Child Tax Credits to two children. The changes implemented have disproportionately affected women, families and those most vulnerable.[33,34]

Additional temporary and some more permanent changes to financial support were made in response to the COVID-19 pandemic. The national furlough scheme was established to financially support employees placed on temporary leave, for some or all of their contracted hours, to ensure they received at least 80% of their usual wages whilst furloughed.[39,40] For those on a low wage, this was insufficient and even the loss of a small proportion of income was enough to tip families into perilous financial difficulty, and potentially further exacerbate health inequalities.[41] However, during this time, access to financial support services and financial support from the government was also challenging for many families.[42] For the most vulnerable groups, face-to-face access to organisations for support with welfare and housing was curtailed, which is how these services would normally be accessed.[43] Furthermore, as a result of long periods of austerity over the preceding decade, the provision of welfare advice services in the UK had already been falling steadily owing to reduced funding for local authorities and were already overstretched.[44,45]

For individuals and families, long periods of austerity and economic instability, coupled with ongoing changes to the benefit system means that their benefits entitlement may have changed over time, in addition to the way in which they access them. The changing landscape of the social security system can also generate confusion for those already accessing benefits, as well as those who may be entitled to them but do not access them.

1.5 EQUITY OF ACCESS TO WELFARE ADVICE SERVICES

There is emerging evidence to suggest that there may be unequal access to, and uptake of, benefits and income support for those who are eligible and this has been found to be particularly pronounced in some ethnic minority groups.[46-48]

State benefits are known to make up a larger proportion of income for minority ethnic families than White British families in the UK, particularly Pakistani and Bangladeshi families, but there has been little research into uptake of welfare advice and financial support for minority ethnic families, in comparison to eligibility.[49,50] There is also evidence from self-reported data that young families in the lowest income group claim fewer benefits than those in higher income bands but the reasons for this pattern are unclear.[51] Reasons for reduced uptake of welfare advice and financial support for vulnerable groups have included institutional discrimination, language and communication barriers and stigma.[46-48] There is a need for further research, providing empirical evidence to demonstrate the variation in uptake of welfare advice compared with eligibility, across the range of benefits and other financial support available and by key sociodemographics, most notably ethnic group. Further research is also needed on how best to improve the design and delivery of these services to improve access for the most vulnerable.

1.6 CO-LOCATED WELFARE ADVICE IN HEALTH SETTINGS

Integration of welfare advice services can help to ensure timely and targeted access in a time and place of need. Various schemes have been put in place to improve the accessibility and uptake of welfare advice and the receipt of benefits and other financial support by co-locating welfare advice services within health settings.[45,52,53]

Welfare advice services co-located in health settings are collaborations between organisations specialising in welfare advice and health services. They offer potential benefits for both healthcare professionals and welfare advisors, in addition to the provision of welfare advice. Patients frequently present to healthcare professionals with social welfare problems, which may result from their health condition or are contributing to their illness.[54] Partnerships with welfare advice services can help healthcare professionals to address the social welfare needs of patients, which are beyond their expertise to manage.[55] For welfare advisors, partnerships with healthcare could facilitate intervention at an earlier stage, before social welfare problems escalate and can enable access to the medical information needed to support welfare casework and to advocate for systemic change.[44,56,57] On an individual level, patients are able to access welfare advice through the health service they are attending, benefitting from a co-ordinated and holistic response to their needs.[58]

Co-located services may be physically located in a health setting and accessed through walk-in, recommendation or referral by a healthcare professional. Some co-located services are accessed via recommendation or referral by a healthcare professional but the welfare advice service may be physically located elsewhere, or accessed via telephone or electronic means.

For the purposes of this thesis, health settings are those defined as healthcare related buildings, where the primary purpose is to promote, restore or maintain health.[59] Welfare advice services are defined as the delivery of expert advice concerning general welfare rights and entitlement to and claims for welfare benefits. Further purposes of this thesis, welfare advice services co-located in a health setting are welfare advice services that have a physical presence in a health setting. This excludes welfare advice services that are linked to health settings via signposting or via referral, where the welfare advice service is physically located away from the health setting. The description of welfare advice and its relationship with healthcare delivery is detailed in Table 1.

Table 1 Description of welfare advice and link with healthcare delivery

	Includes	**Excludes**
Areas of welfare advice	▪ Consumer / General contract ▪ Community care ▪ Debt ▪ Education ▪ Employment ▪ Family	▪ Criminal law

	▪ Housing ▪ Immigration ▪ Welfare benefits	
Type of assistance provided	▪ Casework ▪ First line advice ▪ Form filling and letter writing ▪ Tribunal representation	▪ Advocacy
Link with healthcare delivery	▪ Physical co-location of services	▪ Link to welfare advice service physically located away from a health setting e.g., via referral pathways, social prescribing schemes, joint commissioning or contracting ▪ Services limited to signposting between healthcare and welfare service. ▪ Legal services with no defined or explained link to healthcare service

In the United Kingdom, co-located welfare advice services currently exist in many health settings, predominantly with general practices, but a limited number also exist in hospital departments, hospices, mental health, and community health services, among others.[60-62] These services are funded by a variety of sources, including charities, local authorities, the National Health Service (NHS), universities, and multiple or joint streams.

A systematic review, published in 2006, of welfare advice delivered in health settings found that there was evidence that this approach resulted in financial gains but at that time there was limited high quality evidence to determine whether this resulted in improved uptake of welfare advice or measurable health and social benefits.[62] Furthermore, none of the included studies considered variation in uptake or outcomes measures between ethnic groups. Allmark et al. developed a theory of change model, building upon this review with a synthesis of evidence published to 2010, to demonstrate the possible causal pathways linking co-located welfare services and health benefits.[63] Since this time, a further quasi-experimental study has been conducted to examine the impact and cost-consequences of co-located benefits and debt advice on mental health, which demonstrated improved short term mental health and wellbeing for some participants, particularly for Black women.[64] However, further research is required to fully understand the association between co-located welfare advice and improved health and wellbeing. Furthermore, there remains a paucity of empirical evidence and little collective understanding of how best to implement these welfare services in a health setting, how to target those most in need and how best to evaluate its impact.[62]

1.7 UNIVERSAL WELFARE ADVICE CO-LOCATED IN HEALTH SETTINGS FOR MOTHERS AND THEIR FAMILIES

Pregnancy is a unique life event causing significant, wide ranging and long-lasting changes to the lives of the parents and the rest of the family. Such changes may make some families susceptible to financial insecurity and increase their need for financial support. New mothers and their families may subsequently become entitled to different or new benefits, such as Child Benefit that every parent is entitled to, but may not be aware of these.[65-67] Therefore, there is an opportunity for health services to prevent future health inequalities by protecting against and minimising financial insecurity and its consequences in children and their families.

During pregnancy, women have been found to have increased motivation, opportunity and capability for behaviour change in order to protect their unborn child.[68,69] This unique life event has already been harnessed by healthcare professionals to promote behavioural changes, in the antenatal and postnatal periods, to improve the health of both the pregnant women and their families, such as smoking cessation and reducing alcohol use.[68,70-73]

McBride et al.'s theory states that three constructs determine whether a life or health event acts as a teachable moment: an increase in perception of personal risk and outcome expectancies; prompting of strong affective responses; and a redefinition of self-concept and social roles. For this reason, pregnancy is commonly referred to as a unique teachable moment.[74]

Maternity care is also universal in the offer of provision of care and almost universal in the uptake. Pregnancy therefore offers an important opportunity for health professionals to engage with almost all pregnant women, some who may not otherwise have any contact with health or social services, at several occasions throughout their pregnancy and beyond.[75]

A universal offer of welfare advice, through co-location in a maternity setting, could overcome the stigma and cultural issues associated with financial vulnerability and receiving help by normalising access to welfare advice and re-framing financial security as an issue important to the health of the mother and their family. These services could thereby increase the uptake of welfare advice and benefits to which families are entitled, particularly in under-served populations, and improve financial security for families.

However, little evidence exists to guide the implementation of co-located welfare advice services to ensure a universal offer and to reach the populations most in need. Little is known about whether it will work to improve financial security and whether it will have any impact on health and wellbeing and serve to reduce health insecurities. Further research is also required to explore how best to conduct a robust evaluation of service effectiveness and implementation of such co-located welfare advice services.

The proposed intervention and research initially emerged as a priority from discussions with local people in a community workshop in Bradford used to develop ideas for a UK Prevention Research Partnership proposal, ActEarly, which has subsequently been funded and described in Chapter 2.2.3. The workshop involved community members, leaders and representatives who work with children and young people; they were invited to come and share their ideas and insights on how to develop an understanding of how to build a healthier and happier future for the children and young people of Bradford. 51 people attended the workshop: 21 with community, voluntary and social enterprise backgrounds and 30 from statutory organisations such as the Local Authority and the NHS. The workshop used an OpenSpace format where participants set the agenda and identified topics and ideas for discussion, ensuring outcomes are important to the community.

Six topics were identified as research priorities for in-depth discussion. One of the priorities included pregnancy, motherhood and mental health. An appreciative inquiry framework was then used by groups to identify what good would look like and what needed to be done to achieve this goal. Through this consultative process we discovered that more culturally sensitive services were needed, providing a range of support including improving financial stability and security in preparation for a new addition to the family.

In three inner-city, deprived and ethnically diverse wards of Bradford, poverty was identified as a key barrier to engaging in a wide range of parenting interventions. Further consultation events identified tackling financial vulnerability as a way to enable parents to engage in other activities beyond day-to-day ‘survival’. However, being financially vulnerable was also seen as stigmatising and asking for help as unacceptable in some local cultures. An intervention based in maternity services to address these issues, that is offered as part of a universal health service, was thought to be a promising approach prioritised by the community. It was hoped this approach may help to alleviate this stigma and ultimately to contribute to a future with improved health and wellbeing for the children and families of Bradford. I was not involved with the patient and public involvement processes utilised through which this research priority was formed but was interested in leading upon its development.

1.8 RESEARCH AIM

The aim of this thesis is to understand whether co-location of universal welfare advice in health settings for mothers and their families, as a cost-effective measure to improve health and wellbeing, is acceptable and feasible to deliver and evaluate.

1.9 RESEARCH QUESTIONS

a) How could universal welfare advice co-located in health settings improve health and wellbeing?

b) What are the health, social and financial impacts of welfare advice services co-located in health settings?

c) How has the COVID-19 pandemic and subsequent public health and welfare measures affected levels of financial security for mothers and their families in Bradford and what impact did this have on maternal health and wellbeing?

d) Would universal welfare advice co-located within health settings for mothers and their families be acceptable and feasible to deliver and evaluate?

1.10 STRUCTURE OF THE THESIS

The thesis is comprised of eight chapters in total. In Chapter 1, I provide a background to the thesis; describing the relationship between financial insecurity and health and provided an overview of the existing landscape of co-located welfare advice services in health settings. I also establish the rationale for a universal welfare advice service co-located in health settings for mothers and their families. In Chapter 2, I present the city of Bradford and its vast research infrastructure as the setting for this thesis.

In Chapter 3, I conduct and present the results of a narrative systematic review that provides a detailed overview of the current literature relating to the health, social and financial impacts of welfare advice services co-located in health settings and to the facilitators and barriers to successful implementation of these services. This improves the understanding of how best to develop the intervention and improve its implementation in order to reach those populations most in need of this service, whilst representing value for money for commissioners and society.

In Chapter 4, I conduct and present the results of a secondary analysis of survey data (conducted by Born in Bradford during the COVID-19 pandemic) to describe the impact of the COVID-19 pandemic, and subsequent public health measures, on the financial security of mothers and their families in Bradford. I explore what individual factors are associated with changes to financial security and explores how changes to financial security have impacted the health, wellbeing and socioeconomic security of mothers and their families during the pandemic. The chapter improves the understanding of the socioeconomic context for this complex intervention and further establishes the need for a universal welfare advice service co-located in health settings for mothers and their families in Bradford.

In Chapter 6, I conduct and present the results of a mixed methods before and after study, exploring the feasibility of the evaluation of a co-located welfare advice service in a real world setting in Bradford. I investigate whether the proposed evaluation tools and processes are feasible to implement and whether they are able to detect any evidence of promise for this intervention on the health, wellbeing and financial insecurity of participants. I also explore what approach to an economic evaluation of this complex intervention is appropriate, feasible and from which perspective.

In Chapter 6, I specifically explore the feasibility of obtaining validated benefits and income data, as an objective measure of financial security, to support evaluations of such interventions and the acceptability of the consent process for mothers in Bradford.

In Chapter 7,

In Chapter 7, I present the Medical Research Council (MRC) and National Institute for Health Research (NIHR) complex intervention research framework as a methodological approach to the development and implementation of this research. I explore the application of the evidence and learning associated with the core elements and main phases of the implementation framework as an intervention in a typical health setting for mothers and their families and specifically to the setting of Bradford. I began work on developing the elements of the complex intervention framework at the onset of the PhD and built upon these elements in an iterative process throughout the duration of my PhD. Chapter 7 reflects the culmination of my work in this area.

Finally, in Chapter 8 I provide an overview of the key findings from the research and offers a discourse on the development and evaluation of a universal welfare advice service co-located in health settings for mothers and their families, based upon the summation and implementation of the evidence presented by this thesis. I consider the overarching theoretical and methodological limitations in the thesis as a whole before outlining the strengths and contributions of the findings to the broader research and policy context. A series of recommendations based on the research and a final conclusion ends the thesis.

1.11 IMPACT OF THE COVID-19 PANDEMIC

At the onset of my PhD, my original aim was to co-produce, implement and evaluate a welfare advice service co-located within maternity clinics in Bradford, to explore whether the service was feasible to deliver, acceptable to families and had the potential to improve maternal mental health and wellbeing.

Halfway through the first year of my PhD, the World Health Organization declared the COVID-19 outbreak a pandemic, leading to worldwide public health measures to restrict the spread and minimise the impact of the virus, with unintended consequences on socioeconomic security and widening health inequalities.[76] The emergence of the COVID-19 pandemic and subsequent implementation of public health measures to control the spread of the virus had significant impacts on the NHS and welfare advice services alike. As such it was not possible, nor appropriate, to co-produce, implement and evaluate a co-located welfare advice service in maternity clinics during this time. As such, a more adaptive and flexible approach was required to conduct this research.

I chose to adopt a similar aim to explore whether co-location of universal welfare advice in health settings for mothers and their families is acceptable and feasible to deliver and evaluate. However, the methodological approach adopted to achieve this aim was adapted. I adopted a theoretical approach to the development of the intervention, utilising the Medical Research Council (MRC) and NIHR framework for the development and implementation of complex interventions. This approach fostered a thorough and collaborative approach to the theoretical development of the intervention. This framework was then used as an approach to further test the acceptability and feasibility of implementing and evaluating this intervention. As I was unable to implement and evaluate this intervention in its entirety, as originally planned, components of the intervention and approach to evaluation were explored, brought together and analysed at the end of this thesis.

The COVID-19 pandemic offered the opportunity to explore the medium to long-term impacts of the COVID-19 pandemic and subsequent public health measures on financial security in vulnerable families in Bradford and the resultant impact on maternal health and wellbeing. The results of this research established the need for and importance of taking further action to provide financial support to improve the financial security and resilience of families in the recovery from the pandemic and to prevent further worsening of socioeconomic and health inequalities.

A newly commissioned community alliance welfare advice programme co-located in primary care settings in Bradford provided an alternative opportunity to evaluate the feasibility of a similar service, particularly with respect to the feasibility of the evaluation design and the economic evaluation of a welfare service co-located in health settings. However, whilst this service offered an important opportunity to evaluate the feasibility of certain elements of the evaluation of such a service, the service provided was to the general public, not specifically to mothers and their families. It was also not possible to explore specifically whether any participants were indeed parents, reference was only given to single parents. Furthermore, the COVID-19 pandemic imposed further restrictions on elements of the evaluation design.

To explore the impact of the co-located service on primary care and health professionals, it was planned that semi-structured interviews would be conducted with general practitioners, practice managers and receptionists from participating practices. Sampling had included representatives from each practice and included General Practitioners (GP) who had referred and not referred to the service. Interviews were chosen rather than focus groups due to the practicalities of bringing participants together at the same time and to enable practitioners to speak freely. The topic guide would explore the expectations, attitudes and experiences of practices that co-locate services, see Appendices A.4.11 and A.4.12. However, this component of the evaluation was not feasible. Due to the ongoing pressures of the pandemic on the NHS and its health professionals, participation in research was consequently de-prioritised. Despite support from the Clinical Commissioning Group (CCG) Research and Development Team to improve engagement with this research, no health professionals or other members of the primary care teams were recruited into the study.

Other elements of my proposed research were able to continue as originally planned, including my systematic review and approach for exploring the feasibility and acceptability of utilising data linkage as a measure of financial security. These will be fully described later in the thesis.

CHAPTER 2 THE SETTING OF BRADFORD

Chapter two provides a background to the demography and deprivation of the city of Bradford and an overview of its expansive research infrastructure, which forms the setting for this thesis.

2.1 DEMOGRAPHY AND DEPRIVATION

Bradford is the seventh largest local authority in England, in terms of population size, with an estimated population size of 546,400, as of 2021.[77] The 2019 Index of Multiple Deprivation (IMD) ranks Bradford as the 13th most deprived local authority in England, having worsened by six places since the last IMD, published in 2015,[78] with 24% of children living below the poverty line.[79] Bradford district's population is a young one. The under-15 population forms 21.4% of the District's population, the fourth highest percentage in England and the largest percentage in the region.[77]

Bradford district is an ethnically diverse area, with the largest proportion of people of Pakistani ethnic origin in England. The results of the 2021 Census showed that: 56.7% of Bradford district's population identified themselves as White British; 25.5% as Pakistani; 3.6% as Other White, 2.6% as Indian, 2.5% as mixed heritage; 2.3% as Bangladeshi; 2.1% as Black; and 3.6% were from other ethnic groups.[77,80,81]

Bradford is ranked as the 5th most income deprived and 6th most employment deprived local authority in England, the same positions as in 2010 and 2015.[79] Bradford has a low-wage, low-skills economy and the working age population of the district is projected to increase by 1,200 people per year over the next ten years, driving a real need for high paid jobs growth. However, median weekly earnings in Bradford remain relatively low, with median weekly gross pay of £500, compared with £540 for Yorkshire and the Humber and £591 per week for England.[79] Despite improvements in recent years, Bradford's employment rate remains at 55.7%, which is lower than the regional (74%) and national rate (76%).[77]

The population life expectancy at birth is 77.3 for males and 81.5 for females, which is lower than the national average of 78.6 years for males and 82.6 for females.[82] Although women have higher life expectancies, they are more likely to have a lower proportion of healthy life. Women are also more likely to have a lower proportion of disabled-free life than men.[83]

Infant mortality is an indicator of the general health of the entire population and it reflects the relationship between causes of infant mortality and the wider determinants of population health, such as economic, social and environmental conditions. Although infant mortality rates are falling in Bradford, they are still above the average for England and are higher than the rates for the rest of West Yorkshire. In 2018, for Bradford there were 5.7 deaths reported per 1,000 live births, whereas the national rate is 3.9 deaths per 1,000 live births.[79]

2.2 RESEARCH PROGRAMMES

2.2.1 BORN IN BRADFORD RESEARCH PROGRAMME

Born in Bradford (BiB) research programme is an internationally recognised, applied health research programme comprising health and wellbeing information on more than 30,000 Bradfordians enrolled in a family of three large, multi-ethnic prospective birth cohort studies: BiB Family; Born in Bradford's Better Start (BiBBS); and BiB4All, see Figure 1.[84]

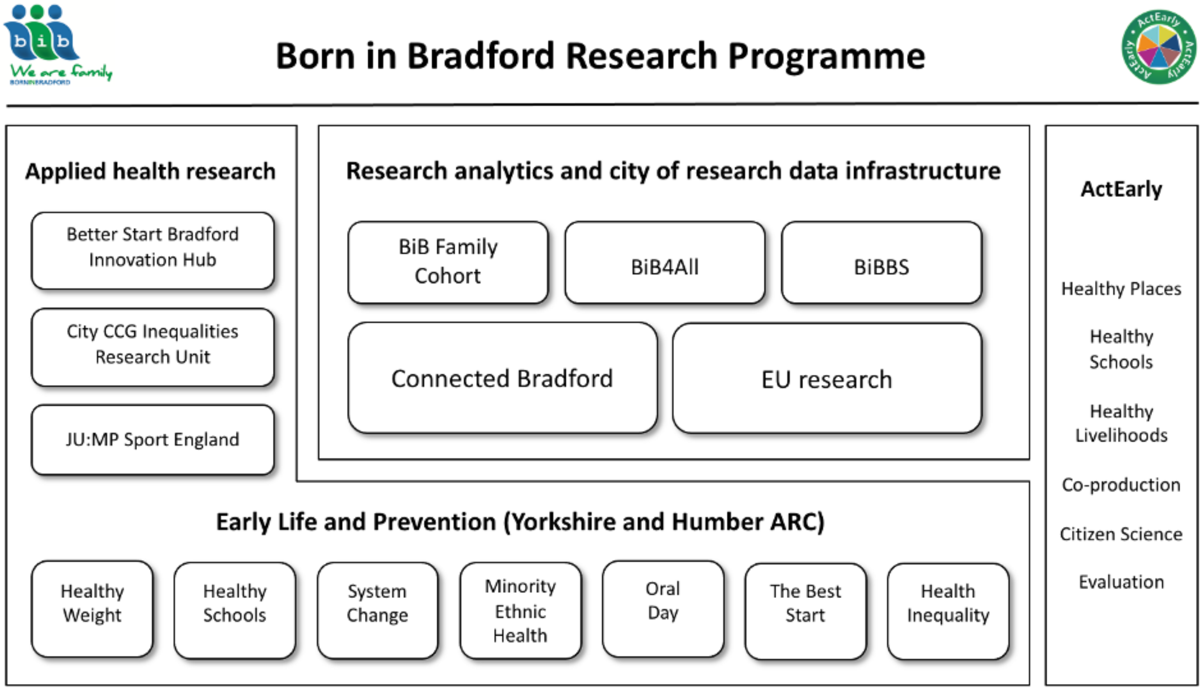

Figure 1 Born in Bradford Research Programme

The aims of the research programme are fourfold: to describe health and ill-health in the largely bi-ethnic population with high economic deprivation; to identify modifiable causal relationships that contribute to ill-health, and design and evaluate interventions to promote wellbeing; to provide an integrated model of epidemiological and evaluative research based on practice in the NHS and related health systems; and to build and reinforce research capacity in Bradford.[85,86]

2.2.1.1 BORN IN BRADFORD FAMILY COHORT STUDY

Born in Bradford was established 2007 in response to concerns about the high infant mortality rate in Bradford compared with other UK cities, and high levels of childhood morbidity, including congenital anomalies and childhood disability. It examines how genetic, nutritional, environmental, behavioural, and social factors affect health and development during childhood, and subsequently, adult life in a deprived multi-ethnic population.[85,87]

The BiB Family cohort is a prospective pregnancy and birth cohort study established in 2007 to examine how genetic, nutritional, environmental, behavioural, and social factors affect health and development during childhood, and subsequently, adult life in a deprived multi-ethnic population. The cohort consists of approximately 12,500 families and 13,700 young people born at the Bradford Royal Infirmary between 2007 and 2011.[88] Bradford Royal Infirmary provides the largest maternity unit in Bradford and assists around 6,000 deliveries a year, approximately 80-90% of all births in Bradford each year.[86]

Women were recruited from the maternity unit, along with their partners, as they attended the clinic for an oral glucose tolerance test, routinely offered to all pregnant women in Bradford. All babies born to these mothers and fathers were eligible to participate; mothers were only excluded if they planned to move away from Bradford before the end of their pregnancy.[85] Over 80% of the women invited for the study accepted the offer to participate.

In 2017, as the children of the BiB Family cohort reached the ages of 7-11 years, the first full follow-up of the cohort took place. The BiB Growing Up (BiBGU) study aims to investigate the determinants of children's pre-pubertal health and development, including through understanding parents' health and wellbeing, and to obtain data on exposures in childhood that might influence future health.[88]

2.2.1.2 BORN IN BRADFORD'S BETTER START

Born in Bradford's Better Start is a Big Lottery funded innovative experimental birth cohort, established in 2016, that simultaneously evaluates the impact of multiple early life interventions to improve outcomes for pregnant women and families with children aged 0-3 years in three inner city deprived, multi-ethnic wards in Bradford. It specifically explores: social and emotional development; communication and language development; and nutrition and obesity.

Women are recruited from the Bradford Royal Infirmary maternity unit as they attend the clinic for an oral glucose tolerance test, routinely offered to all pregnant women. Recruitment is ongoing and, as of the end of May 2023, 4800 women and their children are in the cohort.[89] BiBBS test interventions utilising trials within cohorts and other quasi-experimental designs, where trials within cohorts are neither feasible nor ethical, to evaluate early life interventions.

BiBBS is supported by the Born in Bradford Community Research Advisory Group (CRAG). The CRAG is a group made up of community representatives, including engagement workers, local parents, leaders of local groups, projects and charities and local councillors. The CRAG was involved in the co-production of the BiBBS cohort study and continues to work in partnership with BiBBS by helping to engage with the local community and provide feedback on successes and challenges.[89]

2.2.1.3 BIB4ALL

BiB4All is a data linkage cohort study of babies born in Bradford and their mothers established in 2018. Community midwives invite all pregnant women to participate in the cohort and to consent to data linkage during routine antenatal appointments.[90] BiB4All follows families who join the study by linking a variety of routine data sets together to build a clearer picture of families lives over time. This includes data from health, education, social care and other settings. The purpose of linking these data together and following families over time is to better describe child health and development in Bradford and identify whether patterns exist in the data that might help in the early identification of families with poor health and development.[91]

2.2.1.4 DATA COLLECTION

Participants in the BiB cohorts all consent for routine data linkage to health and education data for research, and to be contacted for future research studies. Participants in the BiB Family Cohort Study and BiBBS cohort study also complete detailed questionnaires at recruitment and in ongoing waves of data collection, including information regarding wider social determinants of health.[61] Questionnaires do not collect detailed financial data regarding income or benefits claims and entitlement because when these data items were piloted, there were high levels of missingness either because women did not know this information or did not wish to answer financial questions.

2.2.2 BRADFORD INEQUALITIES RESEARCH UNIT

Inner city areas of Bradford have some of the highest levels of deprivation and ethnic diversity in England, as well as high levels of morbidity and mortality across the lifespan compared to England averages. In 2019, Bradford City Clinical Commissioning Group (now Bradford District and Craven Health and Care Partnership) received an uplift in funding of £8 million per annum for five years to address these health inequalities. They established the Reducing Inequalities in Communities (RIC) programme which has implemented multiple interventions across three priority areas to reduce health inequalities: pre-conception, pregnancy and early years; premature mortality; and ageing and dying well.[92]

Bradford Inequalities Research Unit (BIRU) is an academic collaboration between Born in Bradford, the University of York and Queen Mary's University London.[93] The RIC programme has commissioned BIRU to support the design and delivery of the RIC programme. BIRU has access to large individual level data through Connected Health Cities[94] and the BiB birth cohorts that enable in-depth evaluation of the health and economic impact of individual interventions across different services and organisations, as well as the cumulative effect of multiple interventions in the RIC programme.[95]

The main objective of the BIRU is to take a data driven approach to inform the planning of the RIC programme, focussing initially on identifying the drivers that underpin health inequalities across inner city areas of Bradford. This enables RIC to shape their priorities and identify appropriate evidence-based interventions to address these issues. Other objectives also include: advising on the design, implementation and evaluation of interventions; enhancing routine data capture and data sharing; and using innovative methods to model the impact of selected interventions and evaluate the effectiveness of selected interventions in terms of both health outcomes and cost effectiveness.

2.2.3 ACTEARLY

ActEarly is a UK Prevention Research Partnership funded research consortium, working in partnership with the BiB research programme, which focuses on upstream early life interventions, in recognition of childhood and adolescence being such critical periods for influencing lifelong health and wellbeing, to improve the health and opportunities for children living in two contrasting areas with high levels of child poverty, Bradford, Yorkshire and Tower Hamlets, London.[96] A city approach provides real world opportunities to scope, deliver and evaluate sustainable and replicable population prevention interventions.

The objectives of this research are: to establish a prevention research consortium that unites broad transdisciplinary expertise with the public, policy leaders and practitioners from across its populations to develop shared understanding and priorities; to identify, co-produce and implement system-wide early life upstream prevention solutions; to provide efficient data platforms and methodological expertise enabling robust population-scale evaluation of the impact of interventions on environments, health-related behaviours and interlinked health, educational, social and economic outcomes; and to evaluate, refine, replicate and disseminate the City Collaboratory approach as a model for addressing upstream determinants of health and inequality.[96]

ActEarly consists of three inter-linked themes: Healthy Places, Healthy Learning and Healthy Livelihoods. These themes are supported by three cross-cutting themes of Play and Physical Activity, Evaluation and Citizen Science and Co-production. In each of theme, ActEarly works with local communities, local authorities and other national organisations to understand how families can live healthier and more active lives. The aim of the Healthy Livelihoods theme is to carry out research and evaluate interventions, initiatives and policies to address child, young person and family wellbeing and opportunities through increasing income, skills and control over community resources.[96] I was embedded as a PhD student within the Healthy Livelihoods theme and wider ActEarly collabatory.

2.3 WELFARE ADVICE SERVICE INFRASTRUCTURE IN BRADFORD

For the period 2016-2023, commissioned welfare advice services in Bradford were delivered through five separate contracts by Bradford City Metropolitan Council. Four services were constituency based and one was provided for people with long term and complex health conditions. These services were delivered by four lead providers who employed a combination of sub-contractors and partners to support service delivery. These were: Bradford and Airedale Citizens Advice Bureau and the Law Centre; Equality Together; Family Action; and St Vincent De Paul. The budget for welfare advice services in Bradford totalled £2 million pounds for this period. Services were commissioned in 2016 by Bradford City Council, initially for a period of four years and in 2020, funding was extended to March 2023. Supplemental funding was granted in 2020 in recognition of the additional needs of the district due to COVID-19 and its economic impacts.[97]

Access to these welfare advice services was almost entirely through face-to-face and walk-in routes at local community centres and office bases. The services also offered sessional appointments based in: children's centres; community buildings; hospitals; and specialist agencies, including mental health and alcohol and drug projects.

2.3.1 CO-LOCATED WELFARE ADVICE SERVICES IN PRIMARY CARE

The Voluntary and Community Sector (VCS) Alliance is a voluntary community organisation that was developed to co-ordinate the voluntary and community sector in Bradford to deliver health and social care projects across the area.[98] The VCS Alliance co-ordinate a welfare advice programme co-located within the primary care network across inner city areas across Bradford, commissioned by the Reducing Inequalities in Communities programme. It brings together nine distinct welfare advice providers, delivering welfare advice services across Bradford. There are six core providers delivering universal welfare advice services across the district and three providers delivering specialist welfare benefits services for those with complex needs: Equality Together provide a specialist service for those with disabilities; Cancer Support Yorkshire for those with cancer and long-term conditions; and AgeUK for the elderly population. Each welfare advice provider is connected to a general practice in Bradford and their services are accessed exclusively through GP referral. All services are registered and delivered by appropriately trained and accredited welfare advisors.

2.4 KEY OUTCOME MEASURES

A number of key financial and health outcome measures are utilised throughout this research. The following sections detail these outcome measures.

2.4.1 SELF-REPORTED FINANCIAL SECURITY

To understand participant perception of their own financial insecurity, the research where relevant employed the question: 'How well would you say you are managing financially right now?'. Answer options included: living comfortably; doing alright; just about getting by; finding it quite difficult; and finding it very difficult.

2.4.2 MENTAL HEALTH

For mental health, the Patient Health Questionnaire-8 (PHQ-8) and Generalised Anxiety Disorder-7 (GAD-7) instruments were used. The eight item PHQ-8 depression scale, is established as a valid diagnostic and severity measure for depressive disorders in large clinical studies.[99] Each item has four response categories on a Likert scale, ranging from 'not at all' to 'nearly every day'. The score from each item were summed to produce a total score between 0 and 24 points. Summed scores were used as a continuous variable with greater scores indicating a presence of depressive symptoms. A PHQ-8 score of ≥10 has a sensitivity of 88% and a specificity of 88% for clinically significant depression.[100] Standard categorisations were employed for the scores: 0 to 4 no depression; 5 to 9 mild depression; 10-14 moderate depression; and 15-24 severe depression.[101] Symptoms suggestive of clinical depression was defined as those with moderate to severe depression scores.

The GAD-7 questionnaire is a seven-item instrument that is used to measure or assess the severity of anxiety symptoms.[102] Each item asks the participant to rate the severity of his or her symptoms over the past two weeks. Each item has four response categories on a Likert scale, ranging from 'not at all' to 'nearly every day'. The score from each item were summed to produce a total score between 0 and 21 points.[103] Summed scores were used as a continuous variable with greater scores indicating a presence of anxiety symptoms. A GAD-7 score of ≥8 has a sensitivity of 92% and a specificity of 76% for generalised anxiety disorder. Standard categorisations were employed for the scores: 0 to 4 no anxiety, 5 to 9 mild anxiety, 10 to 14 moderate anxiety, 15+ severe anxiety.[100,102] Symptoms suggestive of clinical anxiety was defined as those with moderate to severe anxiety scores.

2.4.3 WELLBEING

Wellbeing was measured using the seven-item Shortened Warwick-Edinburgh Mental Well-being Scale (SWEMWBS).[104] This ordinal scale captures a wide conception of well-being, including affective-emotional aspects, cognitive-evaluative dimensions and psychological functioning in a form which is short enough to be used in population-level surveys. It assesses respondents' agreement with statements such as, 'I've been feeling optimistic about the future'. Each item is measured on a five-point scale ranging from 'none of the time' to 'all of the time'. The score from each item was summed to produce a total score between 14 and 35. Summed scores were used as a continuous variable with greater scores indicating a more positive wellbeing. The SWEWMBS is a shortened version of the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) which is Rasch compatible. Raw scores were transformed prior to analysis and to permit comparison of results with other studies using the SWEMWBS.[105] A cross-cultural validation of the English version of WEMWBS has been carried out among English-speaking adults of Chinese and Pakistani family background resident in England.[106]

2.4.4 HEALTH-RELATED QUALITY OF LIFE

The health-related quality of life of participants was measured using the five-item EQ-5D instrument (EQ-5D-5L).[107] The EQ-5D-5L is a preference-based health-related quality of life tool comprising one question for five dimensions of health, including: mobility; self-care; usual activities; pain or discomfort; and anxiety or depression. Each domain has five levels of response: no problems; slight problems; moderate problems; severe problems; and extreme problems or unable to. These domains provide a descriptive profile that were converted into utility scores, based on UK societal preference weights for the health state,[108] ranging between 0 representing death and 1 for perfect health. The EQ-5D-5L questionnaire also includes a Visual Analog Scale (VAS), by which respondents can self-report their perceived health status with a grade ranging from 0 representing the worst possible health to 100 representing the best possible health.

CHAPTER 3 A NARRATIVE SYSTEMATIC REVIEW OF THE EFFECTIVENESS AND EXPERIENCES OF WELFARE ADVICE SERVICES CO-LOCATED IN HEALTH SETTINGS

This chapter describes a narrative systematic review that I conducted that provides a detailed overview of the current literature relating to the health, social and financial impacts of welfare advice services co-located in health settings and to the facilitators and barriers to successful implementation of these services. It explores how this evidence builds upon the theoretical framework for this research and thereby how co-located welfare advice services operate to impact on financial security, health and wellbeing and the NHS.

The results of this systematic review will be used to guide the development of a welfare advice service co-located in health settings for mothers and their families and will provide evidence to guide the development of a successful approach to implementation and evaluation of such an intervention.

3.1 INTRODUCTION

There is a growing evidence base on the health and economic benefits of welfare advice integrated within health settings.[62] Formal evaluations of co-located services in health settings are few in number and limited in other ways. Much of the quantitative research has methodological limitations, such as small sample sizes, lack of a robust comparator and significant loss to follow-up. Reports found in grey literature suggest that welfare services have also been trialled in locations such as children's centres, food banks and schools but no published evaluations of impact or implementation, descriptions of co-location models or evaluations across multiple sites have been conducted.[109-113]

A systematic review, published in 2006 by Adams et al., found that co-location of welfare advice services in health settings resulted in financial gains for participants.[62] Overall, 55 studies were included in this review and whilst efforts were made to conduct a systematic review with an international focus, only one of the included studies was not based in the United Kingdom. It was unclear whether this was due to differences in terminology or provision of welfare advice services or if this reflects a lack of research conducted in this area internationally. Seven studies included a control or comparator group, however it was found that there was a lack of evidence to determine whether welfare advice co-located in a health setting resulted in improved uptake or measurable health and social benefits.[62] It was considered that this was primarily due to lack of high quality evidence, rather than evidence of an absence of effect. Furthermore, none of the included studies considered variation in uptake or outcomes measures between ethnic groups.

Allmark et al. developed a theory of change model, utilising systematic review methodology and building upon this review with a synthesis of evidence published to 2010, to demonstrate the possible causal pathways linking co-located welfare services and health benefits.[63] The authors emphasised that the lack of evidence for the health benefits of welfare advice services in health settings may be a result of the complexity of the intervention, with significant challenges in establishing a clear causal pathway between intervention and health outcomes and aimed to reflect what were considered the elements in a causal pathway between advice interventions and health outcomes in their theory of change model.

Further research is required to fully understand the direction and magnitude of association between co-located welfare advice and improved health and wellbeing. Guided by the theory of change model presented in this thesis, further research is required to understand the effects of co-located welfare advice services on social outcomes and whether co-located services have any impact on health professionals and the wider health sector. Patients frequently present to health services with social welfare problems, which may result from their health condition or are contributing to their illness.[54] This may create an additional burden on health professionals, leading to increase case complexity and an increased workload, which are beyond their expertise to manage.[55]

Finally, this systematic review for the first time considers how best to implement welfare advice services in a health setting, targeting those most in need and how best to evaluate its impact. This systematic review considers these areas from the context of the United Kingdom, given the significant variation in nature, provision and funding of both welfare advice services and healthcare settings globally.

3.1.1 AIMS AND OBJECTIVES

The aim of this narrative systematic review is to assess the literature on the health, social and financial impacts of co-located welfare services in the UK and to explore the facilitators and barriers to successful implementation of these services.

The objectives are to:

a) Determine the evidence of effectiveness of welfare advice services co-located in health settings on health and social outcomes, using a meta-analysis where possible.

b) Explore whether there is evidence of impact of welfare advice services co-located in health settings on health professionals and the wider health sector.

c) Assess the economic benefits of co-located welfare advice services from the perspective of the individual, the NHS, the commissioner and wider society.

d) Identify and explore the relationships between reported facilitators and barriers to implementation, to understand how and why particular barriers and enablers to implementation operate.

3.2 METHODS

This review was conducted and reported in accordance with recommendations from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols 2015 (PRISMA-P) guidelines to ensure systematic and transparent reporting in sufficient detail for repeatability. Cross reference of the review in relation to the PRISMA-P guidelines is detailed in Appendix A.2.1.[114] PROSPERO was checked on 10th November 2020 for ongoing reviews on similar topics and none were identified.[115]

A narrative systematic review[116] approach was utilised, adopting an evidence-led framework described by Rodgers et al.[117] This approach consists of four elements employed in an iterative manner to analyse the included studies: developing a theory of how the intervention works, why and for whom; developing a preliminary synthesis of findings of included studies; exploring relationships in the data; and assessing the robustness of the synthesis. It was anticipated that this review would include a high volume of grey literature, qualitative studies and fewer empirical studies, based on the previously conducted systematic review by Adams et al.[62] and an initial scoping search. The objectives of the review include exploring the potential impact of the services on health services and to consider implementation outcomes. It was expected that the systematic review would involve a significant qualitative component and significant heterogeneity in any reported outcomes measures. It was therefore considered unlikely that a traditional systematic review and meta-analysis would be suitable or feasible overall and that a narrative synthesis approach was considered most appropriate to the objectives and body of evidence anticipated.

3.2.1 INCLUSION AND EXCLUSION CRITERIA

The PICOSS framework was used to identify and summarise the characteristics of the studies for the review,[118] see Table 2.

Table 2 PICOSS Framework

PICOSS Item	Description
Population, participants and conditions of interest	Individuals accessing health services. Not restricted by personal characteristics or health condition.
Interventions or exposures	Welfare advice delivered by a welfare officer, welfare adviser, welfare adviser or Citizens Advice adviser from 2010 onwards.
Comparisons or control groups	None or individuals accessing usual health services without access to welfare advice.
Outcomes of interest	All outcomes, including health, social and financial outcomes. The review also considers uptake of the intervention, feasibility and acceptability to participants, welfare advisors and healthcare staff.
Setting	Primary, secondary and tertiary healthcare settings in the United Kingdom.
Study designs	Any study design.

This systematic review includes studies which qualitatively or quantitatively examined the impact of welfare advice services delivered whilst physically co-located in a healthcare setting in the United Kingdom, on any outcome, including health, social and financial outcomes, published from January 2010 to November 2020. Studies published prior to 2010 were also excluded, owing to the significant reforms made to the social security system in the UK at this time, and the publication of the previous systematic review and theory of change model in this area up to this date.[119,120]

Studies examining the provision exclusively of specialist services, such as housing or employment advice, were excluded from the study. These studies focus on specific populations, such as the homeless population, and thus narrow the analysis and make the results difficult to apply to a general population and the provision of a universal service. Given the significant variation in nature, provision and funding of both welfare advice services and healthcare settings, studies published outside the UK were excluded.

3.2.2 SEARCH STRATEGY

Search strategies were developed, building upon the previous systematic review in this area,[62] separately for each of the academic databases, see Table 3, in order to match the appropriate indexing terms. The University of York Health Sciences Liaison Librarian was consulted during the development of the search strategy. The search strategy was developed in Medline via OVID with a combination of key terms and subject headings. An example Medline via Ovid search strategy can be seen in Appendix A.2.2.

Searches for indexing terms are combined with keyword searches applied to titles and abstracts. Electronic databases were searched from January 1st, 2010, up to and including November 2020. The sensitivity of the search strategies were tested by checking that the resulting records include key papers in the field, identified through existing reviews and known authors. The same keywords were used to search grey literature sources.

3.2.3 INFORMATION SOURCES

The search strategy was conducted for relevant published articles from the sources listed in Table 3.

Table 3 Literature sources searched for effectiveness and implementation studies of welfare advice services co-located in health settings.

Electronic databases	Websites	Other sources
▪ Applied Social Sciences Index and Abstracts (ASSIA) ▪ Humanities Index ▪ Cumulated Index to Nursing and Allied Health Literature (CINAHL) ▪ Cochrane Database of Systematic Reviews ▪ EMBASE	▪ Age Concern www.ageconcern.org.uk ▪ Child Poverty Action Group www.cpag.org.uk ▪ Department of Health (UK) www.dh.gov.uk ▪ General Accounting Office (US) www.gao.gov	▪ Hand searching of key journals ▪ Google ▪ Google Scholar ▪ Reference list of included articles ▪ Author searches ▪ Conference publications

Table 3 Literature sources searched for effectiveness and implementation studies of welfare advice services co-located in health settings.

Electronic databases	Websites	Other sources
▪ Health Management Information Consortium ▪ International Bibliography of the Social Sciences (IBSS) ▪ Medline ▪ NHS Economic Evaluation Database ▪ PAIS Index ▪ Psychinfo ▪ Science Citation Index ▪ Social Policy and Practice and Social Care Online ▪ Social Science Citation Index ▪ Social Services Abstracts ▪ Sociological Abstracts ▪ Taylor & Francis ▪ WorldCat ▪ Zetoc	▪ Home Office (UK) www.homeoffice.gov.uk ▪ Joseph Rowntree Foundation www.jrf.org.uk ▪ MDRC www.mdrc.org ▪ National Audit Office (UK) www.nao.org.uk ▪ Office of Policy (US) www.ssa.gov/policy ▪ Office of the Deputy Prime Minister www.odpm.gov.uk ▪ Rightsnet www.rightsnet.org.uk ▪ Urban Institute www.urban.org	▪ Published policies ▪ Other relevant grey literature

All electronic contents pages of Health and Social Care in the Community (2010-2020) and the Journal of Social Policy (1997-2020) were scanned to identify other relevant publications. These journals were chosen because of their relevance to the subject area based on initial scoping searched and the perception that substantial relevant work has been published in them identified through the results of the previous systematic review in this area.[62]

Searches of the internet search engine www.google.co.uk and Google Scholar were conducted using the same strategies as above. The first 100 results returned by each search strategy were scanned for relevance and those judged to be potentially relevant followed up. Searches were also made of specific websites from organisations that sponsor and conduct social policy research.

The reference lists of included studies assessed to be relevant were scanned to identify other relevant studies. Citation searches were conducted and followed up to identify all citations of studies identified as relevant through the Science Citation Index and Social Science Citation Index.

Searches for other articles by all authors of articles included in the review were performed in Medline and Health Management Information Consortium from January 1st, 2010, up to and including November 2020.

The search results were limited to those written in English with a publication date between January 1st, 2010, and 30th November 2020.

3.2.4 STUDY SELECTION AND DATA EXTRACTION

The study selection and screening process were performed between 16 November 2020 and 31 January 2021. The results of the literature search were first exported to Covidence, a screening and data extraction software tool.[121] Any duplicates were removed. Screening was performed through a process of marking records for inclusion based on the relevance of the title, followed by the abstract and full text. Reasons for exclusion at the abstract and full text assessment stage were recorded. The accuracy of the selection was checked by a second reviewer, another University of York Department of Health Sciences PhD student, who repeated the abstract and full text selection process independently with a random sample of 10% of excluded studies. The selections of the two reviewers were compared; where there were discrepancies, it was planned that these would be resolved through discussion, or if necessary, through a third independent reviewer. However, no discrepancies were identified.

Data were extracted using a structured, pre-piloted, proforma, see Appendix A.2.3, to provide clarity and consistency. Headings adapted from Popay et al. were used to structure the data extraction: setting, participants, aim, sampling and recruitment, method, analysis and results.[116] The form was piloted with five studies and reviewed by my supervisors to ensure it provided sufficient information on study design, population and outcomes. Headings in the data extraction form evolved during the process of data extraction and were reviewed by my supervisors to ensure relevance. The reference management software, EndNote, was used to store and manage the retrieved references.[122]

3.2.5 QUALITY ASSESSMENT

The quality of each study was assessed using tools from the Center for Evidence-Based Management (CEBMa) according to study design, including quantitative and qualitative designs.[123] The CEBMa does not include a tool for studies adopting a mixed methods design.

For mixed methods studies, the Mixed Methods Appraisal Tool (MMAT) was used to assess quality and risk of bias.[124] Studies were assessed based on the clarity of the research question, eligibility criteria, study population and sample size, outcomes measured, and type of statistical analysis employed. After assessing their quality, studies were classified into three appraisal categories (high, medium and low) based on their internal validity indicated by the quality appraisal and risk of bias score, see Table 4.

Table 4 Appraisal categories based on quality and risk of bias assessment using the Center for Evidence-Based Management (CEBMa) tool and Mixed Methods Appraisal Tool (MMAT)

Appraisal category	**Assessment Score**
High	Assigned to studies that used a rigorous and robust scientific approach that largely met all CEBMa benchmarks, equal to or exceeding 7 out of 10 for qualitative studies, 9 out of 12 for cross-sectional surveys, or 5 out of 6 for mixed-methods research.
Medium	Assigned if a study had some flaws but these did not seriously undermine the quality and scientific value of the research conducted, perhaps scoring 5 or 6 out of 10 for qualitative studies, 6–8 out of 12 for cross-sectional surveys, or 4 out of 6 for mixed-methods research.
Low	Assigned to studies that had serious or fatal flaws and poor scientific value and scored below the numbers of benchmarks listed above for medium-level appraisals in each type of research.

Alongside a quality assessment, all studies were appraised using tools to evaluate the relevance and 'richness' of their findings. 'Richness' has been described as 'the extent to which study findings provide in-depth explanatory insights that are transferable to other settings'.[116] The criteria for assessment of 'richness' taken from an approach by Higginbottom et al. are described in Table 5.[125,126] This approach was used in anticipation of the high volume of grey literature, expected to be assessed as of low quality, in order to give an indication of how these studies could contribute to the emerging evidence base through its relevance and richness.

Table 5 Criteria for assessment of 'richness'

Assessment	**Conceptual definition**
Thick papers	Greater insights into outcomes of interest Clear account of processes provided by which findings are produced Clear description of analytical processes Developed and plausible explanation presented

Thin papers	Limited insights provided Lack a clear account of processes Present and underdeveloped and weak interpretation of findings produced Present a weak and underdeveloped interpretation of the analysis based on the data presented

3.2.6 DATA SYNTHESIS

Data extracted from the included studies were analysed using a narrative synthesis, adopting an evidence-led framework described by Rodgers et al., see Figure 2.[117]

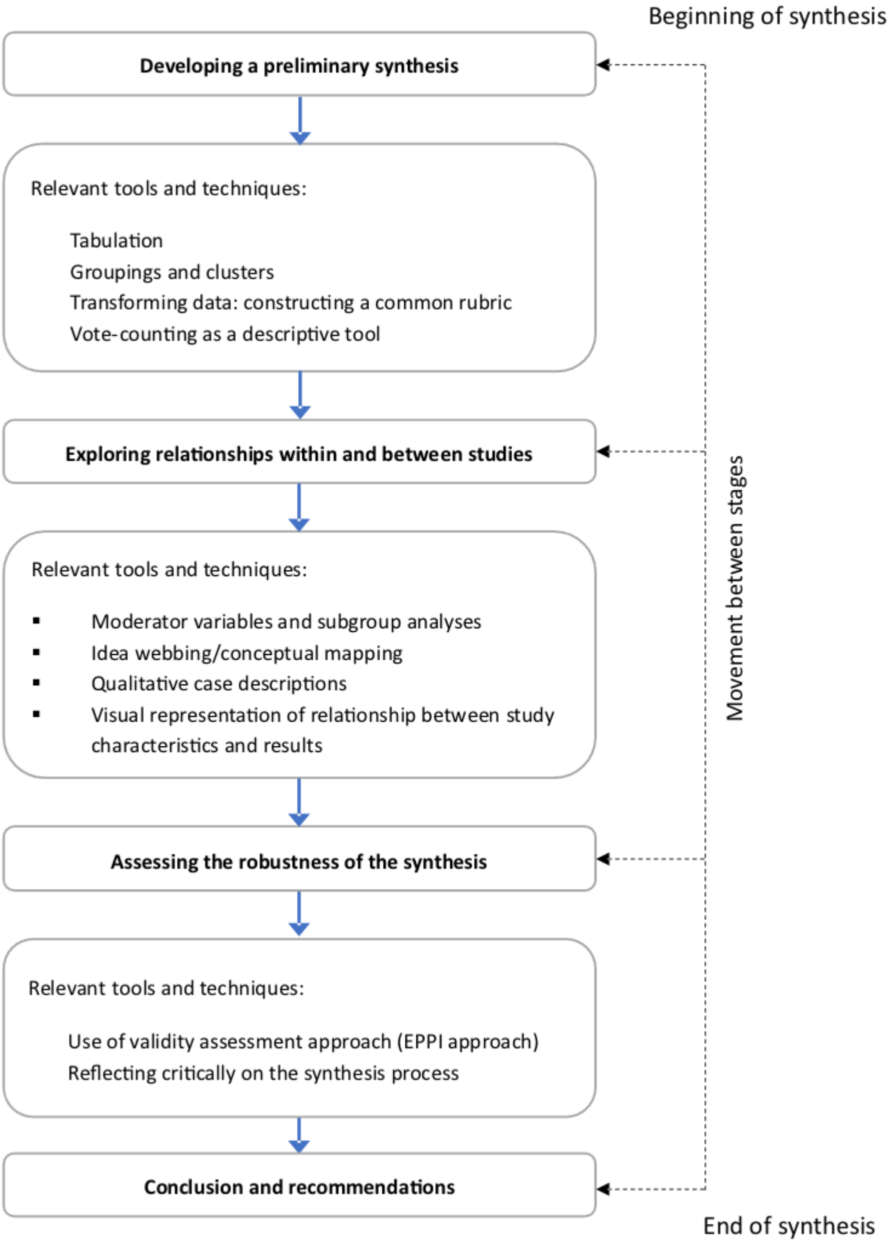

Figure 2 Rodgers et al. critical narrative synthesis framework

(The EPPI approach refers to an approach to the assessment of the strength of evidence of each study, based on the study's soundness, the appropriateness of the design to answering the research questions, and the study's relevance.)

An overarching theory of change was developed a priori and used as an analytical framework against which to assess the emerging evidence from the systematic review and to explain how the intervention works, why and for whom, see Figure 3. The theory of change model utilised the evidence found through an initial scoping search used to develop the search strategy for this systematic review, which includes the results of the previous systematic review by Adams et al. and theory of change model proposed by Allmark et al.[62,63] Allmark et al. demonstrates how access to welfare advice services can improve physical health, wellbeing and mental health through primary outcomes including improves finances, improved health outcomes measures and through improved access to healthcare and housing. Allmark et al. purport that improvements in primary outcomes can improve overall health and wellbeing through improved social environment and relationships, diet, physical mobility and independence. These pathways have been included within this theory of change, with additional components included where this is suggested by the evidence generated from the scoping review. Notably this included the additional impacts observed on the caseload of health professionals. The theory of change model explores the mechanism through which services improve health and wellbeing through measures to address social determinants of health and highlights how co-located services provide benefits to the health service.[119]

A textual description of all included and excluded studies was created alongside the quality assessment to generate summaries of each study that were used to form a cross-study analysis. An example one-page systematic textual narrative summary can be found in Appendix A.2.4.[116,125]

Given the significant heterogeneity in methodology across the included studies, and lack of formal statistical analysis, quantitative data are presented descriptively. The pooled average estimates of effect across the studies are reported, alongside the median and range where appropriate, to give an indication of spread and variability of data.

Qualitative data were translated through a thematic analysis, chosen for its systematic and replicable approach to analysis based on explicit rules of coding.[127] The data were interrogated to explore relationships within and across the included studies. Factors were identified that might explain differences in direction and size of effect across the included studies or in the type of facilitators and barriers to successful implementation of co-located welfare advice interventions.

Heterogeneity is the extent to which variation in the standardised mean difference is attributable to the statistical variability in the data.[128] Considerable heterogeneity was expected between studies due to small sample sizes and diversity of outcomes and measures. Heterogeneity between all studies was explored in consideration of study design, outcomes and study population. Given the complex nature of welfare advice interventions, it was difficult to anticipate the main sources of heterogeneity a priori. Where the main potential sources of variation could be identified, heterogeneity between effects were explored by means of subgroup analysis, based on the theory of change model about how the intervention works and for which groups. Sub-group analysis was performed when there were clearly defined subgroups with at least three studies in the group, the minimum number recommended for meta-analysis in Stata.[129] Where appropriate conceptual models and concept mapping were used to explore and highlight relationships between data.

Facilitators and barriers to implementation of welfare advice services in a health setting were explored using the Consolidated Framework for Implementation Research (CFIR).[130] CFIR consists of five major domains: intervention characteristics (focuses on the attributes of the intervention being implemented e.g. evidence base, complexity); inner setting (organisational context e.g. organisational culture, leadership engagement); outer setting (broader context e.g. external policies, external stakeholders); individuals (characteristics of the individuals involved in the implementation process e.g. knowledge, beliefs, and motivation); and implementation process (factors relating to implementation process e.g. planning, executing the intervention).[130] The CIFR was chosen given its familiarity in implementation science and it’s particular utility for explaining barriers and facilitators to implementation effectiveness.

3.2.7 THEORY OF CHANGE

This theory of change proposes that the implementation of a welfare advice service in a healthcare setting results in improvements to health and wellbeing and generates cost savings to the NHS and social sector, see Figure 3.

Figure 3 Theory of change model of how the implementation of a welfare advice service in a healthcare setting operates as a cost-effective measure to improve health and wellbeing and generate cost savings for the National Health Service.

There are several mechanisms through which welfare advice services co-located in health settings may operate to improve uptake of advice, compared to welfare advice services offered in a conventional setting, owing to the nature of its co-location. Being nested within health settings, the services are considered by patients to be more accessible and anonymous. Due to the connection between welfare advice services and health professionals, the services are perceived by patients to be more trustworthy, less stigmatising and better able to identify and provide early intervention to those most in need of help. The services are thought to offer, by welfare advisors and patients alike, a more enhanced, specialist service, tailored to the needs of those specifically with long-term health and mental health conditions, with better follow-up and continuity of care, compared to conventional services. Overall, some welfare services co-located in health settings report adopting a proportionate universalism approach, distributing resources to favour the disadvantaged, by increasing resources to meet the needs of some of society's most vulnerable people.[131-133]

Access to these services and uptake of the welfare advice provided, improves financial security and stability for individuals through increased household income and support with debt relief. Improved financial literacy and an awareness of their welfare rights, help individuals feel more empowered and better able to manage their finances and improves their financial support seeking when they are in need of financial assistance in the future, instead of relying on overdrafts, credit cards and loans. This breaks the cycle of spiralling financial insecurity and ultimately reduces levels of poverty. These impacts on financial security improve physical health and wellbeing, through reduced levels of mental health and stress-related conditions.

Accessing co-located welfare services could also improve health and wellbeing through measures to address other social determinants of health more directly. The services provide advice and support to improve housing conditions, access to nutritional food and transport, reducing the risk of communicable disease transmission and improving physical health, as well as mental health and wellbeing. Services also raise awareness of and promote access to community services, improving and encouraging appropriate use of health services to improve health and wellbeing generally. This also reduces levels of tobacco and substance misuse directly, where relevant, improving personal relationships and reducing levels of domestic abuse, all improving health and wellbeing.

Finally, improved access to welfare services may also provide benefits to the NHS. Improved uptake of welfare advice services may lead to a reduction in primary care appointments and improved use of secondary health services, particularly mental health services, resulting in significant cost savings for the NHS.

The theory of change model makes several assumptions that are necessary conditions for the proposed theory to improve health and wellbeing for individuals accessing the service. In the first instance, the model assumes that the welfare advice service co-located within health settings for mothers and their families is perceived positively by patients, healthcare professionals and welfare staff. It assumes that the service is integrated and implemented fully within the health system. A significant assumption of the model is that participants who access the service will fully engage with the service and access the financial and welfare support to which they are entitled. It also assumes that any additional income received through access to the service will be used by participants towards measures to improve their standards of living, which will in turn improve their health and wellbeing.

3.3 RESULTS

The search identified 7998 potentially eligible records through bibliographic database searches and an additional 15 from reference and citation searching. Upon removal of duplicates and exclusion after title and abstract review, 138 articles were left for full text review. A total of 14 studies were included in the final review, see Figure 4.

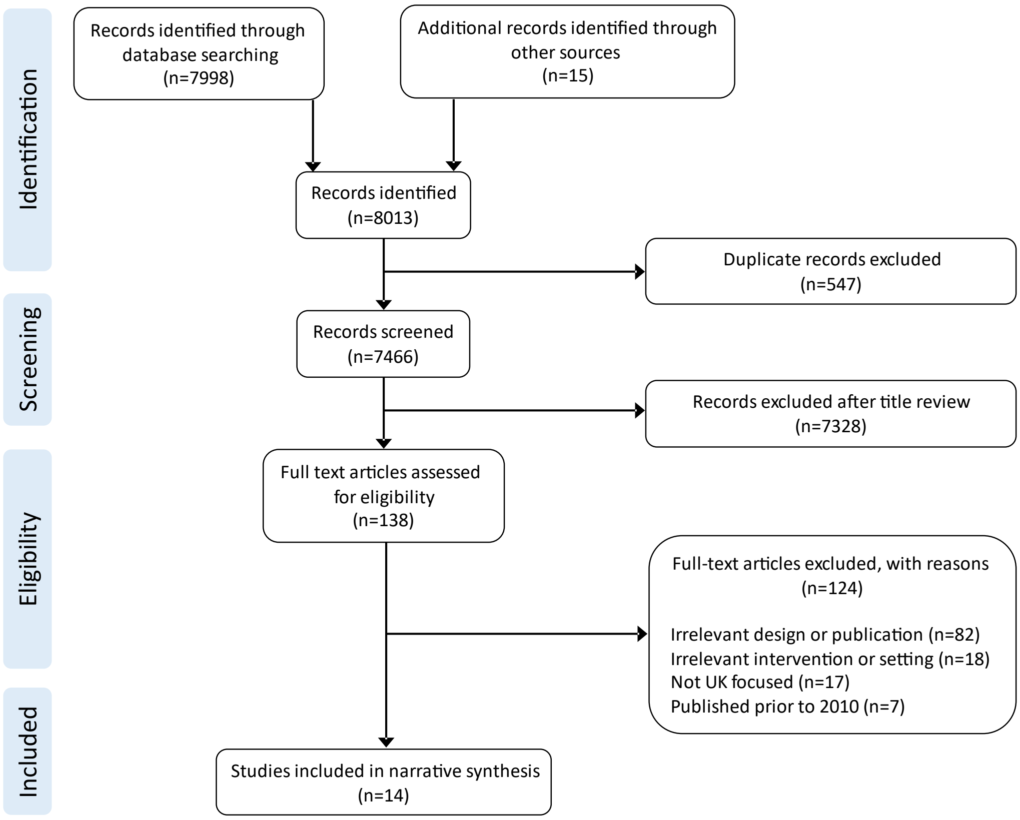

Figure 4 The PRISMA flow chart of the final selection process

A description of each included study is outlined in Table 6. Superscript alphabetic references in the text will be used to refer to the relevant included studies, ordered according to their place in Table 6.

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
a	Moffatt, Noble [134] (2010)	To explore what impacts welfare advice services have on the quality of life and wellbeing of people with cancer	Adults with cancer; Secondary care; oncology	Macmillan Cancer Support appointed three experienced welfare advisors to provide a dedicated welfare service for people with cancer and their carers.	Mixed methods; Descriptive study of welfare outcomes Study designed qualitative interview of patients and carers	User experience; provider experience; healthcare professional experience; financial impact.	▪ 1174 participants ▪ Numbers of participants eligible or approached for inclusion not reported. ▪ Welfare benefit claims resulted in a median increase in weekly income of £70.30. ▪ Service lessened financial impact of cancer and associated stress and anxiety. ▪ Facilitated independence and capacity to engage in daily activities, with overall improvement in wellbeing and quality of life
b	The Money Advice Service [113] (2018)	To evaluate the welfare advice service provided in GP practices in the area.	Adults; primary care	Provision of a full co-located welfare advice service at GP practices by welfare advisors.	Mixed methods; case study Study designed qualitative survey. Social return on investment	User experience; provider experience; healthcare professional experience; social return on investment (SROI); factors facilitators to	▪ Numbers of participants eligible, approached or recruited not reported. ▪ Every £1 invested in the co-location service generated £39 in social and economic benefits. ▪ Service reduced anxiety and stress associated with financial insecurity, leading to improved health and wellbeing.

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
						implementation; barriers to implementation.	▪ Co-located services were better able to target priority groups and those experiencing health inequalities with early intervention. ▪ Services reduced general practice workload, improving practice efficiency and job satisfaction. ▪ Care needs to be given to the practicalities of the service, including adequate office space and implementing a referral pathway and data sharing protocols
c	Hirst and Minter [135] (2014)	To evaluate the welfare advice service provided in GP practices in the area.	Adults; primary care	Provision of Citizens Advice Bureau sessions in GP practices.	Mixed methods; case report Study designed qualitative interviews	User experience; financial impact; return on investment	▪ 6,785 participants ▪ Numbers of participants eligible, approached or recruited not reported. ▪ The service achieved financial gains of £10,569,083 overall and managed £4,524,309 of debt in one year. ▪ Every £1 invested generated an additional £12.53 for clients and managed £2.34 of debt.

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
							▪ Services improved security of income and overall health and wellbeing
d	Kite [136] (2014)	To investigate how delivering advice in a GP setting contributes towards the accessibility of advice and the empowerment of advice clients.	Adults; primary care	Provision of Citizens Advice Bureau sessions in GP practices.	Qualitative; surveys	User experience	▪ 412 participants across ten Citizens Advice Bureauxs from three regions in England and Wales ▪ Numbers of participants eligible, approached or recruited not reported. ▪ Improved control of problem (80%) ▪ Improved understanding of the law and their rights (75%) ▪ Able to enforce their rights (66%) ▪ Feel able to have a say in the decisions that affect them (65%) ▪ Better able to deal with similar problems in the future (64%) ▪ Improve control over life (59%) ▪ Able to influence officials/people in authority (38%)
e	Adderley and Russell [112] (2012)	To evaluate the welfare advice service	Adults; primary care	Provision of Citizens Advice Bureau sessions in GP practices.	Mixed methods; case report	User experience; provider experience;	▪ 2163 participants

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
		provided in GP practices in the area.			Study designed qualitative interview of patients.	healthcare professional experience.	▪ Numbers of participants eligible, approached or recruited not reported. ▪ Clients reported: reduced levels of anxiety and/or depression (76%); reduced anti-depressant use (31%); supported resumption of day-to-day activities (85%); improved their general situation (7%); and reduced GP appointments (7%). ▪ GPs reported: reduced amount of medication (8%); reduced numbers of referrals to other specialist mental health services (85%); and reduced numbers of GP appointments (43%). ▪ Practice managers reported a reduction in GP appointments (22%).
F	Naven, Withington [111] (2012)	To evaluate the Healthier, Wealthier Children project, the provision of welfare advice services to	Pregnant women, families with children under five years and families	Provision of welfare advice services in GP and maternal and child health settings by Money Advice	Mixed methods; case report Study designed qualitative interview of	User experience; provider experience; healthcare professional	▪ 2516 participants ▪ Numbers of participants eligible, approached or recruited not reported.

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
		established referral links between health and money advice services to support pregnant women and families at risk of, or experiencing, poverty.	with additional support needs; community and secondary care settings	Workers. This included alongside health visitors, through referral by midwives where identified at antenatal appointments and in the children's outpatient departments.	patients and carers	experience; financial impact; factors facilitating successful implementation; barriers to implementation.	▪ Average annual client gain of £3,404 ▪ Clients reported a reduction in stress, improved mood and an increased sense of self-worth and security. ▪ Strategies to actively encourage collaboration between health professionals and welfare advisors were key to successful implementation and delivery. ▪ Challenges to successful implementation included navigating existing NHS information sharing and data protection protocols and ensuring adequate welfare advice staff representation on strategic groups
g	Naven and Egan [110] (2013)	To evaluate the Healthier, Wealthier Children project, the provision of welfare advice services to established referral	Pregnant women, families with children under five years and families with additional	Provision of welfare advice services in GP and maternal and child health settings by Money Advice Workers. This included	Mixed methods; case report Study designed qualitative interview of	Financial impact; factors facilitators of implementation; barriers to implementation.	▪ 360 participants ▪ Of 2,516 referrals made, 1,347 (54%) accessed some type of advice. Almost one in two (663) people receiving advice were

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
		links between health and money advice services to support pregnant women and families at risk of, or experiencing, poverty.	support needs; community and secondary care settings	alongside health visitors, through referral by midwives where identified at antenatal appointments and in the children's outpatient departments.	patients and carers		entitled to some type of financial gain. ▪ Numbers of participants eligible not reported. ▪ The total financial gains from this project amounted to £2,323,484. ▪ Flexibility in models of delivery e.g., telephone triage increased client engagement and staff satisfaction ▪ Challenges with identifying appropriate outcomes to measure and demonstrate effect
h	Krska, Palmer [137] (2013)	This study aims to: determine staff perceptions on the impact of the advice service on general practice workload; to quantify the frequency of mental health issues among patients referred to the service; and to measure any impact	Adults; primary care	Provision of Citizens Advice Bureau sessions in GP practices.	Quantitative; before and after study	User experience; provider experience; healthcare professional experience; mental health; health and social care utilisation.	▪ 148 participants from 250 referrals made. ▪ Number eligible not reported. ▪ Qualitative interviews conducted with GPs (n=4), practice managers (n=9) and welfare advisors (n=6) ▪ GP appointments reduced from an average of 4.90 appointments per patient to 4.26 per patient (P=0.017)

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
		of the service on appointments, referrals and prescribing for mental health.					▪ Prescriptions for hypnotics and anxiolytics reduced by 42% (P=0.016) ▪ Non-significant reductions in nurse appointments (1.50 to 1.35 per patient) and prescriptions for antidepressants (1.20 to 0.96) ▪ No change in appointments or referrals for mental health problems
i	Eynon, Robinson [138] (2020)	A retrospective analysis of the service over a period of 11 years was undertaken to look at the range of legal advice sought.	Adults; secondary care; general	Provision of a legal service, including welfare advice, for inpatients in critical care or for those who have suffered trauma.	Mixed methods; case report	Provider experience; healthcare professional experience; financial impact.	▪ 551 participants. ▪ Numbers of participants eligible, approached or recruited not reported. ▪ Addressing complex social issues reduced levels of stress and improved wellbeing. ▪ Access to service reduced costs of healthcare and improved access to preventative healthcare ▪ Co-located services were better able to target priority groups with earlier intervention

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
j	Gabbay, Ring [139] (2017)	The aim of the pilot trial was to test the procedures, recruitment processes and operational strategies that were planned for use in the main trial, evaluating the effectiveness of debt counselling for primary care.	Adults; primary care	Provision of debt counselling and advice by Citizens Advice Bureau.	Quantitative; randomised controlled trial Study designed qualitative interview of patients and carers	User experience; mental health; physical health; health and social care utilisation.	▪ Total of 61 participants (32 intervention, 29 control) were randomised. ▪ 4121 individuals eligible and approached. ▪ Qualitative interviews were conducted with 23 participants and 11 GPs and welfare advisors. ▪ Beck Depression Inventory-II scores fall from 29 [36.6 mean] (7.9 SD) to 24 [29.0] (11.3) at 4 months in the control group. In the intervention group fall from 32 [33.9] (8.4) at baselines to 28 [25.7] (9.9) at 4-month follow-up. ▪ Beck Anxiety Inventory scores fall from 27 [28.2 mean] (13.0 SD) to 23 [22.4] (11.8) at 4 months in the control group. In the intervention group fall from 31 [25.4] (13.3) at baseline to 26 [24.9] (14.0) at 4-month follow-up. ▪ Mean quality of life scores rose by 8.8 versus 3.3 in the intervention group to give a higher mean score at 4 months.

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
							▪ Participants identified two main benefits of advice: first, support in engaging with a range of agencies about debt issues and, second, identifying sources of additional financial support. ▪ Services should provide more opportunity for informal collaboration between health and welfare services to achieve successful implementation
k	Woodhead, Khondoker [64] (2017)	To examine the impact and cost-consequences of co-located benefits and debt advice on mental health and service use in primary care.	Adults; primary care	Provision of Citizens Advice Bureau sessions in GP practices.	Quantitative; quasi-experimental controlled trial; odds ratios, economic analysis	Financial impact; mental health; health and social care utilisation; return on commissioner investment.	▪ 278 participants recruited of 397 eligible, 623 controls. ▪ Per capita, advice recipients received £15 per £1 of funder investment. ▪ Common mental health disorders reduced among women (rOR=0.37, 95% CI 0.20-0.70) and Black advice recipients (rOR=0.09, 95% CI 0.03-0.28) relative to controls ▪ Individuals whose advice resulted in positive outcomes demonstrated improved well-being scores (β co-efficient 1.29, 95% 0.25-2.32)

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
						▪ Reductions in financial strain (rOR=0.42, 95% CI 0.23-0.77) but no change in 3-month consultation rate were found
l Woodhead, Collins [140] (2017)	To develop an initial programme theory for how the provision of co-located advice supports specific general practice outcomes, and to identify salient barriers and enabling factors.	Adults; primary care	Provision of Citizens Advice Bureau sessions in GP practices.	Qualitative; semi-structured interviews	User experience.	▪ 24 semi-structured interviews conducted with GPs (n=9), reception staff (n=4), practice manager (n=3), welfare advisors (n=6) and service funders (n=2) ▪ Participants noted a reduction in GP consultations and practice time spent on non-health issues following access to the service. ▪ Facilitating implementation factors were not limiting access to GP referral and offering booked appointments and advice on a broader range of issues responsive to local need. ▪ Key barriers included pre-existing sociocultural and organisational rules and norms, which maintained perceptions of the GP as the “go-to-location”

Table 6 Characteristics and narrative description of studies included in the narrative synthesis systematic review

	Study	Aim of study	Study population & location	Intervention	Study design	Outcomes measured	Main findings
m	Parsonage[109] (2013)	To report the financial impact of the Citizens Advice Bureau service in a secondary care mental health service.	Adults with mental health conditions; secondary care; mental health.	Provision of Citizens Advice Bureau sessions in secondary care mental health services.	Mixed methods; case report	Financial impact.	▪ 622 participants ▪ Numbers of participants eligible, approached or recruited not reported. ▪ Clients increased their income by £4,274 per annum on average. ▪ Services generated cost savings in three ways: reduction in inpatient lengths of stay; prevention of homelessness; and prevention of relapse of severe mental illnesses.
N	Burrows[58] et al. (2011)	To examine the views and experiences of staff and users of Citizens Advice Bureau (CAB) services located in general practice, and to identify key factors perceived as contributing to the intervention effectiveness.	Adults; primary care.	Provision of Citizens Advice Bureau sessions in general practice.	Qualitative; semi-structured interviews.	User experience; provider experience; healthcare professional experience.	▪ Ten general practice staff and welfare advisors, and 12 service users interviewed. ▪ Co-located advice was found to have financial benefits and was perceived by participants to offer health. ▪ Demonstration of measurable health improvement and wellbeing presented challenges

3.3.1 STUDY CHARACTERISTICS

Of the 14 studies included in this review, half were published in peer-reviewed journals,[a,h-l,n] six studies were published as reports,[b-c,e-g,m] and one was published as a thesis abstract.[d] The included studies were published between 2010 and 2020, nine prior to 2015.[a,c-h,m-n] They employed a range of designs: one non-randomised controlled trial,[k] one pilot randomised controlled trial, which was terminated as a result of low recruitment,[j] one before-and-after-study,[h] three qualitative studies,[d,l,n] and eight descriptive case studies.[a-c,e-g,l,m] The evidence from this review has been mapped onto the theory of change model, see Figure 5, demonstrating the spread of evidence across the model and highlighting areas with a greater evidence base and areas where evidence is limited or lacking.

The welfare advice services evaluated in the reviewed studies all provided general welfare advice for adults aged 18 years and over, 11 were for the general population and three provided services specifically for: adults with cancer;[a] mental health problems;[m] or mothers and their families.[f-g] Nine of the evaluated services were co-located in general practice,[b-e,h,j-l,n] while three were co-located in secondary care in mental health,[m] oncology[a] and intensive care[i] settings. Two linked studies evaluated services co-located across maternal and child health community and secondary care settings.[f-g] Welfare advice services co-located in a primary care setting usually provided advice and support to the general practice patient list, although some offered this more generally to the local population, not limited to those registered with the practice. Access to welfare services was largely appointment based and accessed through referral by a general practitioner. However, some patients could self-refer. Two providers offered a drop-in service.

The co-located welfare advice services were largely provided by the Citizen's Advice Bureau (n=9) including all services co-located in general practice in England.[c-e,h,j-n] For services based in Scotland (n=3), the services were provided by Money Advice Workers[f-g] or welfare advisors accredited under the Scottish National Standards for Information and Advice Providers.[b] The co-located oncology welfare advice service was provided by Macmillan Cancer Support[a] and the welfare advice service co-located in intensive care was provided by trained legal advisors.[i]

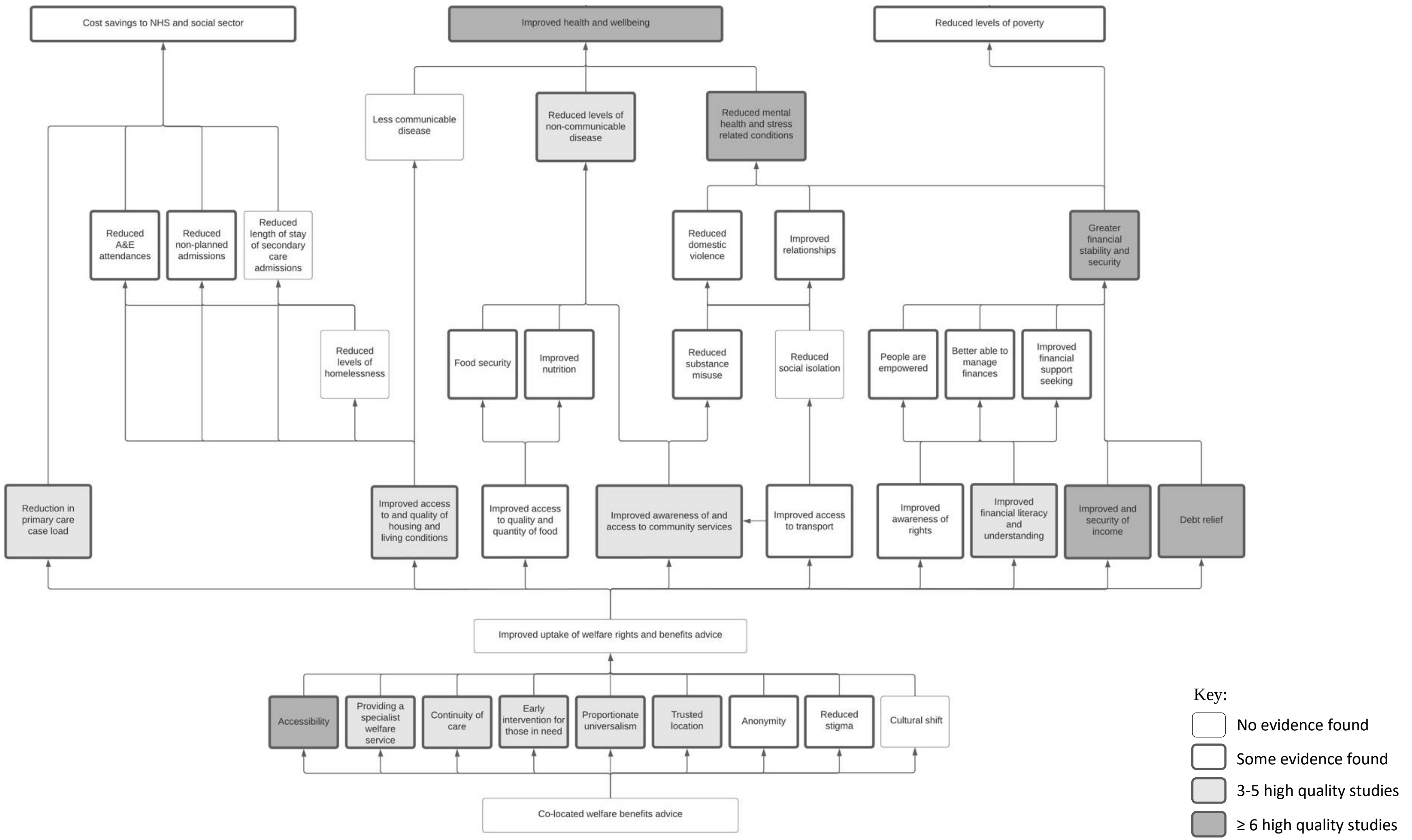

Figure 5 Map of the narrative systematic review evidence against the theory of change model

The majority of reviewed studies reported the effects of the intervention on health[a-c,e-f,h-l,n] (n=11) and social outcomes[a,c,f,i,k-n] (n=8) for the participants. Three papers[h,j-k] utilised quantitative methods and eight papers[a-c,e-fl-n] used forms of qualitative methods to explore physical and mental health outcomes. Social outcomes included improved access to housing, employment and education opportunities and improved relationships. Seven papers[a,c,f,i,l-n] utilised qualitative methods and one paper[k] used forms of quantitative methods to explore physical and mental health outcomes. Three studies reported predominately on the impact of the intervention on mental health outcomes.[h,j,m] Six of the studies evaluated the impact of the intervention on health services, in particular its effect on prescribing, service use and staff workload.[b,e,h,k-n]

Seven studies incorporated an economic evaluation, six reporting from the perspective of the welfare advice recipient,[a-c,f-g,k,m] and two used a Social Return on Investment (SROI) approach,[b-c] which has a broader (e.g. social, economic and environmental) concept of resulting value.[141] Six of the included studies included a review of the effectiveness of the implementation of the co-located welfare advice services.[b,f-g,i-j,m] Nearly half of the reviewed studies explored participant experience of the intervention. Recipients of welfare advice were most commonly studied (n=7),[a-b,d-e,i-j,n] alongside healthcare professionals working in the setting (n=6).[a-b,e,h-i,n] Two studies examined the experiences of welfare advisors delivering the intervention.[a-b]

Table 7 Quality assessment of included studies

	Study	Quality Assessment	Relevance	Richness
a	Moffatt et al. (2010)	High	Medium	Thick
b	The Money Advice Service (2018)	Low	High	Thin
c	Hirst et al. (2014)	Low	High	Thin
d	Kite et al. (2014)	Medium	High	Thick
e	Adderley et al. (2012)	Low	High	Thin
f	Naven et al. (2012)	Medium	High	Thick
g	Naven et al. (2013)	Low	High	Thin
h	Krska et al. (2013)	Medium	High	Thin
i	Eynon et al. (2020)	Low	High	Thin
j	Gabbay et al. (2017)	High	High	Thick

Table 7 Quality assessment of included studies

Study		Quality Assessment	Relevance	Richness
k	Woodhead et al. (2017)	High	High	Thick
l	Woodhead et al. (2017)	High	High	Thick
m	Parsonage et al. (2013)	Low	Medium	Thin
n	Burrows et al. (2011)	High	High	Thick

The quality of over half of the papers was assessed as high (n=5)[a,j-l,n] or medium (n=3),[d,f,h] see Table 7. These better quality studies used robust approaches and made attempts to adjust for observed confounders. The quality of the remaining six studies was assessed as low, owing to a lack of reporting of their methodological and analytical approaches.[b-c,e,g,i,m] The majority of reviewed studies were assessed as being of high relevance to the review objectives[b-l,n] (n=12), with two studies being assessed with medium relevance.[a,m] Half of the included studies were assessed as thick on the 'richness' of their findings.[a,d,f,j-l,n] Studies of high or medium quality were also usually found to be thick on the assessment of the 'richness' of their findings. No studies were rejected on the basis of their quality, relevance or richness of their findings.

3.3.2 STUDY FINDINGS

3.3.3 BASELINE CHARACTERISTICS

The baseline characteristics of participants were similar across the four studies where these characteristics were reported, see Table 8. Participants were more likely to be female, with an average age of 46 years. Few individuals under the age of 24 years sought access to welfare advice services. Details regarding the ethnicity of participants were reported in limited detail across four of the included studies; the majority of participants accessing welfare services described their ethnicity as white (74%).

Table 8 Baseline characteristics of participants across included studies (n=15,028)

	Mean	Number of studies
Gender		
Male	44%	4[a,j-k,m]
Female	56%	4 [a,j-k,m]
Age		
17-24 years	9%	4[h-l,k,m]

Table 8 Baseline characteristics of participants across included studies (n=15,028)

	Mean	Number of studies
25-34 years	11%	4 [h-I,k,m]
35-44 years	16%	4 [h-I,k,m]
45-54 years	22%	4 [h-I,k,m]
55-64 years	21%	4 [h-I,k,m]
65+ years	18%	4 [h-I,k,m]
Mean age	46 years	4 [h-I,k,m]
Ethnicity		
Ethnic minority groups	20%	4[e-f,k,m]
White British	74%	4[f-g,j-k]
Not-specified	6%	4[f-g,j-k]
Household income		
Income (<£4800 per annum*)	51%	2[k,m]
Income (£4800-£12000 per annum*)	37%	2[k,m]
Income (>£12,000 per annum)	12%	2[k,m]
Relationship status		
Co-habiting	38%	3[a,j,m]
Single	51%	4[a,j-k,m]
Other	11%	2[a,j]
Employment status		
Employed	19%	2[a,k]
Not working due to long term illness or disability	42%	2[d,j]
Looking after the home	3%	2[a,j]
Unemployed	18%	4[a,d,j-k]
Retired	18%	4[a,d,j-k]

* The annual income threshold for claiming Universal Credit (a government benefit for working aged people between 18 years old and retirement age on low income or out of work to help with living costs) for single people over the age of 25 years old is £4800. The annual income threshold for joint claimants of universal credit for people over the age of 25 years old is £4800-12000. Correct as of 22 August 2021.

3.3.4 FINANCIAL IMPACTS

The theory of change model proposes that access to co-located welfare advice services leads to greater financial stability, through improved income, support with debt relief and greater financial literacy and an awareness of welfare rights. Greater financial stability was supported by the studies included in this review. All studies included in this review highlighted that there were improvements in financial outcomes for individuals who accessed co-located welfare advice services. This was reported by participants, healthcare professionals and welfare advisors alike. Improved and greater stability of household income arose from backdated payments from unclaimed benefits and regular gains in household monthly income, through successful applications for eligible benefits.[c,e-g,i-k,m-n] Many participants also reported receiving debt advice or support in reducing their levels of debt following access to welfare services in the included studies.[f,i-j,m-n] Detail was not provided by any studies on the specific range of benefits accrued, nor on the uptake of welfare advice and benefits to which participants were entitled.

Several studies reported that participants felt that their knowledge about financial issues, the law and their rights had improved as a result of having access to a welfare advisor.[a,c-d,f-g,i-j,m] They felt better able to deal with current and potential future welfare problems. Even participants who only received advice but did not gain financially reported feeling that their confidence in managing finances had increased. Studies report that those who accessed welfare advice services were also more likely to know where and how to access advice in the future, should they need it.[k-l] They also reported knowing how to avoid financial support-seeking behaviours that are detrimental to financial security, such as using credit cards and overdrafts.

3.3.5 HEALTH AND SOCIAL IMPACTS

The theory of change model proposes that a welfare advice service co-located in health settings improves health and wellbeing through three mechanisms: reduced mental health and stress-related conditions; reduced levels of non-communicable disease; and less communicable disease. Improved physical health, or the perception of such, was reported as a positive outcome in most studies included in this review by participants, healthcare professionals and welfare advisors alike.[a-c,e-f,h-n] Study L noted that “Most respondents [medical professionals and welfare advisors] acknowledged that where underlying social drivers affected patients’ health, health improvement would be unlikely through medical intervention alone.”

3.3.5.1 IMPACTS ON MENTAL HEALTH

Most studies (n=13) reported that participants and welfare advisors felt that access to co-located welfare services led to improvements in mental health and overall feelings of wellbeing, thus achieving a greater quality of life.[a-c,e-n]

For some included studies (n=3), impacts on mental health were explored using qualitative methodology, with two studies conducting a robust qualitative analysis using a thematic analysis[l,n] and one using frequency counts of commonly reported outcomes.[d] Two studies measured mental health and wellbeing outcomes using validated tools, comparing self-reported changes to mental health between an intervention and control group.[j-l] These studies demonstrated improvements to mental health and wellbeing outcomes following intervention compared to controls. One study[j] presented descriptive statistics owing to lack of statistical power and the second study[k] presented outcomes as odds ratios (OR), finding that mental health and wellbeing outcomes only improved significantly for recipients who were female or belonged to black ethnic groups. A meta-analysis for mental health and wellbeing outcomes was not possible due to heterogeneity in outcome measures utilised.

Where reported in included studies, improved mental health and wellbeing were attributed largely to reductions in levels of stress, by way of: improved income;[c,e-g,i-k,m-n] debt relief;[f,i-j,m-n] and support with managing bills and finances.[f-g,l] Study N noted that “[CAB] was invaluable. I’d have killed somebody, or killed myself if I hadn’t got it sorted out because it was just going downhill.”

Three studies of varying quality assessment (low medium and high respectively) found that many of their participants reported a feeling of self-worth and security following use of the services.[d,f,k] Two studies of medium and high quality assessment, found that there were fewer accounts of suicidal ideations and reduced need for medication as a result of improved mental health.[e,h] One high quality study found statistically significant reductions in prescriptions for anxiolytics and hypnotics (42% reduction (P=0.016)) during the six months after referral to the service compared with the six months before and a non-significant reduction in nurse appointments (from 1.50 to 1.34 per participant), suggestive of improved mental health outcomes for participants accessing co-located services.[h] However, this study found no change in appointments or referrals for mental health conditions. No further studies explored prescriptions for anxiolytics or hypnotics as a measure of impact of services upon mental health. Where measured objectively, through access to GP consultation records and as a self-reported measure, there was a 27% average reduction in antidepressant prescribing (range 22-31%) following receipt of co-located welfare advice.[e,h] One medium quality study[e] used simple frequency counts of self-reported outcomes to collect this data and a second before and after study[h] accessed GP records to measure frequency of GP consultations in the six months before and after intervention. Both studies reported their results descriptively owing to a lack of statistical power.

Further improvements in mental health were reported by two studies of medium and high quality.[f,n] One high quality study reported that some participants felt that they were able to talk to family and friends after receiving welfare advice and this had improved close relationships, resulted in fewer arguments in the household and significantly less stress within relationships.[n] One low quality study found there was evidence to suggest that access to welfare advice helped to remove some participants from situations where they were living with abusive partners.[m] This was not described in significant detail but involved re-housing participants away from their abusive relationships and securing their financial situation.

Two high quality studies highlighted that some general practitioners were more sceptical about the long-term improvements to mental health owing to an improved financial situation.[h,l] They felt that the issue of poor mental health and financial insecurity and instability were multi-factorial, each contributing to the other, and solving the issue of poor mental health with a short-term improvement in financial security would not be sufficient to solve the overall problem. This was also reported by some participants who still felt that they had significant money worries to contend with or who were still worried about the future.[h,l]

3.3.5.2 IMPACTS ON SUBSTANCE MISUSE

One high quality study included in the review demonstrated that participants who accessed welfare services also reported reduced substance misuse.[l] This was facilitated by an improved access to primary care, mental health and community drug and alcohol services. Where housing conditions were poor, some participants reported reduced drug and alcohol use following access to the welfare service through improved housing conditions and thus breaking the cycle of the resumption of alcohol and substance misuse.[l]

3.3.5.3 IMPACTS ON PHYSICAL HEALTH

Several studies attributed improvements to physical health from addressing other social determinants of health.[a-c,e-f,h-i,k-n] For all included studies, impacts on physical health was explored using qualitative methodology, with two studies conducting a robust qualitative analysis using a thematic analysis.[l,n] No studies measured physical health using validated tools. Three high quality studies found that access to co-located welfare advice improved engagement with other community health services and thus improved compliance with treatment plans, particularly for chronic, complex disease management.[a,i,n] Two studies, of medium and high quality, found that participants reported overall improved levels of nutrition and greater food security through improved income and access to alternative food sources, such as food banks.[f,n] Several studies reported improved housing conditions for participants through assistance with housing applications and grants by welfare advisors.[a,c,f,i,k,m]

3.3.6 HEALTH SERVICE BENEFITS

Finally, the theory of change model also suggests that access to co-located welfare advice and improved welfare can benefit the NHS through reduced primary and secondary care caseload, resulting in cost savings for the NHS.

Many studies, utilising qualitative methodology, reported that GPs and other administrative staff found co-located services to be time saving for doctors and administrative staff alike. Services reduced practice staff time spent on non-health issues both inside and outside of consultations, where this linked to direct rather than indirect support, such as reducing bureaucratic pressure involved with form-filling, rather than addressing problems such as depression linked to debt.[b-c,e-h,k-l,n]

However, the studies included in this review suggested that there was a mixed experience of whether co-located welfare advice services reduced contact time with healthcare professionals. These studies were limited to a primary care setting. Where explored qualitatively, two studies, of medium and high quality, found that patients reported a reduced need for repeat GP appointments following access to co-located welfare advice.[e,l] In two high quality qualitative studies, they found that there was a difference in experience of the services and its perceived effect on consultation rate by GPs.[l,n] Some GP's felt that the service had no impact upon their consultation frequency and in fact felt that it was their role to consider and to support patients with their social problems where they impacted upon health, despite others stating this was outside their clinical role and feeling unqualified to address them directly.[l] Some participants reported booking additional GP appointments, where they might not have done otherwise, because they were in the building seeing the welfare advisor.[n] Others report perceiving the welfare service as 'an extra' rather than instead of consulting their GP.[l,n]

Where measured objectively, through access to GP consultation records and as a self-reported measure, there was a 7% average (range 0-13%) reduction in GP attendance following receipt of co-located welfare advice, measured between 3 and 6 months following receipt of intervention.[e,h,k] One high quality paper reported a 13.1% reduction in GP attendance (P=0.017) for advice recipients in the six months after being in receipt of the intervention, compared to the six months prior, using a before and after study design.[h] However, one high quality paper found no difference in GP consultation rate in the three months following receipt of the intervention compared to a control group, using a quasi-experimental study design. One high quality paper, using a before and after design, found there was no difference in referrals to mental health services in a six-month period before and after benefitting from co-located welfare advice.[h]

Several studies found that there was a high sense of achievement reported by healthcare professionals who engaged with co-located welfare advice services.[b,f-h,l] In one medium and two high quality studies, many reported a frustration with their inability to support patients with wider determinants of health and being able to refer into a service providing this support gave the health professionals a feeling of satisfaction.[g-h,l] Two low and one medium study reported that healthcare professionals referring into the service felt that their own financial literacy had improved as a result of their interaction with the co-located service, though there was no description of how this idea was explored with these healthcare professionals.[b,f,m]

3.3.7 CO-LOCATED SERVICES AS A SPECIALIST SERVICE

The theory of change model suggests that there are several mechanisms through which welfare advice services co-located in a healthcare setting can increase uptake of advice and ultimately improve welfare, compared to services offered in conventional settings, due to its location and the nature of the integration of services. This element was not a specific research question explored by the studies included in this review. However, qualitative exploration of the impact of co-located services on participants, healthcare professionals and welfare advisors generated findings that contribute to this theory.

Some of the included studies found that welfare advisors felt that co-located services gave a greater sense of confidentiality and trust to participants, which was reflected by the views of participants in these studies.[b,f-g,i-j,l-n] Some studies, including several of high quality, reported that provision of welfare services co-located within a healthcare setting were also more able to target and reach some of the most vulnerable people.[a-b,f-i] The authors identified that health services and healthcare professionals often have a unique access to vulnerable individuals and can strengthen the identification of need for advice among these groups, thereby mitigating poverty.

3.3.8 ECONOMIC EVALUATION

Nine studies provided financial data for 14,468 participants who accessed and were supported by the welfare advice services.[a,c,e-g,i-j,m] Some studies reported details on the costs of the service provided to commissioners and the financial gains for the participants, NHS and wider society, see Table 9.[a,c,e-g,i-k,m]

Participants in receipt of general welfare advice had on average four contacts[1,3,10,13] and four issues resolved per participant.[c,m] Where reported, the majority of participants accessing the services received support on more than one issue.[c,m]

Three studies reported the overall cost of the service to commissioners. [c,f,k] From these three studies, I calculated the crude average cost of this service per study to commissioners was £660,324 per annum, ranging from £79,000 to £1,058,375 per study.[c,f,k] The average cost per client was £272 (£124-421).[c,f,k,m] More established services were found to cost less, owing to less funding being required for set up costs and efficiency savings.[b,f]

Financial gains ranged from one-off payments, owing to unpaid or incorrectly allocated benefits, to improvements in annual household income, as a result of successful claims for entitled benefits. Six studies reported financial outcomes for participants.[a,c,f-g,k,m] Where, participant financial outcome data was reported, I calculated that participants gained £1,840 on average in one off payments and also benefitted from an average increase of £2,757 in household income per annum across studies.[a,c,f-g,k,m]

Two services provided across three of the studies generated on average £27 of social, economic and environmental return per £1 invested. Both studies reported a positive return on investment that ranged from £15 to £39 return on investment per £1 invested.[b,k] The return on investment was calculated by dividing the crude total cost of the service provided by commissioners by the sum of the total financial gains for all participants, for the studies where both the cost and financial outcome data were available.

Table 9 Economic evaluation of co-located welfare services

	Total	Average	Median	Range	Number of papers
Service use					
Participants supported	14468	1608	622	19-6785	9[a,c,e-g,i-k,m]
Number of contacts	23070	7690	1231	28-21811	3[a,c,j]
Number of issues resolved	30347	15174	-	1725-28622	2[c,m]
Average number of contacts per client	-	4	3	1-8	4[a,c,j,m]
Average number of issues per client	-	4	-	3-4	2[c,m]
Service cost					
Cost of service (per annum)	-	£660,324	£843,597	£79,000-1,058,375	3[c,f,k]
Cost of service (per person)	-	£272	£272	£124-421	4[c,f,k,m]
Financial gains					
Participant financial gains (per person)	-	£1,840	£1,394	£776-3,656	6[a,c,f-g,k,m]
Average income increase (per annum)	-	£2,757	£3,046	£963-4,274	6[a,c,f-g,k,m]
Debt managed (per annum)	£4,653,309	£2,326,655	-	£129,000-4,524,309	2[c,i]
Social return on investment (per £1 spent)	-	£27	-	£15-39	2[b,k]

3.3.9 SERVICE IMPLEMENTATION

None of the included studies reported examination of implementation outcomes as an aim of their study. However, some of the studies described the barriers and facilitators to successful implementation of a welfare advice service co-located in health settings within their presented results. No studies utilised a named implementation framework to evaluate barriers and facilitators to implementation.

Co-production of welfare services, effective communication, collaboration, and simple referral pathways were the themes identified as facilitators to the successful implementation of the intervention. These are presented below according to the five domains of the Consolidated Framework for Implementation Research (CFIR) five domains: intervention characteristics, inner setting, outer setting, individuals and intervention process.[130]

3.3.9.1 INTERVENTION CHARACTERISTICS

No specific barriers or facilitators to implementation were reported by studies relating to the characteristics of the intervention.

3.3.9.2 INNER SETTING

Some welfare advisors reported that organisational barriers involving complicated and restrictive NHS information sharing protocols made referral processes more challenging and caused unnecessary delays to implementation.[f]

Across many of the included studies, there was a strong sense that shared values of co-production, collaboration, communication, confidentiality, flexibility, holistic care and trust between all involved with the co-located services was important for a successful and effective service.[g,i-j,l-n]

3.3.9.3 OUTER SETTING

No specific barriers or facilitators to implementation were reported by studies relating to the outer setting of the intervention.

3.3.9.4 INDIVIDUALS

The quality of working relationships was reported among welfare advisors and health professionals as an important contributory factor in achieving successful implementation.[f-g,j,l] Where working relationships were nurtured and created a welcoming, close and trusted relationship, the integrated services thrived. Several studies also reported the importance of higher level strategic buy-in to facilitate effective leadership and strategic working relationships.[f-g] Most studies reported the importance of effective collaboration, communication and integration of the services.[b,f-g,i-j,l-m]

3.3.9.5 IMPLEMENTATION PROCESS

Most studies reported barriers and facilitators to the successful implementation of a welfare advice service co-located in a health setting in the implementation process domain.

Co-production of the welfare advice service within the healthcare setting at the planning stages was seen as an essential factor for the successful implementation of the service.[f-g,m] Involvement of both healthcare professionals and welfare advisors was found to be important, in order to raise awareness of the service amongst healthcare professions and thus improve appropriate referral rates.[f-g,m] Co-production was felt to promote a more sustainable approach and built trust between the NHS and welfare services.

Two studies reported that welfare advice staff felt more integrated within the team when they shared physical space and resources with the healthcare staff, helping them to feel a part of the team.[h,l] Study K noted that “Co-ordination and collaboration do not happen on their own, that co-location is not just about the bricks and mortar. It is also about strategies to bring people together in a meaningful way.”

Simple referral pathways with clear associated documentation for professionals and participants improved referrals into the service.[b,e,g,j,n] The most common form of referral was directly by healthcare professionals, who are considered to know their patients well and are best able to identify need.[b,e,g,j,n] Referral by healthcare professionals legitimised the need for the services and helped to convey a sense of trust in the welfare service.[b,j,n] The option to self-refer was available in most services though it was not the most commonly accessed route.[l-n]

3.4 DISCUSSION

3.4.1 SUMMARY OF KEY FINDINGS

This narrative synthesis systematic review considers 14 research studies exploring the integration of welfare services within various healthcare settings. Most of the studies were qualitative and before and after studies, with only one study demonstrating causal evidence supporting the links between improved mental health and use of co-located welfare services.[k]

This review overall demonstrated clear financial gains and improved financial security for participants, which reinforces previous findings from Adams et al.[62] The reviewed studies suggest that access to co-located services improved knowledge about financial issues, the law and welfare rights.

Co-located welfare advice was reported to both directly and indirectly improve both physical and mental health and wellbeing through action on key social determinants of health. The review also found some evidence to suggest that co-located welfare advice reduces the workload for primary and secondary care services, resulting in cost savings for the NHS. If demonstrated by further high-quality studies, this could suggest that co-located services are able to improve the availability of resources required for those most in need.

This review suggests that co-located services generated these outcomes through provision of a greater sense of confidentiality and trust to participants and were better able to target and reach some of the most vulnerable people. These mechanisms were not explored as primary outcomes for the studies included in the review and have not yet been formally studied.

Importantly, several studies highlighted challenges in conducting evaluations of welfare services of relevance to future studies conducted in this area. Many struggled to recruit sufficient participants or were unable to follow-up sufficient numbers to achieve reasonable statistical power, suggesting an alternative design may be better suited to evaluations of co-located welfare advice services. Several studies reported challenges in identifying suitable effectiveness and implementation outcome measures, resulting in significant heterogeneity in reported outcomes across the included studies. The challenge of recruiting minority groups into the study was also raised as a particular concern in many studies.

The results of this review provided a wide range of evidence to build upon the theory of change model proposed earlier in the thesis. Figure 5 demonstrates the scope and strength of evidence supporting the theory of change model. There was a wide range of high-quality evidence that explored the mechanisms by which welfare advice services co-located in health setting operate to improve uptake of advice compared to conventional settings. Significant evidence was presented to strengthen the association between the receipt of welfare advice and improved security of income and debt relief, leading to greater financial stability and security. Several high-quality studies also demonstrated evidence of promise of reduced mental health and stress related conditions for participants accessing services. Few studies were included in the review that evaluates whether welfare advice services co-located in a health setting generates improvements for the wider health system. These studies were of poorer quality and presented mixed findings towards this proposed theory. It recommended that this proposed association is explored further in future research.

3.4.2 LIMITATIONS

This review includes a wide range of studies utilising a variety of methodological approaches, statistical techniques and outcome measures. A large proportion of the studies included in this review were grey literature, not published in peer reviewed journals. Quality assessment of these studies was challenging as the methodological approaches were not well described. Although many of the included studies were found to be of limited scientific quality, it was felt that it was important to include these studies in the review, as they often included legitimate data on financial outcomes and population coverage of the services and ensured the review was representative of the available evidence base. However, as grey literature is not well indexed, it is also difficult to be sure that all available evidence has been accessed, despite the systematic approach to the search strategy.

The significant heterogeneity in the research methodology and outcome measures prevented robust comparison of effect between studies. Each study which evaluated changes in mood used a different measure of depression, level of anxiety or measure of wellbeing. There is also a lack of statistical analyses of outcomes presented from service evaluations with the majority reporting simple descriptive measures. Therefore, it was inappropriate to perform formal meta-analysis and our interpretations and conclusions are drawn from a narrative review.

Finally, this review is limited to studies conducted in the United Kingdom given that health and welfare systems are country specific with significant variation existing between countries, therefore the results may not be generalisable internationally. However, some conclusions may be applicable, such as how the co-located services are implemented and evaluated.

3.4.3 IMPLICATION OF FINDINGS

This review builds upon the previous body of evidence provided by the systematic review published by Adams et al.[62] Together, we find that co-located welfare advice improved financial security and in our review, we find some but limited convincing evidence of measurable health or social benefits by addressing social determinants of health. One experimental study with adequate power reporting short-term improvements in mental health and wellbeing, reduced financial strain and considerable financial returns compared to control groups.[k] Qualitative methods have largely been favoured to explore the effects of co-located services on health and wellbeing because of difficulties in identifying and obtaining quantitative outcome measures in this area and challenges with participant recruitment. However, there remains a lack of evidence from experimental studies of changes to health and wellbeing and there is a need for high quality research in this area to further build upon this theory and to measure the strength of these pathways over time. Further work is also needed on how to deliver a service that best meets the needs of minority groups who are under-represented in existing research.

Future research in this area needs to be sufficiently powered with a robust comparator group to build upon the theoretical models proposed in this review. This review highlights the need for future research to utilise common health outcome measures that can enable comparisons to be made across the literature and for economic evaluations incorporating both a patient and a health services perspective. In order to draw firm conclusions about the links between the provision of welfare advice and improvements in health and wellbeing and reducing health inequalities, research needs sufficient resources to follow-up patients over the short, medium and long term.

Research so far has a significant under-representation of ethnic minority groups, despite them being amongst those with the greatest need. Further research needs to be conducted to explore who is engaging with services and who is not to facilitate the development of the intervention to ensure that co-located services are best able to reach those most in need and to explore the health and social impacts of the services for these groups.

Most of the studies in our review examined welfare services co-located in a primary care setting, which is perhaps reflective of the more established relationship between welfare service providers and primary care providers. However, this may also reflect a lack of formal evaluations conducted in a secondary care setting and research should be planned to ensure it reflects the scope of available services.

Future research should consider the capacity of the voluntary and community sectors to provide welfare services in the context of an evolving pandemic and in the future recovery from the pandemic, when the strains in the health sector make addressing the facilitators to co-working more challenging. Given reductions in funding, evidencing about the cost-effectiveness of these interventions will help protect them from cuts to services in the future.

3.5 CONCLUSION

This review contributes to the growing body of evidence that welfare advice co-located in a healthcare setting can improve health and wellbeing and provides cost savings to the NHS. Given the complexity of the UK welfare system and the ongoing and disproportionate impacts of austerity, and current evidence of widening inequalities, this review provides further evidence of promise that welfare services could be key to efforts to mitigate the impact of these wider policy impacts.

The review offers important knowledge regarding development of a welfare advice service co-located in health settings for mothers and their families as a complex intervention and provides evidence to guide the development of a successful approach to implementation and evaluation of such an intervention.

CHAPTER 4 THE IMPACT OF THE COVID-19 PANDEMIC ON FINANCIAL SECURITY IN VULNERABLE FAMILIES IN BRADFORD

In this chapter, I explore the medium to long-term impacts of the COVID-19 pandemic and subsequent public health measures on financial security in vulnerable families in Bradford and the resultant impact on maternal health and wellbeing. It seeks to improve the understanding of the socioeconomic context for this complex intervention and further establishes the need for a universal welfare advice service co-located in health settings for mothers and their families in Bradford.

4.1 INTRODUCTION

In response to the COVID-19 pandemic, the UK government, like many others internationally, implemented stringent lockdowns to slow the spread of the virus throughout the population and to limit the number of severe COVID-19 cases and consequent pressures on the National Health Service. During the first UK lockdown, implemented from March 23rd, 2020, to June 2020, this included the closure of all schools, non-essential shops and businesses, reduced health and social care provision and imposed restrictions on daily activities. Where possible people were advised to work from home. Key worker status was given to public and private-sector employees whose work was deemed critical to the COVID-19 response status.[142] These employees were permitted to travel to work, where necessary. The national furlough scheme was established to financially support employees placed on temporary leave, for some or all of their contracted hours, to ensure they received at least 80% of their usual wages whilst furloughed.[39,40]

There is growing recognition that the public health measures employed to control the spread of the COVID-19 pandemic had unintended consequences on socioeconomic security and have increased inequalities, with families from deprived and ethnically diverse backgrounds most likely to be adversely affected.[143,144] However, many of the longitudinal studies conducted during the pandemic that focused on socioeconomic security conducted within the UK, focused on participants of White European ancestry from relatively affluent populations and did not have pre-COVID-19 baseline data.[145,146]

The Born in Bradford research programme has been following the health and wellbeing of over 36,000 Bradford residents since 2007, hosting three birth cohort studies, as well as an internationally recognised programme of applied health research with a focus on health inequalities in deprived and ethnic minority populations. This placed this research programme in a unique position to assess the socioeconomic impact of the pandemic longitudinally on a key vulnerable population (pregnant women and families with pre-school and school aged children) living in a highly deprived and ethnically diverse city.[79,82,83] Participants in all BiB cohorts consent to the use of their routine health and education data and to be contacted for future research and offered the opportunity to follow participants prospectively throughout the COVID-19 crisis to understand the impact of the crisis on health and well-being through this unpredictable time.

Data published from the BiB COVID-19 survey conducted during the first UK lockdown[30] found that more than one-third of families reported financial insecurity. Financial insecurity at that time was associated with previous financial security, employment status and ethnicity. There were also strong associations found between financial insecurity and poor mental health. It was therefore important to understand the impact over time to gain a better understanding of whether the observed associations were short term or whether there was a longer-term effect on financial security and whether the associations between financial insecurity and factors, such as employment status, ethnicity and mental health persisted in the long term. This will help to improve the understanding of the socioeconomic context for the implementation of an intervention with the aim of improving socioeconomic security and health and wellbeing. It will also help to improve understanding of whether the effects of the pandemic have ultimately increased the need for such an intervention and for whom.

4.1.1 AIMS AND OBJECTIVES

In this chapter, I aim to explore the medium to long-term impacts of the COVID-19 and subsequent public health measures on financial security for families in Bradford.

The objectives of this chapter are to:

a) Identify the impacts of the COVID-19 pandemic and subsequent public health measures on financial security for mothers in Bradford.

b) Identify what individual maternal factors were associated with changes to financial security during the pandemic for mothers in Bradford.

c) Explore how changes to financial security have impacted the health, wellbeing and socioeconomic security of mothers in Bradford during the pandemic.

4.2 METHODS

4.2.1 STUDY DESIGN

A longitudinal study collected survey data at three time points during the COVID-19 pandemic and compared to data collected prior to the onset of the pandemic from mothers who participated in one of two prospective cohort studies in Bradford: BiBGU cohort study, with mothers of children aged 9-13 years;[88,147] and BiBBS cohort study, with mothers of children aged 0-5 years old.[89]

4.2.2 DATA COLLECTION

All participants from the BiBBS and BiBGU cohort studies were contacted to ask if they wished to participate in this study. Participants were recruited and data were collected using a combination of methods, including emails, text and telephone, with a follow-up postal survey in order to facilitate a rapid response. Participants were recruited in their main language wherever possible. Full details of the data collection of the survey can be found elsewhere.[30,148] The phase one survey was administered between April and June 2020 (during the first UK national lockdown), the phase two survey was administered between October and December 2020 (during the second UK national lockdown) and the phase three survey was administered between May and July 2021 (during the phased removal of all public health restrictions).[149]

Pre-COVID-19 baseline levels of self-reported financial security and mental health outcomes for BiBGU participants were derived from two sources: participant ethnicity and age were collected during pregnancy between 2007-2011;[150] and recent follow-up data on maternal mental health and financial security were collected between 24th June 2017 and 12th March 2020.[88] Pre-COVID-19 baseline data for BiBBS participants were taken from data collected during pregnancy between 6th January 2016 and 8th February 2020.[89] The median time since most recent pre-COVID-19 data collection was 15 months (range 1 to 35 months) for BiBGU and 29 months (range 2 to 52 months) for BiBBS participants. Full details of the protocol and data collected for the BiBBS experimental birth cohort and the BiBGU cohort study are described in full in the published protocols.[88,89]

4.2.3 PATIENT AND PUBLIC INVOLVEMENT

Born in Bradford is a 'people powered' research study. The local community were consulted to identify key research priorities throughout the pandemic as a part of the BiB COVID-19 research programme. This included consultation with key community groups, seldom-heard communities and local policy and decision makers to ensure that the focus of the research was relevant to local needs. The COVID-19 survey and recruitment approach were tested through established community research advisory groups. The findings of the study were also shared with these groups to enhance interpretation and ensure useful dissemination back to the community. Full details can be found in the protocol paper.[151]

4.2.4 OUTCOME MEASURES

All survey questions were selected from validated questionnaires, from previous Born in Bradford questionnaires or were devised specifically for this survey. The key domains were: household circumstances[152]; family relationships and social support[153-155]; financial security[156,157]; and physical and mental health.[100,102,158,159]

Ethnicity was coded using Census 2011 categories as 'White British', 'Pakistani Heritage' and 'Other'. There were small numbers of non-White British and non-Pakistani Heritage mothers from multiple ethnic groups who were grouped and categorised within the 'Other' category to facilitate analysis.

Residential address (as at 31st March 2019) was linked to the 2019 IMD.[160] IMD decile categories were collapsed into quintiles. Residential status was categorised as homeowner (comprising of 'own it outright', 'buying it with the help of a mortgage', and 'part own and part rent/shared ownership') and not homeowner (comprising of 'rent it', 'live here rent free' and 'squatting') to facilitate the analysis owing to small sample sizes.

To establish financial insecurity, the surveys employed the question: 'How well would you say you are managing financially right now?'. Answer options included: living comfortably; doing alright; just about getting by; finding it quite difficult; and finding it very difficult. The latter two options were grouped and categorised as indicating financial insecurity.[153]

To explore the effect of the pandemic related changes to financial security on the socioeconomic security of families in Bradford, data were collected on the ability of families to pay for household bills and food security. A number of categories within these variables were collapsed to support the analysis owing to small sample sizes within survey responses. These included: food insecurity; secure (comprising of 'never true' or 'sometimes true' that food didn't last) and insecure (comprising of 'often true' that food didn't last); balanced meals: secure (comprising of 'never true' or 'sometimes true' that the household couldn't afford to eat balanced meals) and insecure (comprising of 'often true' that the household couldn't afford to eat balanced meals); and housing security: secure (comprising: 'strongly disagree', 'disagree' and 'neither disagree or agree' that I worry about being evicted or having my home repossessed) and insecure (comprising of 'strongly agree' or 'agree' that I worry about being evicted or having my home repossessed); mortgage and rental security: secure (comprising of 'strongly disagree', 'disagree' and 'neither disagree or agree' that I worry about paying for the rent or mortgage) and insecure (comprising of 'strongly agree' or 'agree' that I worry about paying for the rent or mortgage); household bills security: secure (comprising of 'strongly disagree', 'disagree' and 'neither disagree or agree' that I am up to date with household bills) and insecure (comprising of 'strongly agree' or 'agree').

For mental health, the PHQ-8 and GAD-7 instruments were used, described previously in Chapter 2.3.[100,102] For the PHQ-8 instrument, the scores from each item were summed to produce a total score between 0 and 24 points. Summed scores were used as a continuous variable with greater scores indicating a presence of depressive symptoms. Standard categorisations were employed for the scores: 0 to 4 no depression; 5 to 9 mild depression; 10-14 moderate depression; and 15-24 severe depression.[101] For the GAD-7 instrument, the scores from each item were summed to produce a total score between 0 and 24 points. Summed scores were used as a continuous variable with greater scores indicating a presence of anxiety symptoms. Standard categorisations were employed for the scores: 0 to 4 no anxiety; 5 to 9 mild anxiety; 10 to 14 moderate anxiety; 15+ severe anxiety.[102] Symptoms suggestive of depression and anxiety were defined as those with moderate to severe depression and anxiety scores respectively. Self-reported general health was categorised as satisfactory (comprising of ‘excellent’, ‘very good’ and ‘good’) and unsatisfactory (comprising of ‘fair’ and ‘poor’) to facilitate analysis given the small sample sizes.

4.2.5 DATA ANALYSIS

Descriptive statistics are presented for each of the survey domains. Descriptive analyses of risk of financial insecurity were conducted at the pre-COVID-19 timepoint and at each survey timepoint during the pandemic. Population risk of financial insecurity was examined over time.

Longitudinal multi-level logistic regression models were used, clustered at the level of the individual, to explore differences in financial insecurity by key explanatory variables; age, ethnicity, deprivation, level of education, employment status, key worker status and baseline health. Separate longitudinal multi-level logistic regression models, clustered at the level of the individual, were also conducted to explore whether changes in financial security over time are associated with maternal health and wellbeing outcomes and socioeconomic insecurity.

In order to explore whether or not the magnitude of the association between exposure variables differed between ethnic groups, the multi-level regression models were repeated separately for Pakistani, White British and ‘Other’ ethnic groups. This approach avoids the difficulties inherent in interpreting the ethnicity coefficient in regression models controlling for other variables.[161] Missing data on measures was small for most variables and was not adjusted for in the analyses. All statistical analyses were carried out using Stata 15.[162]

4.2.6 ETHICS

This study involved human participants and was approved by the HRA and Bradford/Leeds Research Ethics Committee (substantial amendments to BiBGU 16/YH/0320 and BiBBS 15/YH/0455).

Participants gave informed consent to participate in the cohort study before taking part. Verbal consent was taken for questionnaires completed over the phone and implied consent was assumed for all questionnaires completed via post or online.

4.2.7 DATA MANAGEMENT

In order to obtain access to the required data, an Expression of Interest form was submitted to the Born in Bradford Executive Committee, see Appendix A.3.1. Following approval of the Expression of Interest application, a Data Sharing Agreement was established between myself and the Bradford Institute of Health Research, see Appendix A.3.2. Once approved, the required data were extracted by the BiB Data Manager and transferred via the Cisco Registered Envelope Service for the secure transmission of encrypted data. The received data were stored on the University of York drive accessible via a password protected computer in a secure location on the University campus. The requirement of the University of York's Data Management Policy to evidence ownership and rights in respect to the data and research conducted is satisfied by the BiB Collaboration Agreement.[163]

4.3 RESULTS

4.3.1 STUDY POPULATION

2043 mothers participated in the phase one survey (administered between 10th April and 30th June 2020); 730 mothers participated in the phase two survey (administered between 29th October and 23rd December 2020); and 903 mothers participated in the phase three survey (administered between May and July 2021). The CONSORT diagram in

Figure 6 shows the response rates from those invited to participate. Whilst the response rates are low, participants were representative of the Bradford population in terms of ethnicity and levels of deprivation and were comparable with regard to key sociodemographics across each phase, details published elsewhere.[30]

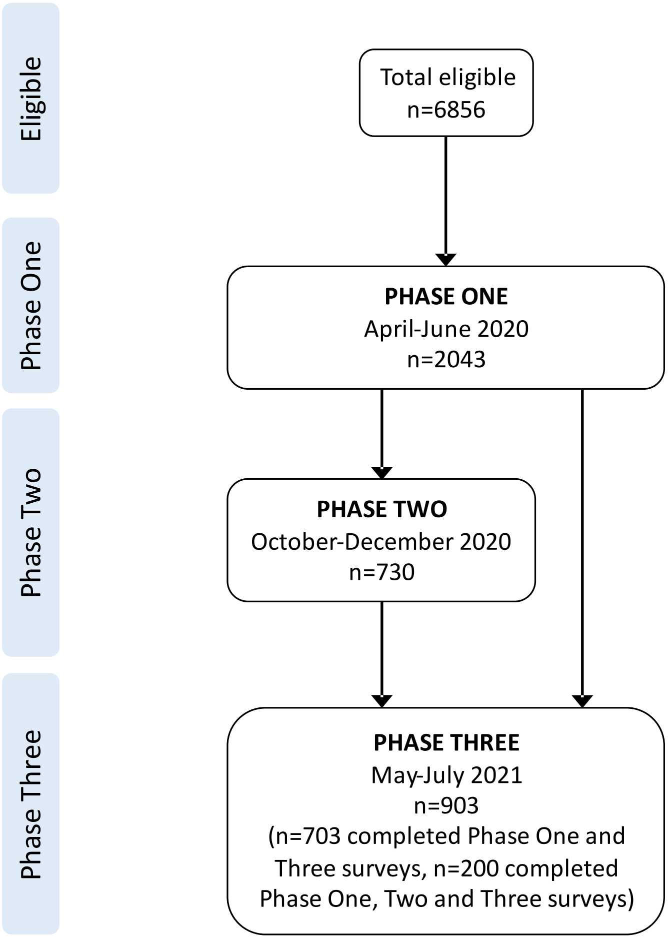

Figure 6 Consort diagram for the analysis of the COVID-19 pandemic on financial security in vulnerable families in Bradford

Table 10 describes the number of mothers participating at each phase as a proportion of the eligible population (total BiBBS and BiBGU cohort participants) and phase one survey population by BiBGU and BiBBS cohorts.

Table 10 Number of mothers participating at each phase as a proportion of the eligible population (total BiBBS and BiBGU cohort participants) and phase one survey population by BiBGU[88,147] and BiBBS[89] cohorts

		Phase One		Phase Two			Phase One and Two Complete			Phase Three			Phase One, Two and Three Complete		
	Eligible population	**n**	**Proportion of eligible (%)**	**n**	**Proportion of eligible (%)**	**Proportion of phase one (%)**	**n**	**Proportion of eligible (%)**	**Proportion of phase one (%)**	**n**	**Proportion of eligible (%)**	**Proportion of phase one (%)**	**n**	**Proportion of eligible (%)**	**Proportion of phase one (%)**
BiBBS	2239	541	24	136	6	25	80	4	15	200	9	37	46	2	9
BiBGU	4617	1502	33	594	13	40	533	12	35	703	15	47	154	3	10
Total	6856	2043	30	730	11	36	613	9	30	903	13	44	200	3	10

Table 11 details the sample baseline characteristics of the phase one study population and by ethnic group. Baseline characteristics displayed according to ethnic group are calculated as a proportion of the total number of participants in the ethnic group for each stratum. Participants who completed the phase one survey had a mean age of 37 (SD 7) years. Participants were ethnically diverse: 922 (48%) were of Pakistani heritage; 706 (34%) were White British; and 345 (18%) comprised of mothers from other ethnic groups. The majority of participants lived in the first (63%) and second (22%) most deprived IMD quintiles in England. At the onset of the pandemic, most participants reported that the main earner of the household was employed and still working (55%) or was employed and on furlough (15%). Other participants reported that the main earner of the household was self-employed and working (8%), self-employed and not working (11%) or unemployed (11%). Key worker status was reported by 51% of participants. Most participants owned their own home (66%). Some participants privately (23%) or socially (5%) rented their home. Household composition varied across participants. The average number of adults per household was 2.36 (SD 1.17, range 1-10) with an average of 0.08 (SD 0.31, range 0-3) adults over 70 years old per household. On average, there were 2.52 (SD 1.26, range 0-12) children per household, with an average of 0.63 (SD 0.80, range 0-6) children under the age of 4 years per household. Most participants (78%) reported that they were married. A small proportion of participants reported that they were in a relationship but not married (10%) or were single (12%). 61 (3%) mothers were single parents.

There were several notable differences in key sociodemographics between ethnic groups. Families of Pakistani Heritage (77%) and from other ethnic groups (72%) were significantly more likely to be from the most deprived IMD quintile, compared to White British families (39%), with White British families forming the majority of families from IMD Quintile 3 (17%), IMD Quintile 4 (12%) and IMD Quintile 5 (4%) respectively. Mothers of Pakistani Heritage were significantly more likely to have no qualifications (25%) compared to White British mothers (11%) or mothers of other ethnicity (16%).

During the first lockdown, the employment status of the main earner of the households was broadly similar between ethnic groups. Notably, the main earner in families of Pakistani Heritage were notably more likely to be self-employed and not working (18%) compared to White British (4%) and other (9%) households. There were slightly more White British mothers who were key workers (63%) compared to mothers of Pakistani Heritage (42%) or mothers from other ethnic groups (50%).

Household ownership and composition was broadly similar between ethnic groups. Families of Pakistani Heritage (16%) and of ‘Other’ ethnic groups (14%) were more likely to have greater numbers of children under 4 years old in the household compared to White British (6%) families. Similarly, families of Pakistani Heritage (18%) and ‘Other’ ethnic groups (19%) were more likely to have more people per bedroom than White British families (8%) who were most likely to fewer than 2 people per bedroom.

Mothers of Pakistani Heritage were more commonly married (92%). The majority of mothers who were single (20%) or who were in a relationship and not married (22%) were White British. The majority of single mothers were also White British (7%). Levels of self-reported general health, anxiety and depression were broadly similar between ethnic groups.

Table 11 Sample baseline characteristics of the total phase one study population and by ethnic group with 95% confidence intervals (CI)

	Total Phase One Population (n=2043)		**White British (n=706)**		**Pakistani Heritage (n=922)**		**Other (n=345)**	
	Number	**Frequency (%) (95% CI)**	**Number**	**Frequency (%) (95% CI)**	**Number**	**Frequency (%) (95% CI)**	**Number**	**Frequency (%) (95% CI)**
Age								
18-25 years	219	11 (10, 12)	57	8 (6, 10)	112	12 (10, 15)	41	12 (9, 16)
30-34 years	421	20 (19, 22)	122	17 (15, 20)	208	22 (20, 25)	76	22 (18, 27)
35-39 years	572	28 (26, 30)	172	24 (21, 28)	282	30 (27, 33)	91	26 (22, 31)
40-44 years	480	23 (22, 25)	167	24 (21, 27)	215	23 (21, 26)	86	25 (21, 30)
Over 45 years	353	17 (16, 19)	186	26 (23, 30)	105	12 (10, 14)	50	15 (11, 20)
Missing	<5		<2		<2		<5	
IMD 2019 Quintile								
IMD 1 (most deprived)	1286	63 (61, 65)	274	39 (37, 44)	713	77 (73, 79)	254	72 (69, 74)
IMD 2	442	22 (20, 24)	196	28 (25, 33)	175	19 (16, 25)	64	19 (14, 21)
IMD 3	155	8 (7,9)	119	17 (13, 25)	20	2 (1, 4)	15	4 (1, 6)
IMD 4	111	5 (5, 7)	87	12 (6, 18)	9	1 (0, 5)	11	3 (0, 5)
IMD 5 (least deprived)	34	2 (1, 2)	30	4 (0, 20)	<5		<5	
Missing	15		<5		<5		<5	
Educational status								
No qualifications	367	19 (17, 21)	80	11 (8, 16)	230	25 (22, 28)	55	16 (12, 19)
5 or fewer GCSEs (grade A-C) or equivalent	432	22 (21, 24)	181	26 (22, 31)	207	23 (21, 26)	44	13 (9, 15)
5 or more GCSEs (grade A-C) or equivalent	316	16 (15, 18)	124	18 (14, 20)	134	15 (11, 18)	58	17 (14, 23)
A Levels or equivalent	680	35 (33, 37)	232	33 (36, 54)	321	35 (31, 39)	127	37 (35, 39)
Degree or equivalent	121	6 (5, 7)	54	8 (36, 54)	30	3 (0, 4)	30	9 (6, 11)
Missing	127		35		<5		31	
Employment status of main earner								
Employed: working	1085	55 (52,57)	436	62 (58, 64)	429	47 (43, 49)	195	57 (54, 60)
Employed: on furlough	292	15 (13-16)	107	15 (9, 19)	132	14 (8, 20)	41	12 (8, 15)
Self-employed: working	163	8 (7, 9)	44	6 (2, 9)	84	9 (2, 17)	26	8 (1, 13)

Self-employed: not working	228	11 (10, 13)	30	4 (1, 9)	164	18 (11, 25)	30	9 (1, 14)
Unemployed	221	11 (10, 13)	81	11 (6, 19)	90	10 (3, 17)	43	12 (5, 17)
Missing	54		8		23		10	
Whether mother is a key worker								
No	1000	49 (47, 52)	261	37 (34, 40)	531	58 (55, 63)	171	50 (45, 56)
Yes	1025	51 (48, 53)	444	63 (60, 67)	384	42 (35, 45)	174	50 (47, 53)
Missing	18		<5		7		<5	
Whether mother is pregnant								
No	1964	97 (96, 97)	693	98 (97, 99)	880	95 (93, 98)	330	96 (94, 99)
Yes	71	3 (3, 4)	12	2 (1, 3)	42	5 (2, 7)	15	4 (1, 7)
Missing	8		<5		<5		<5	
Homeownership status								
Owner occupied	1341	66 (64, 68)	464	66 (63, 69)	671	73 (66, 77)	196	57 (55, 59)
Private rental	455	23 (21, 24)	198	28 (23, 35)	145	16 (12, 20)	110	32 (22, 39)
Social rental	94	5 (4, 6)	15	2 (0, 6)	67	7 (1, 15)	12	3 (0, 6)
Other	131	7 (6, 8)	<5		<5		<5	
Missing	22		27		36		26	
Total adults in household (n)								
Fewer than 2	288	15 (14, 17)	129	18 (11, 26)	99	11 (6, 16)	58	17 (16, 25)
2 or more	1649	85 (83, 86)	567	80 (77, 82)	763	83 (80, 85)	280	81 (75, 86)
Missing	106		10		60		7	
Total adults over 70 years old in household (n)								
Fewer than 2	1867	99 (98, 99)	684	97 (95, 99)	817	89 (85, 93)	316	92 (90, 94)
2 or more	26	1 (1,2)	<5		20	2 (0, 4)	6	2 (1, 4)
Missing	150		22		85		23	
Total children in household (n)								
Fewer than 2	322	19 (17, 21)	140	20 (15, 24)	116	13 (7, 17)	59	17 (15, 22)
2 or more	1367	81 (79, 83)	465	66 (63, 67)	641	70 (68, 73)	222	64 (62, 66)
Missing	354		101		165		64	
Total children under 4 years old in household (n)								

Fewer than 2	1592	86 (85, 88)	593	84 (79, 87)	685	74 (72, 77)	268	78 (75, 80)
2 or more	249	14 (12, 15)	43	6 (2, 9)	152	16 (7, 19)	47	14 (11, 20)
Missing	202		70		85		30	
People per bedroom (n)								
Fewer than 2	1540	81 (79, 83)	596	84 (80, 87)	508	55 (51, 59)	202	59 (52, 65)
2 or more	364	19 (17, 21)	53	8 (5, 11)	166	18 (13, 23)	67	19 (13, 24)
Missing	139		57		248		76	
Current relationship status								
Single	243	12 (11, 14)	138	20 (11, 27)	53	6 (1, 11)	45	13 (8, 16)
Married	1571	78 (76, 80)	406	58 (55, 59)	852	92 (91, 94)	270	78 (76, 80)
In a relationship	199	10 (9, 11)	158	22 (17, 26)	<5		30	9 (7, 11)
Missing	30		<5		13		<5	
Whether single parent								
Yes	61	3 (2, 4)	46	7 (5, 8)	7	1 (0, 3)	6	2 (1, 3)
No	1940	97 (96, 98)	656	93 (92, 95)	895	97 (96, 99)	336	97 (95, 98)
Missing	42		<5		20		<5	
Pre-COVID-19 baseline PHQ-8 category								
None	1123	57 (55, 59)	370	52 (47, 57)	560	61 (56, 66)	193	56 (49, 60)
Mild	466	24 (22, 26)	141	20 (14, 28)	204	22 (18, 26)	73	21 (17, 25)
Moderate	213	11 (10, 12)	43	6 (2, 9)	70	8 (5, 12)	24	7 (5, 9)
Moderately severe/severe	159	8 (7, 9)	34	5 (3, 9)	39	4 (1, 6)	6	2 (1, 4)
Missing	82		118		49		49	
Pre-COVID-19 baseline GAD-7 category								
None	1206	61 (59, 63)	402	57 (55, 59)	601	65 (61, 67)	203	59 (55, 63)
Mild	444	23 (21, 24)	107	15 (14, 16)	122	13 (10, 15)	40	12 (9, 17)
Moderate	183	9 (8, 11)	38	5 (2, 7)	52	6 (2, 10)	13	4 (1, 7)
Severe	135	7 (6, 8)	22	3 (2, 4)	38	4 (1, 7)	8	2 (1, 5)
Missing	75		137		109		81	
Self-reported general health								
Excellent	197	10 (9, 11)	57	8 (5, 11)	94	10 (5, 17)	36	10 (4, 16)

Very good	455	23 (21, 24)	199	28 (23, 32)	159	17 (14, 21)	80	23 (15, 26)
Good	814	40 (38, 43)	262	37 (30, 46)	393	43 (40, 47)	138	40 (35, 43)
Fair	412	20 (19, 22)	141	20 (10, 30)	195	21 (16, 25)	68	20 (13, 24)
Poor	135	7 (6, 8)	43	6 (2, 10)	74	8 (4, 10)	18	5 (1, 9)
Missing	30		<5		7		<5	
Whether anyone in household is clinically vulnerable								
No	1567	77 (75, 79)	591	84 (81, 86)	656	71 (68, 73)	269	78 (76, 80)
Yes	464	23 (21, 25)	114	16 (12, 21)	265	29 (27, 31)	76	22 (18, 24)
Missing	12		<5		<5		<5	
Whether anyone in household has self-isolated								
No	1471	73 (71, 74)	545	77 (75, 79)	673	73 (69, 76)	253	73 (70, 76)
Yes	558	28 (26, 30)	100	14 (11, 17)	188	20 (10, 30)	51	15 (12, 20)
Missing	14		61		61		41	

*Including 70 missing from ethnicity variable

4.3.2 IMPACT OF COVID-19 PANDEMIC ON FINANCIAL INSECURITY

Financial insecurity was frequently reported by families in Bradford throughout the pandemic, most notably in phase one, with the proportion of families reporting financial insecurity having improved but not completely returned to baseline pre-pandemic levels by phase three. Table 12 describes the levels of financial insecurity at pre-pandemic baseline and each COVID-19 survey timepoint. The largest reduction in financial insecurity occurred for families who reported that they were living comfortably, which almost recovered to baseline pre-pandemic proportions by phase three. The proportion of families reporting that they were doing alright remained fairly constant throughout the pandemic. The proportion of families just about getting by did not return to baseline pre-pandemic levels by phase three. More families reported that they were finding it quite or very difficult financially at phase one (12%) compared to baseline (7%). This improved in phase two (9%) and almost returned to baseline by phase three (8%).

Table 12 Levels of financial security at pre-COVID-19 baseline and COVID-19 surveys

Financial security	**Pre-COVID-19 baseline**		**COVID-19 phase one**		**COVID-19 phase two**		**COVID-19 phase three**	
	n	**Frequency (%) (95% CI)**	**n**	**Frequency (%) (95% CI)**	**n**	**Frequency (%) (95% CI)**	**n**	**Frequency (%) (95% CI)**
Living comfortably	684	32 (30, 35)	403	20 (18, 22)	190	26 (23, 29)	257	29 (26, 32)
Doing alright	852	40 (38, 42)	857	42 (40, 44)	290	40 (36, 44)	339	39 (35, 42)
Just about getting by	410	19 (18, 21)	501	25 (23, 27)	167	23 (20, 26)	197	22 (20, 25)
Finding it quite difficult	100	5 (4, 6)	180	9 (8, 10)	51	7 (5, 9)	46	5 (4, 7)
Finding it very difficult	42	2 (1, 3)	57	3 (2, 4)	16	2 (1, 4)	24	3 (2, 4)
Missing	34		45		16		40	
Total	2122	100	2043	100	730	100	903	100.00

The risk of being financially insecure was greatest in phase one (OR 2.33, 95% CI 1.79, 3.05), with the risk of experiencing financial insecurity almost returning to pre-COVID-19 baseline levels by phase three, with the risk no longer statistically significant at phase three, with the confidence interval crossing 1, see

Table 13.

Table 13 Odds ratios (95% CI) from unadjusted mixed-effects logistic regression model for a change in financial security between pre-COVID-19 and each cross-sectional COVID-19 pandemic surveys

	OR	**p-value**	**95% CI**
Financial security (Reference: Pre-COVID-19 baseline financial security)			
Phase One	2.33	0.000	1.79-3.03
Phase Two	1.79	0.003	1.22-2.61
Phase Three	1.34	0.114	0.93-1.94

The probability of being financially insecure for families in Bradford at phase one was 12.05% (95% CI 10.59, 13.50,), at phase two was 10.20% (95% CI 7.99, 12.41,) and at phase three was 8.49% (95% CI 6.66, 10.32), compared to baseline probabilities of 6.96% (95% CI 5.86, 8.07), see Figure 7.

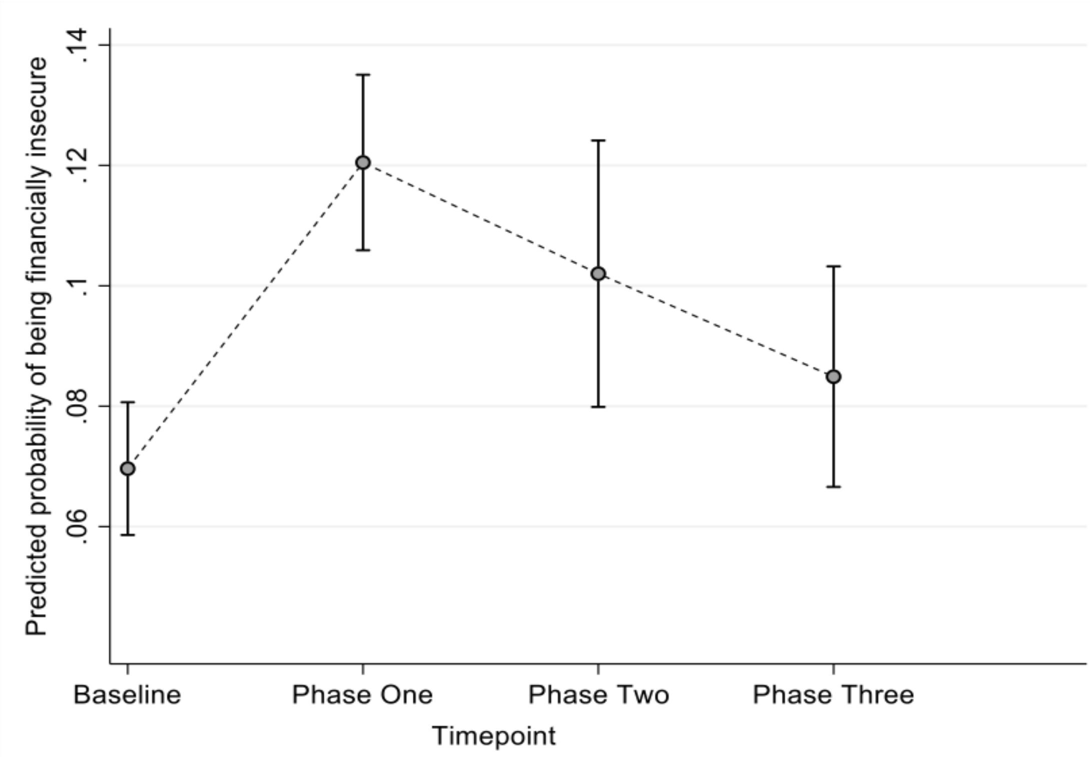

Figure 7 Marginal predicted means of being financially insecure at baseline, phase one, phase two and phase three surveys.

4.3.3 INDIVIDUAL FACTORS ASSOCIATED WITH CHANGES TO FINANCIAL INSECURITY

Several individual characteristics were found to be associated with financial insecurity during the pandemic for mothers and their families. Table 14 describes the probability of experiencing financial insecurity for mothers throughout the pandemic and between pre-COVID-19 baseline and COVID-19 lockdown surveys for individual sociodemographics.

The reported odds ratios of some of the explanatory variables are greater than odds ratios reported for the individual phases. This is often referred to as Simpson's paradox, which occurs when an observed association differs in magnitude or reverses direction within subgroups of the population.[164,165] There are several reasons why this may happen. Upon division into subgroups, the balance of confounding factors may be different, influencing the relationship between the exposure and outcome of interest. A second explanation for this paradox is the potential for sampling variability. Subgroups may have smaller sample sizes leading to greater variability in the estimations. Furthermore, difference in the measurement of variables or errors in data collection within subgroups can also contribute to discrepancies between subgroup specific odds ratios and the overall odds ratio.[164,165] It is difficult to ascertain exactly which factors are contributing to this paradox in these results, evident in Table 14, Table 15 and Table 16. However, it is apparent that there is significant variation in sample size in some of the subgroups, for example, the numbers of participants with 'Severe anxiety' at baseline, which may be a significant contributor to this paradox in these results.

Table 14 Odds ratios (95% CI) from unadjusted mixed-effects logistic regression models for the probability of experiencing financial insecurity for participants across the pandemic and between pre-COVID-19 baseline and COVID-19 lockdown surveys for individual sociodemographic characteristics.

	Overall		**Phase one (n=2043) April – June 2020**		**Phase two (n=730) Oct – Dec 2020**		**Phase three (n=903) May – July 2021**	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Ethnicity (Reference: White British)								
Pakistani Heritage	2.94	2.03-4.25	2.62	1.41-4.85	2.82	1.14-6.96	1.83	0.77-4.33
Other	1.84	1.14-2.97	1.01	0.45-2.27	1.30	0.39-4.33	1.340	0.45-3.97
Age on 1st April 2020 (Reference: 18-30 years)								
30-34 years	1.21	0.51-2.88	2.05	0.56-7.49	0.87	0.08-9.18	-	-
35-39 years	1.02	0.44-2.40	1.30	0.36-4.65	0.92	0.09-9.18	1.61	0.59-4.38
40-44 years	0.77	0.31-1.96	1.11	0.28-4.44	0.23	0.02-2.96	0.70	0.26-1.85
Over 45 years	4.38	0.16-120.04	0.85	0.02-31.33	-	-	-	-
IMD 2019 quintile (Reference: IMD 1 (most deprived))								
IMD 2	0.37	0.25-0.56	1.01	0.52-1.97	1.45	0.59-3.58	0.84	0.30-2.34
IMD 3	0.15	0.07-0.32	0.81	0.22-3.01	1.41	0.29-6.84	0.46	0.05-4.34
IMD 4	0.12	0.04-0.31	0.10	0.01-0.89	-	-	0.63	0.11-3.49
IMD 5 (least deprived)	0.09	0.01-0.54	0.55	0.03-9.35	-	-	-	-
Educational status (Reference: No qualifications)								
5 or fewer GCSE (grades A-C) or equivalent	0.65	0.40-1.04	0.72	0.36-1.41	0.38	0.08-1.82	0.75	0.23-2.49
5 or more GCSE's (grades A-C) or equivalent	0.38	0.22-0.67	0.80	0.35-1.84	1.71	0.44-6.62	1.49	0.43-5.12
A Levels or equivalent	0.38	0.24-0.59	0.92	0.47-1.80	2.23	0.71-7.01	1.13	0.38-3.34
Degree or equivalent	0.89	0.46-1.76	0.60	0.22-1.68	2.01	0.44-9.09	1.48	0.36-6.16
Employment status of main earner (Reference: Employed: working)								
Employed: on furlough	5.30	2.77-10.14	1.28	0.06-28.98	0.91	0.03-29.20	-	-
Self-employed: working	2.09	0.86-5.03	0.20	0.02-2.71	1.12	0.04-29.15	-	-
Self-employed: not working	4.59	2.64-7.98	5.42	1.74-16.87	1.00	0.25-4.02	-	-
Unemployed	9.81	4.82-19.95	2.98	0.13-70.79	23.60	0.79-707.26	-	-

Table 14 Odds ratios (95% CI) from unadjusted mixed-effects logistic regression models for the probability of experiencing financial insecurity for participants across the pandemic and between pre-COVID-19 baseline and COVID-19 lockdown surveys for individual sociodemographic characteristics.

	Overall		**Phase one (n=2043) April – June 2020**		**Phase two (n=730) Oct – Dec 2020**		**Phase three (n=903) May – July 2021**	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Whether mother is a key worker (Reference: Not key worker)								
Key worker	0.49	0.36-0.67	0.48	0.28-0.82	0.42	0.19-0.91	0.89	0.43-1.84
Whether mother is pregnant (Reference: Not pregnant)								
Pregnant	1.04	0.44-2.47	0.81	0.21-3.20	2.33	0.18-30.24	-	-
Homeownership status (Reference: Homeowners)								
Non-homeowners	2.72	1.98-3.72	1.00	0.59-1.71	1.35	0.61-2.96	1.02	0.48-2.16
Total adults in household (Reference: Fewer than 2)								
2 or more	0.61	0.41-0.91	1.80	0.91-3.55	1.27	0.38-4.17	0.94	0.25-3.53
Total adults in household over 70 years old (Reference: Fewer than 2)								
2 or more	0.36	0.06-2.24	0.17	0.01-6.12	-	-	-	-
Total children in household (Reference: Fewer than 2)								
2 or more	1.13	0.76-1.69	1.00	0.49-2.06	0.60	0.19-1.86	0.43	0.12-1.50
Total children under 4 years old in household (Reference: Fewer than 2)								
2 or more	1.05	0.66-1.67	1.46	0.65-3.26	0.85	0.14-5.29	0.71	0.15-3.43
Number of people per bedroom (Reference: Fewer than 2)								
2 or more	1.36	0.92-1.99	1.49	0.28-3.96	1.35	0.25-7.18	-	-
Free school meal (Reference: Not eligible)								
Eligible	2.59	1.69-3.97	0.77	0.39-1.52	0.92	0.33-2.53	0.97	0.35-2.67
Special educational needs (Reference: No special educational needs)								
Special educational needs	0.98	0.61-1.58	2.98	1.23-7.24	2.48	0.76-8.13	1.66	0.43-6.48
Whether single parent (Reference: Not a single parent)								
Single parent	0.40	0.14-1.12	0.36	0.04-3.41	2.09	0.24-18.41	2.96	0.27-32.69

Table 14 Odds ratios (95% CI) from unadjusted mixed-effects logistic regression models for the probability of experiencing financial insecurity for participants across the pandemic and between pre-COVID-19 baseline and COVID-19 lockdown surveys for individual sociodemographic characteristics.

	Overall		Phase one (n=2043) April – June 2020		Phase two (n=730) Oct – Dec 2020		Phase three (n=903) May – July 2021	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
PHQ-8 Category at baseline (Reference: No depression)								
Mild depression	1.77	1.21-2.59	1.75	1.40-2.39	1.55	1.19-2.57	1.76	1.30-2.94
Moderate depression	6.70	3.98-11.30	2.47	2.22-3.99	3.83	2.67-4.97	8.34	7.46-10.88
Severe depression	6.43	3.34-12.39	2.37	1.16-4.89	5.23	1.05-8.45	7.26	2.05-9.35
GAD-7 Category at baseline (Reference: No anxiety)								
Mild anxiety	4.48	2.36-8.48	4.52	2.27-5.01	4.41	2.15-5.14	3.00	2.39-10.59
Moderate anxiety	8.85	3.84-20.39	9.46	6.20-22.06	8.05	4.32-19.47	6.05	1.30-12.61
Severe anxiety	16.73	6.56-42.66	19.32	13.13-29.79	20.21	5.04-56.13	14.52	5.12-42.24
Whether anyone in household is clinically vulnerable to COVID-19 (Reference: Not clinically vulnerable)								
Clinically vulnerable	1.12	0.78-1.61	2.54	1.33-4.85	1.66	0.65-4.22	1.76	0.71-4.36

Missing data omitted due to collinearity indicated by – symbol

4.3.4 SOCIODEMOGRAPHICS FACTORS

Sociodemographic factors, including IMD quintile, employment, and household factors, such as homeowner status and household density, demonstrated expected relationships with financial insecurity, see Table 14. The risk of financial insecurity increased with decreasing IMD quintiles. The risk of being financially insecure decreased with greater levels of educational attainment, being statistically significant, with the confidence intervals not crossing 1, for those with 5 or more GCSE's (grades A-C) or equivalent (OR 0.38, 95% CI 0.22, 0.67) and A Levels (OR 0.38, 95% CI 0.24, 0.59). The most protective employment status was being employed and working at phase one. The risk was greatest for families where the main earner was unemployed (OR 9.81 95% CI 4.82, 19.95), employed and on furlough (OR 5.30 95% CI 2.77, 10.14) and self-employed and not working (OR 4.59 95% CI 2.64, 7.98) respectively compared to being employed and working. Being a key worker was also a protective factor against financial insecurity (OR 0.49 95% CI 0.36, 0.67). Families who did not own their own homes were also more likely to report financial insecurity (OR 2.72 95% CI 1.98, 3.72). Families with two or more adults in the household were less likely to report financial insecurities (OR 0.61 95% CI 0.41, 0.91). Families eligible for free school meals were more likely to report financial insecurities (OR 2.59 95% CI 1.69, 3.97). These associations largely persisted throughout the pandemic but were difficult to examine in detail at each timepoint owing to small sample sizes across strata.

There was no difference observed in the risk of experiencing financial insecurity for the following variables: age; pregnancy status; families with a child with special educational needs; single parents; by numbers of people per bedroom; number of adults over 70 years old and numbers of children in the household.

4.3.5 ETHNICITY

Families were more likely to report being financially insecure if they identified as Pakistani Heritage (OR 2.94, 95% CI 2.03, 4.25) or from other ethnic groups (OR 1.84, 95% CI 1.14, 2.97), compared to White British families.

Over the course of the pandemic, Pakistani Heritage families experienced the sharpest rise in the risk of experiencing financial insecurity at the onset of the pandemic, compared to those of White British families and families from other ethnic groups, see Figure 8. Over the course of the pandemic, the risk of experiencing financial insecurity declined, however had not returned to pre-COVID-19 baseline levels for those of Pakistani Heritage by phase three. Families from other ethnic groups also experienced a rise in probability of financial insecurity in phase one which remained constant across phases two and three, indicating that recovery in this group may also not have occurred. This trend is not statistically significant, likely owing to the smaller sample sizes in this ethnic group. Like families of Pakistani Heritage and other ethnic groups, White British families experienced an increased probability of experiencing financial insecurity during phase one, however this returned to baseline by phase two and appears to have remained at similar levels to baseline at phase three.

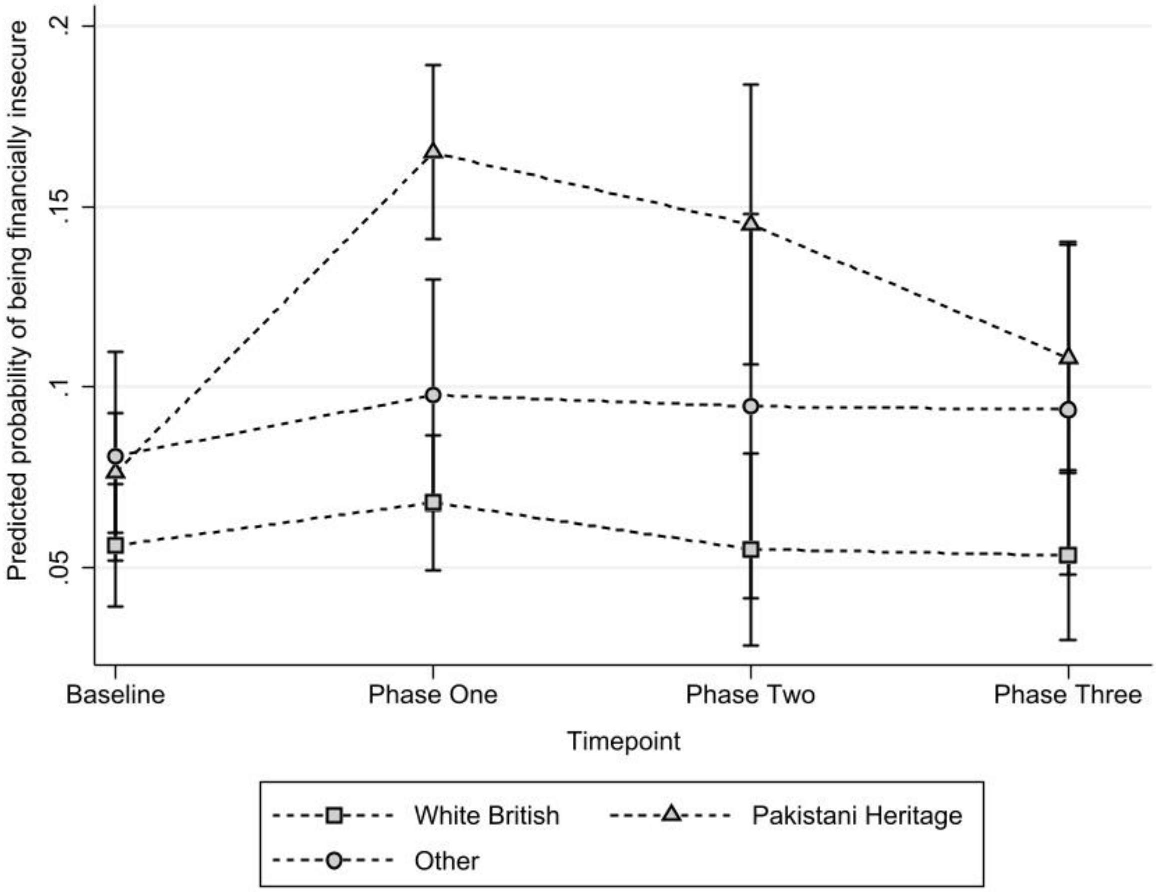

Figure 8 Marginal predicted means of financial insecurity reported by ethnic group across the pandemic

After controlling for employment status, being a key worker, IMD quintile, household composition, homeownership status, self-reported general health and baseline PHQ-8 and GAD-7 categories, there remained an association between experiencing financial insecurity and being of Pakistani Heritage (OR 2.22, 95% CI 1.43, 3.45) compared to families of White

British heritage. This indicates that despite differences in baseline characteristics between these ethnic groups, being of Pakistani Heritage means mothers have an increased odds of experiencing financial insecurity throughout the pandemic.

4.3.6 IMPACT OF FINANCIAL INSECURITY ON MATERNAL HEALTH, WELLBEING AND SOCIOECONOMIC INSECURITY

Table 15 describes the association between financial insecurity and health, wellbeing and socioeconomic security experienced by mothers and their families throughout the pandemic and at individual timepoints.

Table 15 Odds ratios (95% CI) from unadjusted mixed-effects logistic regression models and unadjusted logistic regression models for a change in financial security between pre-COVID-19 and COVID-19 lockdown surveys.

	Overall		**Phase one (n=2043) April – June 2020**		**Phase two (n=730) Oct - Dec 2020**		**Phase three (n=903) May – July 2021**	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Self-reported general health (Reference: Satisfactory)**								
Unsatisfactory	3.36	2.45-4.62						
PHQ-8 Category (Reference: No depression at baseline)								
Mild depression	2.80	2.01-3.89	1.30	0.61-2.76	3.04	1.08-8.58	1.65	0.59-4.58
Moderate depression	4.87	3.22-7.35	0.70	0.28-1.78	1.37	0.38-4.93	0.92	0.27-3.18
Severe depression	13.79	8.71-21.85	1.04	0.39-2.75	1.08	0.28-4.18	1.83	0.51-6.55
Clinically relevant symptoms of depression (Reference: No clinical depression)								
Clinically relevant symptoms of depression	5.27	3.75-7.40	0.84	0.42-1.65	0.59	0.19-1.80	1.20	0.34-4.31
GAD-7 Category (Reference: No anxiety at baseline)								
Mild anxiety	3.52	2.52-4.91	0.91	0.42-1.94	0.55	0.16-1.82	1.33	0.48-3.68
Moderate anxiety	6.05	3.94-9.23	0.83	0.31-2.21	1.40	0.33-5.98	1.92	0.53-6.86
Severe anxiety	13.87	8.50-22.63	0.87	0.31-2.42	0.78	0.16-3.71	1.02	0.26-3.95
Clinically relevant symptoms of anxiety (Reference: No clinical anxiety)								
Clinically relevant symptoms of anxiety	5.70	4.01-8.10	0.88	0.43-1.81	0.97	0.27-3.54	1.05	0.30-3.70
Worry about paying for rent or mortgage (Reference: Not worried at phase one)								
Worried	13.48	8.91-20.40			1.25	0.54-2.91	1.07	0.48-2.40
Worry about eviction (Reference: Not worried at phase one)								

Table 15 Odds ratios (95% CI) from unadjusted mixed-effects logistic regression models and unadjusted logistic regression models for a change in financial security between pre-COVID-19 and COVID-19 lockdown surveys.

	Overall		**Phase one (n=2043) April – June 2020**		**Phase two (n=730) Oct - Dec 2020**		**Phase three (n=903) May – July 2021**	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Worried	9.47	5.88-15.26			0.91	0.30-2.75	0.65	0.21-1.96
Ability to pay bills (Reference: Not up to date with bills at phase one)								
Up to date with bills	0.07	0.04-0.10			0.53	0.21-1.30	0.86	0.37-1.99
Whether food lasted (Reference: Food did last at phase one)								
Food did not last	21.57	14.05-33.11			0.96	0.41-2.26	1.18	0.52-2.64
Ability to eat a balanced meal (Reference: Able to eat a balanced meal at phase one)								
Not able to eat a balanced meal	23.20	14.34-37.53			1.95	0.78-4.85	1.44	0.62-3.34
Needing to skip a meal (Reference: Did not need to skip meals at phase one)								
Needed to skip meals	34.29	16.98-69.22			0.50	0.15-1.68	1.39	0.40-4.81
Feeling hungry (Reference: Not hungry at phase one)								
Hungry	92.77	32.64-263.62			1.08	0.20-5.74	2.91	0.70-12.11

4.3.7 SELF-REPORTED GENERAL HEALTH

Mothers with unsatisfactory self-reported general health were more likely to report being financially insecure throughout the pandemic (OR 3.36, 95% CI 2.45, 4.62) compared to those who reported satisfactory health. There was no association found between financial insecurity and households with a family member who is clinically vulnerable to COVID-19 (OR 1.12 95% CI 0.78, 1.61). However, at phase one, these families had a greater risk of experiencing financial insecurity compared to households who did not have a family member who was clinically vulnerable to COVID-19 (OR 2.54 95% CI 1.33, 4.85). After controlling for employment and key worker status, the association between clinical vulnerability and financial insecurity persisted at phase one (OR 2.06 95% CI 1.07, 3.97).

4.3.8 MENTAL HEALTH

Mothers were more likely to report being financially insecure if they suffered with mild (OR 1.77, 95% CI 1.21, 2.59), moderate (OR 6.70, 95% CI 3.98, 11.30) or severe depression (OR 6.43, 95% CI 3.34, 12.39) compared to those with no symptoms or signs of depression before the onset of the pandemic. The difference between the odds of experiencing financial insecurity reported between mothers with moderate and severe depression at baseline was not significant, although the sample size of mothers with severe depression at baseline was smaller than that of the other categorical groups.

Similarly, mothers were also more likely to report being financially insecure if they suffered with mild (OR 4.48, 95% CI 2.36, 8.48), moderate (OR 8.85, 95% CI 3.84, 20.39) or severe anxiety (OR 16.73, 95% CI 6.56, 42.66) compared to those with no signs or symptoms of anxiety at baseline, with the probability of financial insecurity increasing with increasing GAD-7 categorical group.

Throughout the pandemic, financial insecurity was strongly associated with clinically relevant symptoms of depression (OR 5.27 95% CI 3.75, 7.40) and anxiety (OR 5.70 95% CI 4.01, 8.10), see Figure 9 and Figure 10. At each timepoint across the course of the pandemic, financial insecurity was strongly associated with clinically relevant symptoms of depression, although this was not statistically significant at phase two, see Figure 9. The risk of financial insecurity for those who were clinically depressed was greatest at phase one and three. After controlling for ethnicity, being a key worker, employment status, feeling lonely and feeling worried about paying for the bills, rent, mortgage and being evicted, there remained a strong association between financial insecurity and clinically relevant symptoms of depression (OR 4.47 95% CI 3.13, 6.39).

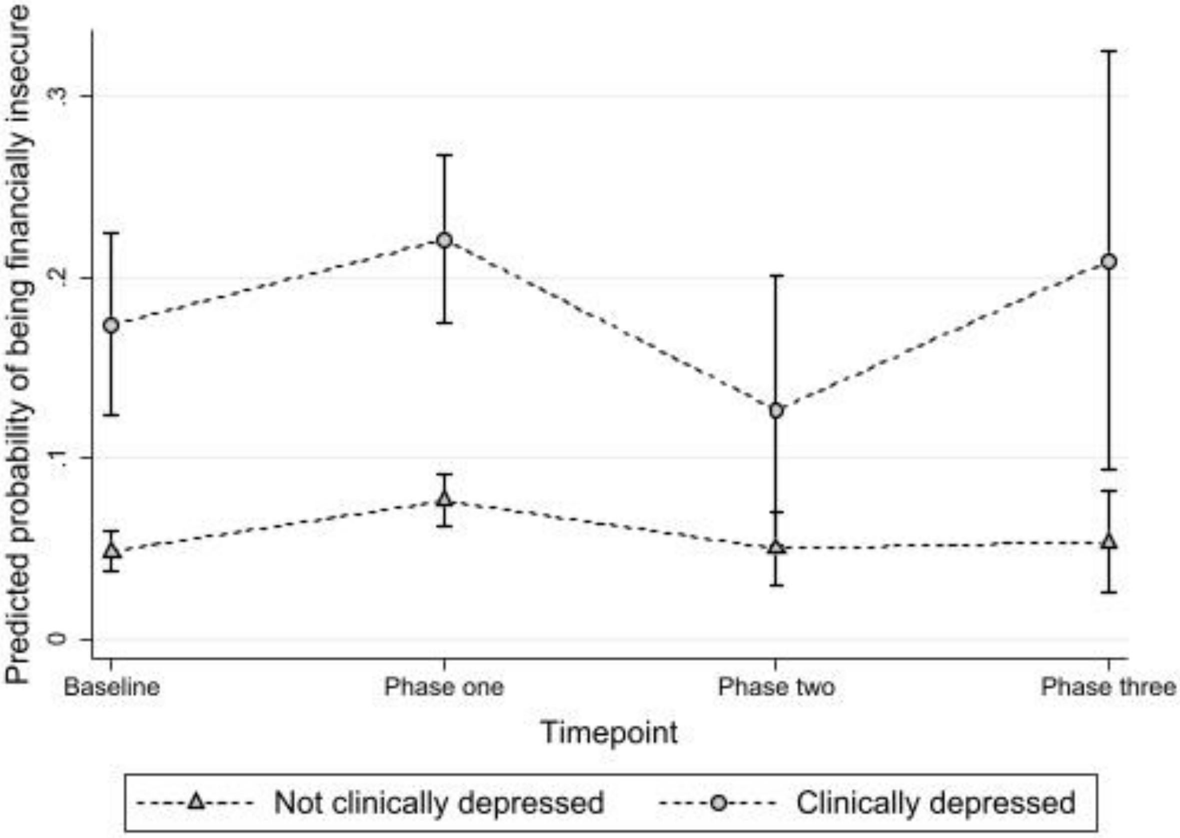

Figure 9 Marginal predicted means of financial insecurity across the pandemic by clinical depression status, adjusted for ethnicity, being a key worker, employment status, feeling lonely and feeling worried about paying for the bills, rent, mortgage and being evicted

At each timepoint across the course of the pandemic, financial insecurity was also strongly associated with clinically relevant symptoms of anxiety, although this was not statistically significant at phase two, see Figure 10. The risk of financial insecurity for those with clinically relevant symptoms of anxiety was greatest at phase one and three. After controlling for ethnicity, being a key worker, employment status, feeling lonely and feeling worried about paying for the bills, rent, mortgage and being evicted, there remained a strong association between financial insecurity and clinical anxiety (OR 4.57 95% CI 3.14, 6.66).

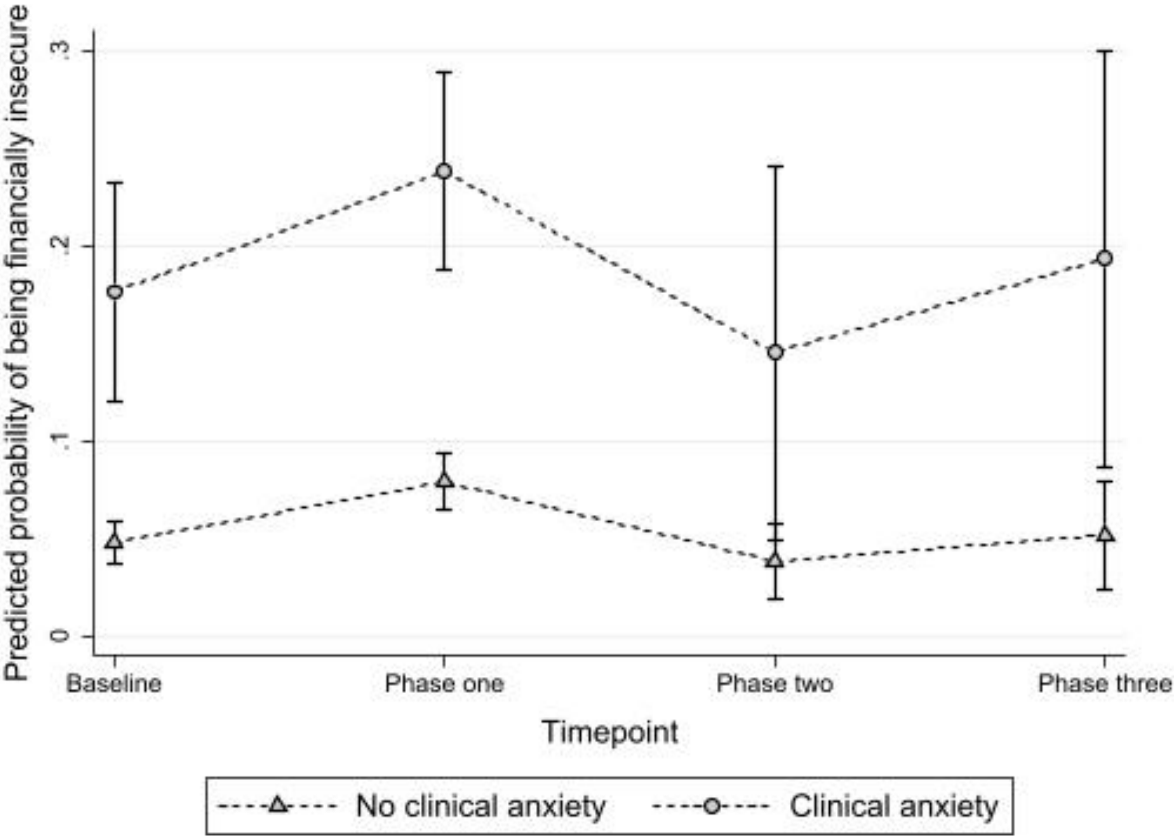

Figure 10 Marginal predicted means of financial insecurity across the pandemic by clinical anxiety status, adjusted for controlling for ethnicity, being a key worker, employment status, feeling lonely and feeling worried about paying for the bills, rent, mortgage and being evicted.

4.3.9 FOOD SECURITY

For those experiencing financial insecurity, throughout the entirety of the pandemic, there were strong associations with food insecurity, with those experiencing aspects of food insecurity not showing any meaningful improvement throughout the pandemic. Families reporting financial insecurity throughout the pandemic were highly likely to report: food not lasting (OR 21.57 95% CI 14.05, 33.11); not being able to eat a balanced meal (OR 23.20 95% CI 14.34, 37.53); feeling hungry (OR 92.77 95% CI 32.64, 263.62); needing to skip meals (OR 34.29 95% CI 16.98, 69.22) and needing to access food banks (OR 6.52 95% CI 2.53, 16.83).

4.3.10 HOUSING SECURITY

Experiencing financial insecurity throughout the pandemic was strongly associated with increased concern and worry about paying for the rent or mortgage (OR 9.47 95% CI 5.88, 15.26) and eviction (OR 13.48 95% CI 8.91, 20.40). Families reporting financial insecurity are also less likely to be up to date with paying their bills (OR 0.07 95% CI 0.04-0.10). Across the pandemic, concerns regarding household security were strongly associated with financial insecurity at each timepoint, with concerns gradually falling across the course of the pandemic.

4.3.11 IMPACT BY ETHNIC GROUP

The impact of financial insecurity on maternal health, wellbeing and socioeconomic insecurity experienced by mothers and their families in Bradford is presented in Table 16. Detailed analysis by ethnic group was limited by sample size and revealed no statistically significant difference between ethnic groups for the impact of financial insecurity on maternal health and wellbeing outcomes and socioeconomic security outcomes.

Table 16 Odds ratios (95% CI) from unadjusted mixed-effects logistic regression model for a change in financial security between pre-COVID-19 and COVID-19 lockdown surveys by ethnic group throughout the pandemic.

	White British (n=706)		**Pakistani Heritage (n=922)**		**Other (n=345)**	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Self-reported general health (Reference: Satisfactory)						
Unsatisfactory	6.23	3.23-12.01	2.97	1.98-4.47	1.31	0.52-3.28
Clinically relevant symptoms of depression (Reference: No clinical depression)						
Clinically relevant symptoms of depressior	7.67	3.94-14.94	4.24	2.78-6.47	6.92	2.69-17.81
Clinically relevant symptoms of anxiety (Reference: No clinical anxiety)						
Clinically relevant symptoms of anxiety	8.38	4.29-16.41	4.28	2.71-6.77	9.73	3.50-27.08
Worry about paying for rent or mortgage (Reference: Not worried)						
Worried	9.20	3.80-22.27	15.15	6.99-32.84	15.85	4.70-53.47
Worry about eviction (Reference: Not worried)						
Worried	4.61	1.25-17.00	9.41	4.19-21.12	14.54	5.32-39.73
Ability to pay bills (Reference: Up to date with bills)						
Not up to date with bills	0.05	0.02-0.13	0.12	0.06-0.22	0.07	0.03-0.18
Whether food lasted (Reference: Food did last)						
Food did not last	27.94	11.43-68.30	17.73	9.26-33.94	32.68	7.71-138.61
Ability to eat a balanced meal (Reference: Able to eat a balanced meal)						
Not able to eat a balanced meal	24.20	9.96-58.82	19.12	9.38-39.00	18.55	4.83-71.17
Needing to skip a meal (Reference: Did not need to skip meals)						
Needed to skip meals	49.75	16.44-150.60	56.41	14.13-225.18	8.24	0.15-461.25
Feeling hungry (Reference: Not hungry)						
Hungry	80.39	20.56-314.42	152.23	19.18-1208.11	132.00	5.15-3385.14

4.4 DISCUSSION

4.4.1 SUMMARY OF KEY FINDINGS

This longitudinal study, nested within two longitudinal Born in Bradford cohort studies, describes some of the key experiences of families living in the deprived and ethnically diverse city of Bradford during the COVID-19 pandemic. These findings highlight that financial insecurities were frequently reported by mothers in Bradford throughout the pandemic, most notably in phase one, with the risk of experiencing financial insecurity almost having returned to pre-COVID-19 baseline levels by phase three. The probability of being financially insecure for mothers in Bradford at phase one was 12.05% (95% CI 10.59, 13.50), at phase two was 10.20% (95% CI 7.99, 12.41) and at phase three was 8.49% (95% CI 6.66, 10.32), compared to baseline probabilities of 6.96% (95% CI 5.86, 8.07).

The study highlighted that there were several individual sociodemographic characteristics that were associated with financial insecurity throughout the pandemic. Financial insecurity was strongly associated with homeowner status and free school meal eligibility. Several characteristics were identified as protective against financial insecurity: higher IMD Quintiles (i.e., families living in more affluent areas); greater levels of educational attainment; and families with two or more adults in the household. Several employment factors were also found to be protective. The main earner of the household being employed and working during the pandemic was most protective against being financially insecure. The risk was greatest for families where the main earner was unemployed, employed and on furlough, self-employed and not working respectively, compared to being employed and working. Being a key worker was also a protective factor against financial insecurity. There was no difference in the risk of experiencing financial insecurity: according to age; for those who were pregnant; for families with a child with special educational needs; for single parents; by numbers of people per bedroom; or by household composition with respect to number of adults over 70 years old and numbers of children.

Notably, the findings from this study have demonstrated that families of Pakistani Heritage and from other ethnic groups have been disproportionately affected by financial insecurity owing to the COVID-19 pandemic and subsequent public health measures implemented to control the virus. Ethnicity was demonstrated to be an independent predictor of financial insecurity throughout the COVID-19 pandemic, with families of Pakistani Heritage and families from other ethnic groups being more likely to experience financial insecurity than White British families. This association persisted after controlling for employment status, being a key worker, IMD quintile, homeownership status, household composition, self-reported general health and baseline PHQ-8 and GAD-7 categories.

Over the course of the pandemic, Pakistani Heritage families experienced the sharpest rise in risk of financial insecurity at the onset of the pandemic, compared to those of White British families and families from other ethnic groups, and had not returned to baseline levels towards the end of the pandemic. For White British families, recovery from financial insecurity had been achieved by Phase Two. Further studies are required to establish the causal mechanisms through which this association occurs.

This study demonstrates that there were strong associations also demonstrated between financial insecurity and poor maternal health and wellbeing outcomes. Mothers experiencing financially insecurity were more likely to report unsatisfactory general health, clinically relevant symptoms of depression and anxiety. The association between financial insecurity and clinically relevant symptoms of depression and anxiety persisted throughout the pandemic with levels of clinically relevant symptoms of depression and anxiety appearing to recover in phase two, then beginning to rise again in phase three.

Families experiencing financial insecurity throughout the pandemic were also significantly more likely to suffer detrimental impacts to household and food security. Experiencing financial insecurity throughout the pandemic was strongly associated with increased worries about paying for bills and the rent or mortgage, with consequent concerns regarding eviction. Families were also significantly more likely to report: food not lasting; not being able to eat a balanced meal; feeling hungry; needing to skip meals; and needing to access food banks as a result of financial insecurity.

Several studies have since provided further evidence demonstrating the unequal effects of the pandemic on ethnic minority groups, further exacerbating existing inequalities. In recently published studies, ethnic minority groups were found to be more likely to experience economic hardship immediately after the first national lockdown[166,167] in keeping with the results of this study. Furthermore, people from ethnic minority groups were found to be more likely to experience loss of employment and less likely to receive furlough payments compared to White British populations.[166] Several studies have confirmed that levels of financial insecurity have not yet returned to baseline levels for ethnic minority groups.[167,168] The findings together with the findings of this study, provide evidence that the pandemic has exacerbated entrenched socioeconomic inequalities along intersecting ethnic lines.[166-168]

Other studies have published evidence supportive of the findings of this study to suggest that mental health and wellbeing worsened throughout the pandemic and was associated with financial insecurity. Solomon-Moore et al. described that impacts on mental health were the greatest for women, people living with young children and those between 18 and 34 years old.[169] Whilst this study did not examine differences in gender, the study did look at women of child-bearing age, many of whom already had children who were expecting children and describe findings consistent with this study. While there is some research available on how COVID-19 lockdown restrictions have had an impact on mental health for UK adults,[170,171] data are limited, and not enough is known about potential long-term effects of the pandemic. This study expands on this data, and alongside the findings of some other studies, demonstrates that mental health and wellbeing are improving across time, suggesting that any negative effects of the pandemic on mental health may be reversible.[169] This perceived recovery in mental health and wellbeing may have been due to the easing of public health restrictions, which enabled increased freedom to see family and friends, participate in hobbies and allow some individuals to return to work and thereby lessening financial insecurity. However, the results of this study, provide evidence suggestive of another fall in levels of mental health and wellbeing. Further work needs to be conducted to examine this trend over time and if and how this correlates with financial insecurity and the effects of other emerging socioeconomical and political factors.

4.4.2 LIMITATIONS

A wide array of methods were employed in order to maximise survey response rates in a time sensitive manner. However, the overall low response rates to each survey, as a proportion of both the eligible population and of those having completed previous surveys, may have introduced selection bias. It is difficult to appreciate the effect of this on the results. It may be that individuals coping better felt better able and had more capacity to engage with research during this time. Thus, the results, particularly on mental health may be underestimated. Conversely, individuals who were struggling more, whether with their financial circumstances or with their mental health, may have been more willing to engage to share their experiences, leading to on over-estimation of the observed associations. Comparing results with other studies of similar and differing populations will be important to gain a fuller picture of the impact of the pandemic and its management on health and social inequalities. Notably, response rates were lower in phase two and three compared to phase one, limiting analysis at the later stages of the pandemic. However, whilst it is possible that the results are influenced by the overall survey response rates, participants were representative of the Bradford population and BiBGU[88,147] and BiBBS[89] cohorts, were comparable across phases, and have demonstrated a wide variability in most characteristics.

This study reports several associations with financial insecurity for mothers and their families in Bradford. It is not possible from this analysis to establish temporality and thus determine causality for these associations. However, the study has highlighted the direction of these relationships for this population, emphasising the need to address all health, social and economic factors to support families to recover holistically, with targeted support to those most vulnerable.

A number of variables were also collapsed to support the analysis owing to small sample sizes within each stratum across survey timepoints. For example, financial insecurity was defined as those ‘finding it quite difficult’ and ‘finding it very difficult’ to manage financially. Families ‘living comfortably’, ‘doing alright’ and ‘just about getting by’ were considered financially secure. Similarly, families were defined as having food security if it was ‘never true’ or ‘sometimes true’ that food didn’t last and being food insecure if it was ‘often true’ that food didn’t last. Such categorisations were conservative and several mid-point categories could be considered true for either categorisation. This may have led to more individuals being classified as being financially insecure and struggling with food insecurity, for example. This may have then led to an under-estimation of the measured associations.

Furthermore, baseline pre-COVID-19 measurements were taken from data collected over the four years preceding the onset of the pandemic, therefore all changes cannot with confidence be attributed to the pandemic and subsequent public health measures implemented.

4.4.3 IMPLICATION OF FINDINGS

This study offers a unique assessment of the socioeconomic impact of the pandemic longitudinally in a highly ethnically diverse, seldom studied population, with a pre-pandemic baseline, the majority of whom live in the most deprived centiles in the UK and are more vulnerable to mental health conditions. During the pandemic, the national furlough scheme was established to financially support employees placed on temporary leave, for some or all of their contracted hours, to ensure they received at least 80% of their usual wages whilst furloughed.[39,40] For those on a low wage, this was insufficient and even the loss of a small proportion of income was enough to tip families into perilous financial difficulty, and potentially further exacerbate health inequalities.[41] Furthermore, recovery from the effects of the pandemic has been further hampered by the recent cost of living and energy crisis. A report from the International Monetary Fund highlights that the energy crisis is currently affecting UK households harder than any country in western Europe, with the difference between the cost burden on poor and rich households being far more unequal in the UK compared with other countries.[32] With ever increasing cost of living, energy prices and inflation since the pandemic, the ability of families to recover from the effects of the pandemic is untenable without intervention.

Furthermore, the potential ethnic differences in the magnitude of the associations between financial insecurity and health, wellbeing and socioeconomic security reported in this study warrant further investigation, including an understanding of potentially differing risk and protective factors in different ethnic groups.

4.5 CONCLUSION

This longitudinal study provides a comprehensive analysis of some of the key and unequal experiences of families living in the deprived and ethnically diverse city of Bradford during the COVID-19 pandemic. This research, with an extended time scope and pre-COVID-19 baseline data, provides an extensive analysis of the financial and subsequent impacts on health and wellbeing across several social groups. The findings of this study highlight that the impact of financial insecurity experienced by mothers and their families throughout the COVID-19 pandemic was severe, wide ranging and affected the most vulnerable. The risk of financial insecurity experienced by families in Bradford rose sharply during the pandemic and for White British families and families of other ethnicities had almost returned to pre-COVID-19 baseline levels by mid-2021. This study highlights strong associations between financial insecurity and physical and mental health. Although there were indications that severe financial insecurity was recovering towards the end of the pandemic, the recent and ongoing cost of living and energy crisis means that the recovery from the effects of the pandemic is likely to be short lived and continues to threaten the health, wellbeing and socioeconomic security of vulnerable families and widen existing health inequalities for the most vulnerable. This chapter highlights the clear need for intervention from policy makers and commissioners to act to support vulnerable families to prevent further financial, fuel and food debt, homelessness, poor health and widening existing health and social inequalities. A welfare advice service co-located in health settings for mothers and their families could provide the crucial and timely support needed to take steps towards addressing this need for the most vulnerable families in Bradford.

Having established the core elements and socioeconomic context towards the development of a welfare advice service co-located in health settings for mothers and their families as a complex intervention, there remains a need to establish how best to evaluate such an intervention. The following chapters seek to explore the acceptability and feasibility of evaluating a welfare advice service co-located in health settings for mothers and their families to guide the development of the most appropriate approach to an evaluation of such a complex intervention as guided by the complex intervention framework.

CHAPTER 5 THE FEASIBILITY OF EVALUATING A WELFARE ADVICE SERVICE CO-LOCATED IN PRIMARY CARE IN BRADFORD

This chapter presents a mixed methods before and after evaluation of an existing welfare advice service co-located in general practices across Bradford. Using this evaluation, I investigate whether the proposed evaluation tools and processes are feasible to implement and whether they are able to detect any evidence of promise for this intervention on health, wellbeing and financial insecurity for participants in a deprived and ethnically diverse city.

5.1 INTRODUCTION

The choice of outcome measures is a crucial aspect of the design of an evaluation to demonstrate evidence of change for a complex intervention.[172] There are several approaches to the choice of appropriate outcome measures. A good theoretical understanding of the intervention, derived from careful development work, is key to choosing suitable outcome measures. It is also important to consider this alongside which outcomes are most important for stakeholders to improve the acceptability, utility and relevance of any outcome data achieved.[172]

This thesis proposes that welfare advice services co-located in health settings operate to improve health and wellbeing through measures to address social determinants of health. The theory of change model, demonstrated in Figure 3**Error! Reference source not found.**, depicts the mechanisms through which these services operate to create this change and highlights a potential range of short and long term outcomes to evaluate the intervention. For example, the model purports that access to co-located welfare advice services and uptake of the welfare advice provided improves financial security and stability for individuals through mechanisms, such as increased household income and support with debt relief, which improves physical health and wellbeing through reduced levels of mental health and stress-related conditions.

A systematic review, published in 2006, of welfare advice delivered in health settings found that there was evidence that this approach resulted in financial gains but at that time there was limited high quality evidence to determine whether this resulted in improved uptake of welfare advice or measurable health and social benefits.[62] Furthermore, none of the included studies considered variation in uptake or outcomes measures between ethnic groups. The systematic review in Chapter 3 builds upon this systematic review. The included studies demonstrated improved financial security for participants, generating an average of £27 of social, economic and environmental return per £1 invested. Some studies reported improved mental health for individuals accessing services. Several studies attributed subjective improvements in physical health to the service through action on key social determinants of health. Importantly, several studies highlighted challenges in conducting evaluations of welfare services of relevance to future studies conducted in this area. Many struggled to recruit sufficient participants or were unable to follow-up sufficient numbers to achieve reasonable statistical power. Several studies also reported challenges in identifying suitable effectiveness and implementation outcome measures, resulting in significant heterogeneity in reported outcomes across the included studies. More recently published studies have also highlighted the challenge inherent in choice of appropriate follow-up time. Outcome measures collected at 24 months suggested where improvements might exist, they may not persist beyond this time.[173] The challenge of recruiting minority groups was also raised as a particular concern in many studies. Furthermore, given the overall, generally poor scientific quality of the studies, care must be taken in drawing firm conclusions about the impact of co-located services on health, social and financial outcomes from both systematic reviews of the existence evidence base in this area.

The Voluntary and Community Sector (VCS) Alliance co-ordinate a welfare advice programme co-located within the primary care network across inner city areas across Bradford, commissioned by the Reducing Inequalities in Communities programme.[98] The programme is fully described in Chapter 2.3.1. The VCS Alliance welfare advice programme sought collaboration with an academic partner to conduct an evaluation of their co-located welfare advice programme. The programme offers co-located welfare advice services in 26 general practices across Bradford. The services are accessed through referral via general practitioners to all adults over 18 years of age. Whilst the programme is not specifically tailored to mothers and their families, this evaluation offered the opportunity to conduct a feasibility evaluation of a welfare advice service in a health setting in the ethnically diverse and deprived setting of Bradford. This evaluation represents the first known evaluation of a co-located welfare advice service in an ethnically diverse setting.

5.2 AIMS AND OBJECTIVES

This aim of this chapter is to explore the feasibility of evaluating a welfare advice service co-located in a health setting in practice in an ethnically diverse and deprived population. It seeks to investigate whether the proposed evaluation tools and processes are acceptable and feasible to implement and where permitting, whether they are able to detect any evidence of promise for this intervention on the health, wellbeing and financial security of participants in an ethnically diverse and deprived population.

The objectives of this chapter are to:

a) Explore the feasibility of recruiting and retaining participants for an evaluation of a welfare advice service co-located in a health setting within an ethnically diverse and deprived population.

b) Explore the acceptability and utility of the proposed evaluation tools to evaluate the impact of this intervention on the health, wellbeing and financial security of participants with respect to completeness of outcome measures and their ability to detect change in outcome measures for the intervention in this population.

c) Where the above outcomes permit, to explore the magnitude and direction of effect of the impact of the intervention on the health, wellbeing and financial security of participants that may also inform sample size calculations in future evaluations.

d) Where the above outcomes permit, to explore whether a cost-utility approach to an economic evaluation is feasible and from an appropriate perspective.

5.3 METHODS

5.3.1 STAKEHOLDER CONSULATION

Extensive consultation with key stakeholders from within the VCS Alliance and its nine welfare advice providers was conducted in the design, preparation and conduct of this study. I conducted preliminary meetings with senior colleagues within the VCS Alliance to gain an understanding of the purpose, nature and scope of the evaluation. These senior colleagues were keen to conduct an evaluation of the services provided primarily to demonstrate the impact of services on the health and wellbeing of the clients served and the value for money they represent to commissioners. I then conducted several meetings with the senior management team to gain an understanding specifically of their existing project model and operating procedures to facilitate an appropriate evaluation design to complement existing processes. The VCS Alliance explained their existing data collection procedures to me and their expectations for provider participation with the evaluation. Collaboration with the VCS Alliance and its providers was highlighted as an important value and approach to the design and conduct of the evaluation.

I then held meetings with senior representatives of the VCS Alliance welfare advice providers. My initial meetings with the providers focused on the rationale and utility of a research led evaluation of the service to demonstrate the impact of their service, particularly with respect to health and wellbeing outcomes . I ensure that time and care was taken to listen to and understand the thoughts and concerns of the providers regarding such an evaluation and considered with the representatives how best to tailor the approach to balance the need for high quality data collection against the administrative burden for the providers and their clients. During these meetings, I discussed potential evaluation outcome measures to explore their thoughts and concerns regarding their appropriateness and suitability for their respective communities and client base. Following these initial scoping meetings, I conducted several further meetings with the VCS Alliance senior management team and service providers to review pilot participant questionnaires with respect to their ease of use and specific language and accessibility requirements. Following approval and acceptance of the participant questionnaires and associated recruitment and consent procedures, I provided specific training was provided to the providers on participant recruitment, consent and data collection. This was repeated where required given the high turnover of staff within the individual service providers and VCS Alliance senior management team.

During the evaluation, I provided support to providers with all aspects of the conduct of the evaluation and the supply of additional participant questionnaires and vouchers. Monthly drop-in sessions were also scheduled providing ad hoc troubleshooting advice and support where required.

5.3.2 STUDY DESIGN

An uncontrolled before and after study, designed and conducted in collaboration with the VCS Alliance and its providers, was utilised to conduct this feasibility evaluation. Data were collected by VCS Alliance welfare advisors from participants at two time points: at baseline prior to receiving welfare advice at their first appointment with the welfare advisor; and at three months following their first appointment with the welfare advisor.

5.3.3 DATA COLLECTION

All individuals aged 18+ years who accessed the VCS Alliance welfare advice service through referral by their GP during the recruitment period were eligible. Where a participant spoke a language other than English, written information was provided in additional commonly spoken languages as required, including Arabic, Bangla, Hebrew, Latvian, Malay, Polish, Romanian, Slovenian and Urdu.

Participants were offered a £15 Love2Shop voucher[174] upon completion of their 3 month follow-up survey. Love2Shop vouchers were chosen given their familiarity of use within the University of York for participant participation and given their ability to be used in store and online in a wide range of high street stores.

At their first appointment with the welfare advisor and prior to the provision of any welfare advice, all eligible clients were approached by their welfare advisor to seek consent for participation in the evaluation. Participants were provided with a participant information sheet and consent form for information and completion, see Appendix A.4.3 and A.4.3. After obtaining written consent, participants were asked to complete a baseline survey to assess their current levels of self-reported financial security and health and wellbeing prior to receiving their welfare advice, see Appendix A.4.7. The surveys were self-reported and took approximately 10 minutes to complete.

Three months following their initial appointment with the welfare advisor, participants were requested to complete the follow-up survey, see Appendix A.4.8. This follow-up period was chosen to increase the confidence in the association between advice receipt and changes to health and wellbeing, particularly in a multiply disadvantaged population, in which other factors could influence outcomes and underestimate the benefit of advice.[64] Secondly, it was chosen to minimise attrition, optimising statistical power and minimising the risk of bias.[175,176]

Finally, the Citizens Advice Bureau and VCS Alliance indicated a resolution time of three months for most cases.[64]

At their final appointment with their welfare advisor, or shortly after this appointment, individuals were routinely contacted by their welfare advisor to seek feedback about the programme for the purposes of VCS Alliance monitoring and evaluation. Most commonly this occurred through face-to-face contact with their welfare advisor at their final appointment approximately 3 months following their first appointment. This appointment sometimes took place via telephone or postal contact where face-to-face contact was not feasible or desirable by clients. Participants were invited to complete their 3-month follow-up during this final contact with the welfare advisor as appropriate. Participants who received their final appointment with the welfare advisor fewer or later than three months following their initial appointment were contacted by their welfare advisor by telephone to complete their follow-up survey 3 months following their initial appointment. Non-respondents were contacted by their welfare advisors by telephone one week later as a prompt to complete the survey.

5.3.4 OUTCOME MEASURES

5.3.4.1 RECRUITMENT AND RETENTION

Recruitment and retention rates were calculated to establish the feasibility of recruiting and retaining participants for an evaluation of a welfare advice service co-located in a health setting within this ethnically diverse and deprived population. For this study, it was expected that there would be moderate recruitment rates, approximately 40-50% of all new referrals received, with low retention rates of approximately 20-30% for the follow-up survey.

5.3.4.2 COMPLETENESS OF OUTCOME MEASURES

The acceptability and utility of the proposed evaluation tools to evaluate the impact of this intervention on the health, wellbeing and financial security of participants was assessed with respect to the completeness and missingness of the proposed outcome measures for these domains.

5.3.4.3 PARTICIPANT SOCIODEMOGRAPHICS

Sociodemographic data for individuals accessing the welfare advice programme were ordinarily collected by welfare providers and sent to the VCS Alliance monthly for collation.

To reduce the administrative burden for providers and participants, it was preferred that existing sociodemographic variables collected by the providers as routine project monitoring data were utilised for this evaluation where possible. A number of additional bespoke sociodemographic variables were added to the baseline questionnaire to improve the understanding of the baseline socioeconomic security of participants, see Table 17. These variables were adopted from the BiBBS baseline recruitment questionnaire, as validated measures to explore socioeconomic security in this community.[89] A number of sociodemographic variables and outcome measures were collapsed to facilitate analysis, these are indicated in Table 17 with the use of superscripts. A copy of the participant survey can be found in see Appendix A.4.7.

Table 17 Sociodemographic variables and outcome measures collected

Baseline characteristics and outcome variables	Collapsed variable strata (as indicated by superscript number)	Data source
Gender		
Female Male Other Prefer not to say	n/a	Routine VCS Alliance project monitoring data
Age		
Age in years Prefer not to say	n/a	Routine VCS Alliance project monitoring data
Current relationship status		
Civil Partnership^1 Cohabiting^1 Divorced^2 Formerly in a civil partnership^2 Married^1 Separated^2 Single^3 Widowed^4 Prefer not to say	^{1}Living with a partner ^{2}No longer living with partner ^{3}Single ^{4}Widowed	Routine VCS Alliance project monitoring data
Whether single parent		
Yes		

Table 17 Sociodemographic variables and outcome measures collected

Baseline characteristics and outcome variables	**Collapsed variable strata (as indicated by superscript number)**	**Data source**
No Prefer not to say		Additional bespoke sociodemographic variable collected via participant survey
Ethnicity		
Bangladeshi (Asian/Asian British)^{3}	^{1}White British	Routine VCS Alliance project monitoring data
Chinese (Asian/Asian British) ^{3}	^{2}Pakistani Heritage	
Indian (Asian/Asian British) ^{3}	^{3}Other	
Pakistani (Asian/Asian British)^{2}		
Other Asian background (Asian/Asian British) ^{3}		
African (Black/African/Caribbean/Black British) ^{3}		
Caribbean (Black/African/Caribbean/Black British) ^{3}		
Other Black/African/Caribbean (Black/African/Caribbean/Black British) ^{3}		
Mixed White and Asian (Multiple ethnic groups) ^{3}		
Mixed White and Black African (Multiple ethnic groups) ^{3}		
Mixed White and Black Caribbean (Multiple ethnic groups) ^{3}		
Mixed Other (Multiple ethnic groups) ^{3}		
Other (Other ethnic group) ^{3}		
Arab (Other ethnic group) ^{3}		
British/English/Welsh/Scottish/Northern Irish (White)^{1}		
Irish (White) ^{3}		
Eastern European (White) ^{3}		
Other (White) ^{3}		
Irish Traveller^{3}		

Table 17 Sociodemographic variables and outcome measures collected

Baseline characteristics and outcome variables	Collapsed variable strata (as indicated by superscript number)	Data source
Gypsy/Romany[3]		
Roma ethnic group[3]		
Prefer Not To Say/Don't Know		
Religion		
Atheist[4]	[1]Christian	Routine VCS Alliance project monitoring data
Buddhist[4]	[2]Hindu	
Christian (including all Christian denominations)[1]	[3]Muslim	
Hindu[2]	[4]Other	
Jewish[4]		
Muslim[3]		
Sikh[4]		
Other[4]		
Prefer not to say		
Preferred language		
Afghani[5]	[1]English	Routine VCS Alliance project monitoring data
Arabic[5]	[2]Urdu	
Bengali[5]	[3]Punjabi	
Bengali/Sylheti[5]	[4]Mirpuri	
English[1]	[5]Other	
Farsi[5]		
Gurumukhi[5]		
Hindko[5]		
Left blank[5]		

Table 17 Sociodemographic variables and outcome measures collected

Baseline characteristics and outcome variables	**Collapsed variable strata (as indicated by superscript number)**	**Data source**
Mirpuri^{4}		
Mirpuri/Punjabi^{4}		
Nepalese^{5}		
Other^{5}		
Other – Bosnian^{5}		
Other – Czech^{5}		
Other – German^{5}		
Other – Gujerati^{5}		
Other – Hungarian^{5}		
Other – Pahari/Punjabi^{5}		
Other – Romanian^{5}		
Other – Spanish^{5}		
Punjabi$^{\mathbf{3}}$		
Pushto^{5}		
Slovakian^{5}		
Sylheti^{5}		
Urdu^{2}		
Prefer not to say		
Self-reported health issues		
Physical Disability^{2}	^{1}Long-term health condition	Routine VCS Alliance project monitoring data
Learning Disability^{2}	^{2}Physical or other disability	
Mental Health Issues$^{\mathbf{3}}$	^{3}Mental health condition	
Visual Impairment^{2}	^{4}Other	

Table 17 Sociodemographic variables and outcome measures collected

Baseline characteristics and outcome variables	Collapsed variable strata (as indicated by superscript number)	Data source
Hearing Impairment[2]	[5]None	
Long Term Condition[1]		
Other[4]		
None[5]		
Prefer not to say		
Employment status of main earner in household		
Employed	n/a	Additional bespoke sociodemographic variable collected via participant survey
On furlough		
Self-employed: working		
Self-employed: not-working		
Unemployed		
Prefer not to say		
Worry about job security of main earner in household		
Yes	n/a	Additional bespoke sociodemographic variable collected via participant survey
No		
Don’t know		
Prefer not to say		
Worry about eviction		
Never	n/a	Additional bespoke sociodemographic variable collected via participant survey
Sometimes		
Often		
Prefer not to say		

Table 17 Sociodemographic variables and outcome measures collected

Baseline characteristics and outcome variables	Collapsed variable strata (as indicated by superscript number)	Data source
Worry about whether food will last		
Never	n/a	Additional bespoke sociodemographic variable collected via participant survey
Sometimes		
Often		
Prefer not to say		
Self-reported financial security		Participant survey
Living comfortably[1]	[1]Financially secure	
Doing alright[1]	[2]Financially insecure	
Just about getting by[1]		
Finding it quite difficult[2]		
Finding It very difficult[2]		
Mental health (PHQ-8)		
0-4 score	No depression	Participant survey
5-9 score	Mild depression	
10-14 score	Moderate depression	
15-24 score	Severe depression	
Wellbeing (SWEMWBS)		
7-19.5 score	Low wellbeing	Participant survey
19.6-27.4 score	Moderate wellbeing	
27.5-35 score	High wellbeing	
Quality of Life (EuroQol EQ-5D)		
Health utilty score	n/a	Participant survey
Visual Analog Scale		

Current relationship status was collapsed into four variables: ‘living with a partner’; ‘no longer living with partner’; ‘single’; and ‘widowed’. ‘Married’, ‘civil partnership’, and ‘co-habiting’ variables were collapsed into ‘living with partner’. ‘Divorced’, ‘formerly in a civil partnership’, and ’separated’ variables were collapsed into ‘no longer living with a partner’.

Ethnicity was coded using Census 2011 categories as ‘White British’, ‘Pakistani Heritage’ and ‘Other’. There were small numbers of non-White British and non-Pakistani Heritage mothers from multiple ethnic groups who were grouped and categorised within the ‘Other’ category.

Religion was coded as ‘Christian’, ‘Hindu’, Muslim and ‘Other’. There were small numbers of non-Christian, non-Hindu and non-Muslim participants who were grouped and categorised within the ‘Other’ category.

Preferred language was categorised as ‘English’, ‘Urdu’, “Punjabi’, ‘Mirpuri’ and ‘Other’. Similarly to the ethnicity and religion variables, there were small numbers of participants with a preferred language other than English, Urdu, Punjabi and Mirpuri, who were grouped and categorised within the ‘Other’ category.

Current health status was collapsed into five variables: ‘long-term health condition’; ‘physical or other disability’; ‘mental health condition’; ‘other’; and ‘none’. ‘Physical disability’, ‘visual impairment’, ‘learning disability’, and ‘hearing impairment’ were grouped and categorised as ‘physical or other disability’.

5.3.4.4 SELF-REPORTED FINANCIAL SECURITY

To establish participant self-reported financial security, the surveys employed the question: ‘How well would you say you are managing financially right now?’.[177] Answer options included: ‘living comfortably’; ‘doing alright’; ‘just about getting by’; ‘finding it quite difficult’; and ‘finding it very difficult’. The latter two options were grouped and categorised as indicating financial insecurity.

5.3.4.5 MENTAL HEALTH, WELLBEING AND HEALTH-RELATED QUALITY OF LIFE

Mental health, wellbeing and health-related quality of life were measured using the PHQ-8, SWEMWBS and EuroQol EQ-5D tools respectively, described previously in Chapter 2.3.[100,178,179] Mental health was measured using the PHQ-8 questionnaire.[100] The scores from each item were summed to produce a total score between 0 and 24 points. Summed scores were used as a continuous variable with greater scores indicating a presence of depressive symptoms. Standard categorisations were employed for the scores: 0 to 4 no depression; 5 to 9 mild depression; 10-14 moderate depression; and 15-24 severe depression.[101] Symptoms suggestive of depression were defined as those with moderate to severe depression scores.

Wellbeing was measured using the seven-item SWEMWBS.[104] The score from each item was summed to produce a total score between 14 and 35. Summed scores were transformed and used as a continuous variable with greater scores indicating a more positive wellbeing. SWEMWBS scores were further categorised into low (7-19.5), average (19.6-27.4) and high (27.5-35) wellbeing groups.

The health-related quality of life of participants was measured using the five-item EQ-5D instrument (EQ-5D-5L).[107] These domains provide a descriptive profile that were transformed into health utility scores, based on UK societal preference weights for the health state,[108] ranging between 0 representing death and 1 for perfect health. The EQ-5D-5L questionnaire also includes a Visual Analog Scale, by which respondents can self-report their perceived health status with a continuous grade ranging from 0 representing the worst possible health to 100 representing the best possible health.

All outcome measures were selected based on the experience of the Born in Bradford Research Programme and their successful use of these tools within the local community.[85,89] Furthermore, the availability of a wide range of validated translated and transliterated versions of these tools was seen as important and necessary for an evaluation of a programme providing services to a diverse community with many preferred spoken languages.

5.3.4.6 WELFARE AND FINANCIAL OUTCOMES

Data on the type of welfare advice provided and the financial outcome of individual client case work were routinely collected by the welfare advice providers and sent to the VCS Alliance monthly, see Table 18. Overall costs of the VCS Alliance welfare advice programme, broken down by individual provider, were also provided by the VCS Alliance to facilitate an economic analysis of the service.

Table 18 Type and range of welfare advice case work

Welfare advice case work
Attendance Allowance
Benefits Check
Bereavement Support Payment
Blue Badge Application
Carers Allowance
Child Benefit
Child Maintenance
Child Tax Credit
Community Care
Consumer Goods & Services
Council Tax
County Court Judgement (N245)
Debt
Disabled Bus Pass
Disabled Facilities Grant application
Disability Living Allowance
Education
Employment
Employment and Support Allowance
Food Parcel
Free School Meals
Funeral Payment
Grant
Housing
Housing Benefit
Immigration
Income Support
Insurance
Job Seekers Allowance
Legal Expenses
Mandatory Reconsideration
National Insurance (NINO) Application
Passport
Pension Advice
Pension Credit
Personal Independence Payments
Private Pension Form
Relationships & Family
Respite Care

Table 18 Type and range of welfare advice case work

Welfare advice case work
School Transport
State Pension
Statutory Sick Pay
Student Finance Application
Universal Credit
Utility Bills
Working Tax Credit
Other

5.3.5 SAMPLE SIZE

Prior to the evaluation, the VCS Alliance welfare advice programme advised that they received approximately 230 new referrals per month. Loss to follow-up is a commonly identified challenge with the use of surveys and for evaluations of welfare advice services in particular.[62] A recently conducted evaluation of welfare advice services, using similar survey tools with a 3 month postal follow-up, achieved greater than 70% follow-up retention rates for both their advice and control groups. However, the use of financial incentives may explain the larger than average retention rates for this study.[64]

The number of participants eligible for recruitment to this study was limited by the number of individuals that the programme had the capacity to support, in addition to the study recruitment and retention rate. The study recruited as many participants as possible in a twelve-month period in order to increase the statistical power of the study to detect potential effect sizes.

The Difference ELicitation in TriAls (DELTA^2) guidance provides specific guidance on choosing target differences in outcomes and on associated sample size calculations.[180] Sample size calculation is often based on a single primary outcome, the DELTA^2 guidance advises that different candidate outcomes are considered in turn, and the corresponding sample size explored. Based on this guidance and given the lack of certainty regarding effect sizes for this intervention with respect to the chosen mental health, wellbeing and quality of life outcome measures, indicative sample sizes have been calculated and presented for each of the outcome measures respectively. This will improve the understanding of the potential effect size of this intervention and thus inform sample size calculations in future evaluations. Table

19 provides indicative sample sizes required utilising change in mean PHQ-8 scores according to effect size and power required as an example, assuming a significance level of 0.05 for a two sided t-test.[181] Effect sizes with respect to change in mean PHQ-8 score used to inform sample size calculations are detailed in Table 20.

Table 19 Indicative sample sizes required to detect change in mean PHQ-8 scores according to effect size and power required, assuming a significance level of 0.05 for a two sided t-test **[181]**

Effect size	70% power	80% power	90% power
Small	676	860	1151
Medium	169	215	288
Large	76	96	128

Table 20 Estimated effect size in relation to change in mean PHQ-8 score, where the mean and standard deviation of PHQ-8 at time point 1 is taken from results from the Born in Bradford cohort of women**[182]**

Group	Mean	Standard deviation	Difference in means
Time point 1	12.8	7.4	
Time point 2: small effect size	11.8	7.4	1
Time point 2: medium effect size	10.8	7.4	2
Time point 2: large effect size	9.8	7.4	3

Table 21 provides indicative sample sizes required utilising change in mean transformed SWEMWBS scores according to effect size and power required as an example, assuming a significance level of 0.05 for a two sided t-test.[181] Effect sizes with respect to change in mean transformed SWEMWBS score used to inform sample size calculations are detailed in Table 22.

Table 21 Indicative sample sizes required to detect change in mean transformed SWEMWBS scores according to effect size and power required, assuming a significance level of 0.05 for a two sided t-test**[183,184]**

Effect size	70% power	80% power	90% power
Small	297	377	505

Medium	75	95	127
Large	33	42	57

Table 22 Estimated effect size in relation to change in mean transformed SWEMWBS score, where the mean and standard deviation of transformed SWEMWBS scores at time point 1 is taken from results from the Born in Bradford cohort of women[182,183]

Group	Mean	Standard deviation	Difference in means
Time point 1	26.7	4.9	
Time point 2: small effect size	27.7	4.9	1
Time point 2: medium effect size	28.7	4.9	2
Time point 2: large effect size	29.7	4.9	3

Table 23 provides indicative sample sizes required utilising change in mean transformed EQ-5D-5L utility scores according to effect size and power required as an example, assuming a significance level of 0.05 for a two sided t-test.[181] Effect sizes with respect to change in mean transformed EQ-5D-5L utility score used to inform sample size calculations are detailed in Table 24.

Table 23 Indicative sample sizes required to detect change in mean transformed EQ-5D-5L utility score according to effect size and power required, assuming a significance level of 0.05 for a two sided t-test[179,185,186]

Effect size	70% power	80% power	90% power
Small	3200	4069	5448
Medium	1800	2289	3065
Large	1152	1465	1962

Table 24 Estimated effect size in relation to change in mean transformed EQ-5D-5L utility score, where the mean and standard deviation of PHQ-8 at time point 1 is taken from results from the Born in Bradford cohort of women[179,182,185,186]

Group	Mean	Standard deviation	Difference in means
Time point 1	0.650	0.0483	

Time point 2: small effect size	0.653	0.0483	0.03
Time point 2: medium effect size	0.654	0.0483	0.04
Time point 2: large effect size	0.655	0.0483	0.05

5.3.6 DATA ANALYSIS

Participant recruitment rate, retention rate and completeness of health, wellbeing and financial outcome measures are presented descriptively for participants. Baseline sociodemographics and all health, wellbeing and financial outcome measures are also presented descriptively for participants. Where data are parametric, mean values and standard deviation (SD) are presented. Where data are non-parametric, median values and the interquartile range (IQR) are presented. Missing data on measures was small for most variables and was not adjusted for in the analyses. All statistical analyses were carried out using Stata 15.[162]

5.3.6.1 SELF-REPORTED FINANCIAL SECURITY

Multiple logistic regression models were used to explore individual differences in self-reported financial security before and after the provision of welfare advice.

5.3.6.2 MENTAL HEALTH, WELLBEING AND HEALTH-RELATED QUALITY OF LIFE

Mean PHQ-8, transformed SWEMWBS, transformed EQ-5D-5L utility scores and VAS scores are considered to approximate to a normal distribution with sufficient sample sizes.[100,183,187] Multiple linear regression models were used to explore individual change in PHQ-8, transformed SWEMWBS, transformed EQ-5D-5L utility scores and VAS scores before and after the provision of welfare advice. To minimise regression to the mean, financial outcome data were also included in regression analyses where available. Where data were non-parametric Spearman’s rank co-efficient was used.

McNemar test was used to explore change in clinically relevant symptoms of depression, wellbeing and EQ-5D categories before and after the provision of welfare advice. Fischer’s exact test was used where sample sizes were small (<5) for individual categorical variable stratum.

5.3.6.3 WELFARE AND FINANCIAL OUTCOMES

Data collected on type and range of welfare advice provided for each participant, alongside financial outcomes awarded for participants, are presented descriptively. To calculate a return on investment measure, the total financial gains for all participants were divided by the total cost of the service to commissioners over the data collection period. Total financial gain includes any additional income gained, one off payments and any debt managed for participants. Participants with missing financial outcome data were excluded from this analysis.

The inclusion of a health-related quality of life measure within this evaluation facilitates a cost utility analysis. The quality-adjusted life year (QALY) is a composite indicator combining quality and quantity of life in a single index.[188] Health states and utility scores can be calculated using various techniques or by means of pre-scored health state scoring systems, such as the EuroQol 5Q-5D tool utilised in this evaluation.[107] To calculate the QALY value for this intervention, the utility value associated with a given state of health was multiplied by the years lived in that state (1 year of life x 1 utility = 1 QALY).[188]

5.3.7 ETHICS

Ethics approval was sought and granted from the Hull York Medical School, see Appendix A.4.1. Ethical principles, Good Clinical Practice and Research Governance were upheld by providing participant information sheets, obtaining informed written consent and adhering to the approved study protocol. Health Research Authority approval was also received to conduct qualitative interviews with selected general practice participants, see Appendix A.4.2, although this element of the evaluation was no longer feasible owing to general practice workload in the recovery of the COVID-19 pandemic.

5.3.8 DATA MANAGEMENT

Routine project monitoring data and results of the participant questionnaires were collated by the welfare advisors and sent monthly to the VCS Alliance. The required data were anonymised and extracted by the VCS Alliance Data Manager and transferred to the Bradford Institute of Health Research via encrypted USB. A data protection impact assessment was conducted for the purposes of sharing data between the VCS Alliance and BIHR, see Appendix A.4.14. The Data Sharing Agreement established between the VCS Alliance and BIIHR can be found in Appendix A.4.13.

5.4 RESULTS

5.4.1 RECRUITMENT AND RETENTION

Participants were recruited into the study between 1st March 2022 and 28th February 2023, with follow-up completed by 31st May 2023. During the study recruitment period, a total of 893 clients were referred into the VCS Alliance welfare advice programme and accessed the welfare advice services. Of these clients, a total of 181 participants were recruited into the study, see Figure 11. Thereby, the recruitment rate for this study was calculated as 20.3%.

Initially, there was some confusion on the part of the welfare advisors regarding the eligibility criteria for participant recruitment. One provider recruited individuals into the study who were not referred through the VCS Alliance welfare advice programme by a primary care practitioner and were clients who had accessed the welfare advice service via other means, for example via walk-in. A total of 162 non-VCS Alliance participants were recruited and a total of 8 participants had completed follow-up surveys. Upon recognition, this error was explained to the participants involved and no further non-VCS Alliance clients were approached for follow-up. All non-VCS Alliance participants were excluded from the analysis.

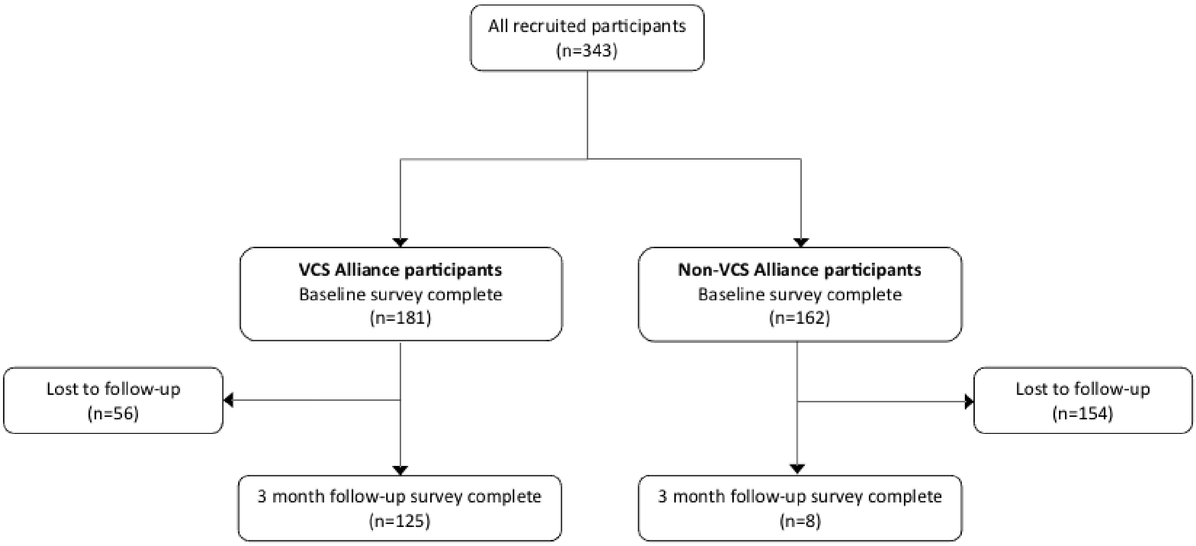

Figure 11 Consort diagram for the feasibility evaluation of a welfare advice service co-located in primary care in Bradford

Of the 181 eligible participants recruited into the study, 125 participants completed the 3-month follow-up survey. The overall retention rate for this study was therefore calculated as 69%.

A total of nine welfare advice providers worked collaboratively to deliver the VCS Alliance welfare advice programme. Five out of the nine providers recruited participants into the evaluation, with one provider (Provider 1) contributing the majority of the participants to the study (n=89). One provider (Provider 4) did not complete any follow-up surveys with participants. When limiting the sample population to clients referred to the five participating providers, the recruitment rate rose from 20.3% to 27%, see Table 25. It is not known why four provides did not recruit any participants. It was suggested by the VCS Alliance that this may because they did not agree with the utility of the evaluation in demonstrating the value of the services or to avoid additional administrative burden.

Table 25 Participant recruitment and retention rate by individual provider.

	Provider 1	**Provider 2**	**Provider 3**	**Provider 4**	**Provider 5**	**Total**
Service provided	Core	Complex	Core	Core	Core	
Referrals and welfare advice received (n)	116	91	182	168	107	664
Baseline survey complete (n)	89	10	48	14	20	181
Recruitment rate (%)	**77**	**11**	**26**	**8**	**19**	**27**
3-month follow-up survey complete (n)	88	5	12	0	20	125
Retention rate (%)	**99**	**50**	**25**	**0**	**100**	**69**

5.4.2 COMPLETENESS OF OUTCOME MEASURES

The completeness of outcomes measures was calculated at baseline, 3-month follow-up and overall for the study evaluation with respect to: self-reported financial security; mental health, wellbeing and health-related quality of life; and financial outcome measures.

Overall, the majority of key outcome measures were extremely well completed. The additional sociodemographic variables added to the baseline survey questionnaire to improve understanding of participant socioeconomic security and how this is experienced were completed by most participants (94-99%). Participant response rate for self-reported financial security was also high at follow-up (95%). The completeness of health, wellbeing and health-related quality of life outcomes was universally high (99%) across the evaluation overall.

Completeness of financial outcome measures collected by the VCS Alliance providers was variable. The completeness of type of welfare advice case work managed for participants was high (100%). However, it was difficult to know whether any types of case work were missing given that more than one type of case work was often managed per participant. Financial outcomes were not well completed in comparison to other outcome measures (45%). The majority of participants (55%) were documented to be still awaiting the outcome of their claims. No detail was included on any debt managed.

5.4.3 STUDY POPULATION

Table 26 describes the sociodemographics of the study participants who completed baseline and 3-month follow-up surveys (n=125). Participants who were referred into the welfare advice service via the VCS Alliance welfare advice programme and consented to be part of the evaluation had a mean age of 49 (SD 11.8) years. A greater proportion of participants were female (63%) than male (36%). The majority of participants were living with a partner (59%), with 27% of participants being single, 10% being widowed and less than 5% reporting their current relationship status as no longer living with a partner. 33 (27%) participants reported that they were single parents.

Participants were predominately of Pakistani Heritage: 82 (87%) were of Pakistani Heritage; less than 5% identified as White British; and 10 (9%) were of other ethnic groups. There was a wide range of preferred languages reported by participants: 29 (30%) reported their preferred language as Punjabi; 18 (18%) as Mirpuri; 18 (18%) as Urdu; 15 (15%) as English; and 18 (18%) as another language.

Over half of participants (58%) reported that they had a physical or mental health concern at the time of accessing the welfare advice service: 31 (32%) reported having a mental health condition; 29 (30%) reported a physical or other disability; and 9 (9%) reported a long-term health condition.

The majority of participants reported that the main earner in the household was unemployed (79%). A small proportion of participants reported that the main earner in the household was employed (15%) or self-employed (7%). 16% of participants were worried about the job security of the main earner in the household over the next year, compared to 6% of participants who were not.

At the time of accessing welfare advice services, most participants (64%) reported that they often worried about eviction or losing their home, compared to 25% of participants who sometimes worried about losing their home and 23% of participants who never worried. Similarly, most participants (52%) reported that they often worried about food lasting, compared to 33% of participants who sometimes worried about losing their home and 15% of participants who never worried.

There were some differences observed between the study population and the general VCS Alliance population. The majority of the study population were between the ages of 35-44 (34%) and 45-54 (32%), whereas there was a smaller proportion of people in these age groups in the general population (24%) and (24%), with greater numbers and more even spread of people across other age groups. There was a greater proportion of Pakistani Heritage participants in the study population (87%) compared to the general VCS Alliance population (69%), with a greater proportion of study participants in the 'Other' (9%) ethnic group compared to the general study population (22%). Participants in the study population were more likely to be of Muslim faith (94%) and less likely to be of Christian faith (<5%) compared to the general population (73% and 12% respectively). Study participants were less likely to report English as their first language (15%) compared to the general population (58%) and more likely to report Punjabi (30%) and Mirpuri (18%) as their preferred language compared to the general population (6% and 1% respectively).

Table 26 Sociodemographic characteristics of study participants, participants lost to follow-up and the general VCS Alliance population

	Study participants		**Participants lost to follow-up**		**VCS Alliance population**
	Number (n=125)	**Frequency (%) (95% CI)[*]**	**Number (n=56)**	**Frequency (%) (95% CI)**	**Frequency (%) (95% CI)**
Gender					
Female	63	63 (55-74)	26	47 (34-61)	62
Male	36	36 (26-74)	29	53 (39-66)	38
Missing	26		<5		
Age					
18-24	<5	<5	<5	<5	7
25-34	6	6 (3-13)	<5	<5	13
35-44	34	34 (26-44)	<5	<5	24
45-54	32	32 (24-42)	13	23 (14-36)	24
55-64	12	12 (7-20)	37	66 (53-77)	17
65 and above	15	15 (9-24)	<5	<5	15
Missing	24		<5		
Current relationship status					
Living with partner	59	60 (50-69)	37	68 (55-80)	54
No longer living with partner	<5	<5	<5	2 (0-13)	2
Single	27	27 (19-37)	10	19 (10-31)	38
Widowed	10	10 (5-18)	6	11 (5-23)	6
Missing	25		<5		
Whether single parent					
Yes	33	27 (20-35)	19	35 (23-48)	-

Table 26 Sociodemographic characteristics of study participants, participants lost to follow-up and the general VCS Alliance population

	Study participants		Participants lost to follow-up		VCS Alliance population
	Number (n=125)	**Frequency (%) (95% CI)[*]**	**Number (n=56)**	**Frequency (%) (95% CI)**	**Frequency (%) (95% CI)**
No	91	73 (65-80)	36	65 (52-77)	-
Missing	<5		<5		
Ethnicity					
Pakistani Heritage	82	87 (81-96)	20	36 (29-41)	69
White British	<5	<5	31	55 (46-60)	9
Other	10	9 (5-14)	<5	<5	22
Missing	30		<5		
Religion					
Christian	<5	<5	17	38 (25-53)	12
Hindu	<5	<5	<5	<5	1
Muslim	89	94 (86-97)	25	56 (41-70)	73
Other	<5	<5	<5	<5	14
Missing	23		11		
Preferred language					
English	15	15 (9-24)	46	84 (71-91)	58
Urdu	18	18 (12-27)	<5	<5	25
Punjabi	29	30 (21-39)	7	13 (6-25)	6
Mirpuri	18	18 (12-27)	<5	<5	1
Other	18	18 (12-27)	<5	<5	10
Missing	27		<5		

Table 26 Sociodemographic characteristics of study participants, participants lost to follow-up and the general VCS Alliance population

	Study participants		Participants lost to follow-up		VCS Alliance population
	Number (n=125)	**Frequency (%) (95% CI)[*]**	**Number (n=56)**	**Frequency (%) (95% CI)**	**Frequency (%) (95% CI)**
Self-reported health issues					
Long term health condition	9	9 (5-17)	21	38 (27-53)	12
Physical or other disability	29	30 (21-39)	<5	2 (0-6)	32
Mental health condition	31	32 (23-42)	9	17 (9-29)	21
Other	<5	<5	15	27 (17-41)	9
None	25	26 (18-35)	9	16 (9-29)	26
Missing	27		<5		
Employment status of main earner in household					
Employed	15	15 (9-23)	14	26 (16-39)	-
Self-employed	7	7 (3-14)	<5	6 (2-16)	-
Unemployed	81	79 (70-86)	36	67 (53-78)	-
Missing	22		<5		
Worry about job security of main earner in household					
Yes	20	16 (10-24)	21	39 (27-53)	-
No	7	6 (3-24)	6	11 (5-23)	-
Don't know	97	78 (70-85)	27	50 (37-63)	-
Missing	<5		<5		
Worry about eviction					
Never	29	23 (17-32)	20	35 (24-49)	-
Sometimes	31	25 (18-33)	25	45 (32-58)	-

Table 26 Sociodemographic characteristics of study participants, participants lost to follow-up and the general VCS Alliance population

	Study participants		**Participants lost to follow-up**		**VCS Alliance population**
	Number (n=125)	**Frequency (%) (95% CI)***	**Number (n=56)**	**Frequency (%) (95% CI)**	**Frequency (%) (95% CI)**
Often	64	52 (43-60)	11	20 (11-32)	-
Missing	<5		<5		
Worry about whether food will last					
Never	19	15 (10-23)	23	41	-
Sometimes	41	33 (25-42)	21	37	-
Often	65	52 (43-61)	12	22	-
Missing	10		<5		

*Frequency calculations do not include missing data

- denotes data that is unavailable

Some differences were observed between participants who engaged in follow-up and participants lost to follow-up. Participants who were lost to follow-up were slightly older with a mean age of 56 (SD 9.5) years. There was a greater proportion of males in the lost to follow-up group (53%) compared to the general study participants (36%), creating a more balanced split between males and females. Participants who were lost to follow-up were more like to be White British (55%) and report English as their preferred language (84%) compared to those who participated in follow-up (less than 5% and 15% respectively). More participants who were lost to follow-up lived in a household where the main earner was employed (26%) compared to those followed up at 3 months (15%) and fewer participants lived in a household where the main earner was unemployed (67%) compared to the follow-up group (79%). A greater proportion of participants who were lost to follow-up reported having a long-term health condition (38%) and less likely to have a physical disability (2%) or mental health condition (17%) than study participants who were not lost to follow-up (9%, 30% and 17% respectively). Finally, participants who were lost to follow-up were less likely to report being worried about eviction (35%) and whether food will last (41%), reporting that they never worried about these issues, compared to those not lost to follow-up (23% and 15% respectively). There was no observed difference in current relationship status, single parent status or employment status between those who participated in the 3-month follow-up and those who did not.

5.4.4 SELF-REPORTED FINANCIAL SECURITY

Most participants reported that they were finding it very (50%) or quite (15%) difficult to get by financially or were just about getting by (25%). Few participants reported living comfortably (less than 5%) or doing alright (7%) at the time of accessing the welfare advice services.

Fewer participants reported feeling financially insecure at their 3-month follow-up appointment (59.42% 95% CI 50.68%, 68.11%) compared to baseline (64.31% 95% CI 56.53%, 73.68%), see Table 27. The difference between these groups was small and the reported p-value for this difference was 0.059 suggesting that there may be little evidence for the utility of this outcome measure to detect a change at this point in time.

Table 27 Results of a multiple logistic regression model demonstrating the effects of a welfare benefits advice programme on the health, wellbeing and financial security of participants between baseline and 3-month follow-up, adjusting for known financial outcomes

	Baseline		3-month follow-up		
	Number	**Frequency (%) (95% CI)**	**Number**	**Frequency (%) (95% CI)**	**p-value**
FINANCIAL SECURITY					
Self-reported financial insecurity (Baseline n=125, Follow-up n=119)					
Secure	44	35.59 (27.32-44.47)	48	40.58 (32.89-49.32)	0.059
Insecure	81	64.41 (56.53-73.68)	71	59.42 (50.68-68.11)	0.059
MENTAL HEALTH					
PHQ total score	**Median**	**Interquartile range**	**Median**	**Interquartile range**	
PHQ total score	13.00	4.00-20.00	12.00	2.50-19.50	0.344
Clinically relevant symptoms of depression	**Number**	**Frequency (%) (95% CI)**	**Number**	**Frequency (%) (95% CI)**	
No or few clinically relevant symptoms of depression	51	40.80 (32.31-49.17)	54	43.31 (34.10-52.09)	0.414
Clinically relevant symptoms of depression	74	59.20 (50.83-67.69)	71	56.69 (47.91-65.90)	0.414
WELLBEING					
SWEMWBS score	**Median**	**Interquartile range**	**Median**	**Interquartile range**	
Adjusted score	17.98	15.32-23.35	19.25	15.84-24.11	0.048
SWEMWBS category	**Number**	**Frequency (%) (95% CI)**	**Number**	**Frequency (%) (95% CI)**	
High wellbeing	76	60.73 (51.96-69.00)	73	58.54 (49.76-67.47)	0.027
Average wellbeing	26	20.08 (14.90-28.25)	33	26.04 (19.72-35.28)	0.027
Low wellbeing	23	23.19 (12.49-26.11)	18	14.42 (9.83-22.67)	0.027
HEALTH-RELATED QUALITY OF LIFE					

Table 27 Results of a multiple logistic regression model demonstrating the effects of a welfare benefits advice programme on the health, wellbeing and financial security of participants between baseline and 3-month follow-up, adjusting for known financial outcomes

	Baseline		3-month follow-up		
	Number	**Frequency (%) (95% CI)**	**Number**	**Frequency (%) (95% CI)**	**p-value**
EQ-5D-5L score	**Mean**	**Standard deviation**	**Mean**	**Standard deviation**	
VAS score	50.82	25.40	54.93	27.35	<0.001
EQ-5D health state index score	**Number**	**Interquartile range**	**Number**	**Interquartile range**	
EQ-5D health state index score	0.4535	0.117-0.887	0.587	0.100-0.887	<0.001

5.4.5 MENTAL HEALTH, WELLBEING AND HEALTH-RELATED QUALITY OF LIFE

Following access to welfare advice services, participants experienced improvements across all mental health, wellbeing and health-related quality of life domains. Mean group PHQ-8 scores fell from 13.00 (IQR 4.00, 20.00) at baseline to 12.00 (IQR 2.50, 19.50) at 3-month follow-up. The proportion of participants with symptoms suggestive of clinical depression fell from 59.20% (95% CI 50.83%, 67.69%) to 56.69% (95% CI 47.91%, 65.90%). This change was small and not statistically significant (p value 0.344 and 0.414 respectively). However, the sample size was not sufficient to detect any meaningful change should there be one.

Wellbeing improved between baseline and follow-up following receipt of welfare advice and support. Mean group adjusted SWEMWBS scores improved from 17.98 (IQR 15.32, 23.35) at baseline appointments to 19.25 (IQR 15.84-24.11) at follow-up appointments. Following access to services, a greater proportion of participants were found to have average wellbeing categorical scores (26.04% 95% CI 19.72%, 35.28%) compared to baseline (20.08% 95% CI 14.90%, 28.25%) and a smaller proportion of participants were found to have low wellbeing categorical scores (14.42% 95% CI 9.83%, 22.67%) compared to baseline (23.19% 95% CI 12.49%, 26.11%). Improvements in mean group participant wellbeing SWEMWBS scores and improved wellbeing categories were found to be statistically significant, demonstrating evidence of promise for improvements in wellbeing following access to services (p value 0.048 and 0.027 respectively).

Mean group EQ-5D-5L VAS scores improved from 50.82 (SD 25.40) at baseline to 54.93 (SD 27.35) following welfare advice at 3-month follow-up. Mean group EQ-5D health state index scores also demonstrated improvements from 0.4535 (IQR 0.117, 0.887) at baseline to 0.587 (IQR 0.100, 0.887) at 3-month follow-up. Improvements in mean group participant health-related quality of life VAS scores and health state index scores were found to be statistically significant, demonstrating evidence of promise for improvements in wellbeing following access to services (p value <0.001 respectively).

5.4.6 WELFARE AND FINANCIAL OUTCOMES

The VCS Alliance welfare advice programme provided a wide range of welfare advice and support to participants throughout the evaluation period, see Table 28.

Table 28 Type and range of welfare advice work provided

Welfare advice case work	Number (n)	Frequency (%)
Attendance Allowance	7	3%
Benefits Check	10	5%
Bereavement Support Payment	2	1%
Blue Badge Application	3	1%
Carers Allowance	7	3%
Child Benefit	5	2%
Child Maintenance	3	1%
Child Tax Credit	0	0%
Community Care	1	0%
Consumer Goods & Services	4	2%
Council Tax	11	5%
County Court Judgement (N245)	0	0%
Debt	3	1%
Disabled Bus Pass	3	1%
Disabled Facilities Grant application	0	0%
Disability Living Allowance	11	5%
Education	1	0%
Employment	5	2%
Employment and Support Allowance	4	2%
Food Parcel	0	0%
Free School Meals	0	0%
Funeral Payment	1	0%
Grant	2	1%
Housing	12	5%
Housing Benefit	0	0%
Immigration	3	1%
Income Support	2	1%
Insurance	1	0%
Job Seekers Allowance	0	0%
Legal Expenses	3	1%
Mandatory Reconsideration	2	1%
National Insurance (NINO) Application	0	0%
Passport	9	4%
Pension Advice	2	1%
Pension Credit	3	1%
Personal Independence Payments	50	23%
Private Pension Form	0	0%
Relationships & Family	0	0%
Respite Care	0	0%

Table 28 Type and range of welfare advice work provided

Welfare advice case work	Number (n)	Frequency (%)
School Transport	1	0%
State Pension	4	2%
Statutory Sick Pay	0	0%
Student Finance Application	0	0%
Universal Credit	24	11%
Utility Bills	11	5%
Working Tax Credit	7	3%
Other	3	1%

There were a total of 220 welfare advice issues managed with an average of 1.76 welfare advice work issues managed per participant. The most frequent welfare advice and support provided was associated with benefits eligibility checks and applications (5%), including Personal Independence Payments (23%), Universal Credit (11%), Disability Living Allowance (5%), Attendance Allowance (3%), Working Tax Credit (3%) and Carers Allowance (3%). Welfare advisors also commonly provided support with utility bills (5%), council tax (5%) and housing issues (5%). As previously reported, all participants had a type of welfare advice work provided documented. However, participants often received advice and support on more than one issue. Therefore it is not clear if any type of advice work is missing from this information. Given the high completeness it is considered unlikely.

Of the 125 participants who completed follow-up, 56 participants had complete financial outcome data. For these participants, the welfare advice service generated a total financial gain of £21,823.05. Participants with complete data on their financial outcome gained an average of £389.70 per participant, with a range of £0 to £9878.45 awarded per participant and a median of £34.12 following access to the service.

As has been reported, four out of nine providers did not provide recruit participants for this evaluation. Furthermore, the participants recruited from the five providers who were able to recruit participants to this evaluation did not represent the entirety of the client base for these providers. Therefore, it is not appropriate to extrapolate the costs of the service to the costs of the service for solely for the participants included in this evaluation. This issue, in conjunction with the lack of completeness of financial outcome data, led to the conclusion that it would be inappropriate to conduct any further economic analysis, including a return of investment for commissioners, nor a calculation of the quality adjusted life years for this intervention.

5.5 DISCUSSION

5.5.1 SUMMARY OF KEY FINDINGS

This chapter describes some of the key impacts of a welfare advice service co-located in primary care on participant health, wellbeing and financial security. It explores whether a cost utility approach to an economic evaluation is feasible and whether the proposed evaluation tools are suitable to evaluate this intervention with respect to recruitment rate, retention rate and completeness of outcome measures.

Overall, there were low participant recruitment rates into the study. It is unclear to what degree this reflects a lack of engagement from some of the welfare providers and associated welfare advisors and a lack of engagement from potential participants. The recruitment rate rose slightly from 20.3% to 27.7%, when limiting the calculation to providers who recruited participants into the study suggesting that there was an element of inter-provider variation in participant recruitment rate. Therefore there may be individual provider level factors affecting the ability or willingness of providers and the associated welfare advisors to engage with the evaluation. It may also reflect a potential difference in client base between providers. It is not clear why there was variation in recruitment and retention rates between providers and welfare advisors. An evaluation of the welfare advice service in conjunction with an academic partner was a requirement for funding for this service. It was suggested anecdotally by senior leaders within the VCS Alliance that the variation may relate to some providers and welfare advisors having difficulty in realising the benefit of having the evaluation and not wishing to take on the administrative burden. However, this assumption was not formally assessed and warrants further research.

The calculated retention rate (69%) was high and comparable to a similarly conducted evaluation. Woodhead et al. reported a retention rate of 71.6% for an evaluation of a welfare advice service conducted in Tower Hamlets, London utilising financial incentives for participation in follow-up.[64] Explanations for this could include the timing of follow-up to fall in line with completion of welfare advice case work and the use of financial incentives, which is also comparable to similarly conducted evaluations.[64]

There were some significant differences between the study population and participants lost to follow-up. Notably, participants who were lost to follow-up were more likely to be White British (55%) and report English as their preferred language (84%) compared to those who participated in follow-up (less than 5% and 15% respectively). More participants who were lost to follow-up lived in a household where the main earner was employed (26%) compared to those followed up at 3 months (15%) and fewer participants lived in a household where the main earner was unemployed (67%) compared to the follow-up group (79%). Moreover, participants who were lost to follow-up were less likely to report being worried about eviction (35%) and whether food will last (41%), reporting that they never worried about these issues, compared to those not lost to follow-up (23% and 15% respectively). These findings could suggest that participants who were lost to follow-up were reflective of the more financially secure participants. However, disparities between each provider client base and the variation in retention rate between providers may also contribute to the observed difference between study participants and those lost to follow-up.

Overall, the majority of key outcome measures were well completed, indicating participant acceptability of these measures in this participant population. Participant response rate for job security of the main earner in the household was also high (98%), however the majority of participants reported that they did not know whether they were concerned about the employment status of the main earner in the household (78%). This uncertainty may reflect the high unemployment rate of the main earners in the household of this participant group (79%) who may have not found this question relevant or may have found this question difficult to answer for this reason. Financial gains outcomes were not well completed in comparison to other outcome measures (45%), however this data were collected and reported by the VCS Alliance.

There was evidence suggestive of an improvement in the felt and lived experience of financial security for participants following access to these services. However, this improvement was small and demonstrated little evidence of promise of a significant impact on self-reported financial security following access to services. A larger sample size may increase the statistical power to detect a change in this area should there be one. However, this finding may indicate that a longer duration of follow-up may be required to detect a reported difference in financial security following access to services. Furthermore, this finding may suggest that levels of financial security have remained stable for many following access to the intervention, that may have worsened without access to the services.

This evaluation demonstrated evidence of promise for improvements in measured wellbeing and health-related quality of life for participants accessing services in a highly ethnically diverse population. There were small improvements in group mental health, as indicated by PHQ-8 scores, however this study was not powered sufficiently to detect any meaningful change in PHQ-8 scores. However, given that no control group was included for this study, it is not clear whether these associations are causal and the role of chance cannot be excluded.

This is the first known evaluation globally to utilise PHQ-8 and EQ-5D instruments to measure mental health and health-related quality of life in an evaluation of welfare advice services co-located in a health setting. Woodhead et al. reported improved wellbeing scores for participants whose advice resulted in positive outcomes (ß co-efficient 1.29, 95% 0.25-2.32).[64] Krska et al. also reported preliminary findings of improved WEMWBS scores at 3 month follow-up following receipt of welfare advice within a primary care setting, although these improvements were not quantified.[189] A study published by Howel et al. exploring the financial and health-related quality of life impacts of a co-located welfare advice service in a similarly deprived population found no intervention effect. Howel et al. explored outcomes at 24 months and suggests that where improvements might exist, they may not persist beyond this time.[173] Given that the findings of this evaluation are suggestive of improvements to wellbeing and quality of life, similar to other published evaluations, this indicates that research is required to further establish causality and to establish the magnitude of this association. In this evaluation, there was little evidence to suggest improvements in reported financial security alongside improvements in wellbeing and quality of life. This warrants further investigation to ascertain causality and the direction and magnitude of any impact on financial security and health and wellbeing.

Financial outcomes for participants of this study are lower in value in comparison to other published studies. Participants from the studies included in the systematic review of welfare advice services co-located in health settings, presented in Chapter 3, gained on average £1,840, with a range of £776 to £3656 gained on average per participant between published studies.[64,109,111,135,190,191]

Owing to a paucity of financial outcome data for participants and variation in recruitment and retention rates between and within providers, any further detailed economic analysis was not considered feasible nor appropriate. Costings for other published evaluations of such services were more detailed, including details of cost per participant to facilitate a more accurate calculation of return on investment. This may suggest that a three month follow-up period is not sufficient to collect financial outcome data and that future studies may benefit from a longer follow-up time to improve completeness of financial outcome data for participants.

5.5.2 LIMITATIONS

The reasons for lack of participation at baseline and at 3-month follow-up are not fully understood and may relate to provider or participant related factors. The overall low recruitment rate and demonstrable inter-provider variability in recruitment rates introduces the possibility of selection bias and therefore misleading findings. At follow-up, participant satisfaction and engagement with the welfare advice services may influence and correlate with the decision to engage with follow-up and therefore may overestimate the measured associations and improvements in wellbeing and health-related quality of life for participants. Comparing results with other studies of similar and differing populations is important to gain a fuller picture of the impact of co-located welfare advice services on mental health, wellbeing and health-related quality of life.

Welfare advisors were utilised to facilitate recruitment and to conduct the follow-up surveys. This approach was used to reduce administrative burden and to improve participation in the evaluation. However, this approach introduces the potential for response bias. Participants may have been inclined to respond more positively at follow-up when being asked to complete survey responses by the welfare advisor who has provided to support to them over the preceding three months.

A number of variables were collapsed to support the analysis owing to small sample sizes within each strata across survey timepoints. For example, financial insecurity was defined as those ‘finding it quite difficult’ and ‘finding it very difficult’ to manage financially. Families ‘living comfortably’, ‘doing alright’ and ‘just about getting by’ were considered financially secure. Such categorisations were conservative and several mid-point categories could be considered true for either categorisation.

Financial outcome data were included in the regression analyses where these data were available. This approach was adopted to minimise potential regression to the mean. However, the feasibility analysis highlighted that financial outcomes were not well completed and therefore significant regression to the mean may persist despite attempts to minimise this.

Variation in reported outcome measures was not examined with respect to temporality, where there might have been seasonal themes emergent throughout the course of the year. Such variation could be expected during colder months where families face greater household costs with increased need for energy coupled with rising energy costs. Similarly, the analysis does not take into account additional temporary or alternative sources of financial support received by families, for example the Energy Bills Discount Scheme, Warm House Discounts and Cost of Living Payments introduced by the UK Government in 2023.[192] Furthermore, families may be receiving financial support from alternative and non-documented sources. For example, families from Pakistani Heritage communities in Bradford, have a long standing history of forming informal rotating savings and credit associations (ROSCA), as a means to establishing financial resilience for families.[193] These ROSCAs are often referred to as committees, pronounces 'kaametees' and are seldom spoken of outside of the committees in the community. These other forms of financial support may introduce unknown confounding into the results.

Follow-up was chosen for three months following completion of the baseline questionnaire, as this was considered most feasible to implement and would therefore maximise retention. However, it is unclear whether this follow-up time period is sufficient to measure changes to mental health, wellbeing and health-related quality of life associated with receipt of welfare advice that may take longer than three months to be realised. Conversely, any extension to the follow-up period also needs to be balanced against potential regression to the mean. It is possible that a longer follow-up period, or a second follow-up appointment, perhaps at six months might also improve completeness of financial outcome data that was low at three months follow-up.

Given that the data collection processes for participant sociodemographic data were already established prior to the development of the evaluation protocol and that a priority for the VCS Alliance and their providers was to utilise existing data collection processes as much as possible, some aspects of the sociodemographic data were limited. The main limitation was that it was not possible to ascertain what proportion of the participants were parents or caregivers. The transferability of these findings to a welfare advice service co-located in a health setting for mothers and their families should therefore be interpreted with this limitation in mind.

5.5.3 IMPLICATION OF FINDINGS

Future research in this area should give consideration to the method of recruitment of potential participants to ensure selection bias is minimised. Recruitment should be conducted by an independent researcher and recruitment offered to all potential participants in a standardised manner to minimise selection bias. Where possible, follow-up data collection should also be performed by an independent researcher to minimise observation bias.

This study offers evidence of acceptability and utility of the proposed evaluation tools to participants in receipt of welfare advice services to evaluate the impact of this intervention on the health, wellbeing and financial security of participants with respect to completeness of outcome measures and their ability to detect potential change in outcome measures for the intervention in the population. Chosen measures of mental health, wellbeing and health-related quality of life were extremely well completed and can be considered acceptable for use by participants in the evaluation of this intervention in this setting and within this unique and diverse population. However, the lack of engagement of some providers in this evaluation warrants further exploration of the acceptability of these tools to welfare advisors. It is clear that effort is required on the part of the research and administrative teams to follow-up financial outcome data in order to facilitate an appropriate economic analysis and that this may need to completed at a later point in time to improve completeness. Other approaches to obtaining timely, accurate and validated outcome measures should be considered to facilitate evaluations of co-located welfare advice services, for example routine data linkage. It is still unclear whether a cost-utility approach to economic analysis would be appropriate for an economic evaluation of a complex intervention of this nature.

This study also offers evidence of promise that welfare advice services co-located in health settings improve wellbeing and health-related quality of life in a highly ethnically diverse population, living in the most deprived centiles in the UK. There was little evidence to suggest that this intervention improves mental health, by means of improved PHQ-8 scores, however this study was not powered to detect small effect sizes with respect to change in PHQ-8 scores. Overall, the prospective of the outcome measures utilised for this evaluation to detect potential changes in mental health, wellbeing and health-related quality of life is positive even at short follow-up intervals. These indicative effect sizes can be utilised to guide sample sizes calculations of future evaluations. Future research could also consider the use of an additional follow-up period at six months to assess how impact to financial, mental health, wellbeing and health-related quality of life outcomes changes over time.

Inconsistencies in measured outcomes makes synthesis of evidence difficult, therefore the use of core outcome sets could be considered for future research and development in this area. The use of a core outcomes set has been promoted to harmonise the outcomes used, to facilitate meta-analysis where appropriate, particularly where achieving sufficient sample sizes may be challenging, and to ensure that key stakeholders are consulted on the relevance of what is being measured in evaluations.[194,195] The Core Outcome Measures in Effectiveness Trials (COMET) initiative supports the development of core outcome sets, largely for clinical trials, although includes some resources that may be more widely applicable.[196] However, a core outcome set is not yet available for welfare advice services. Indeed, few core outcome sets have been adapted specifically for public health research in the UK. A core outcome set for early years (COS-EY) has recently been published to increase standardisation and guide the selection of outcome measures for systems-based evaluation of public health programmes and supports evaluation of individual interventions within system change approaches.[197] Whilst this may prove useful for this complex intervention, before this core outcome set can be fully implemented, the authors highlight that further work is undertaken to confirm the definition of each outcome, prior to deciding on the most appropriate measures or data sources.[197]

QALY and ICER measures are used in economic evaluations to assess the value of health and social care interventions and thereby facilitate commissioning decisions. In the UK, the National Institute for Health and Care Excellence (NICE) sets an ICER threshold of £30,000 per QALY for health and social care interventions, which this intervention significantly exceeds.[198] NICE will not reject an intervention based on cost effectiveness alone, however it is a significant factor in the decision making process for approval of commissioning for health and social care interventions.[199] Future sufficiently powered research with complete financial outcome measures should consider re-evaluating a cost-utility approach, given its value to commissioners. However, consideration should also be given to a more comprehensive approach to economic evaluation given the complexity of co-located welfare advice services as interventions.

There are also a number of emerging methodologies that can lend themselves to economic evaluations of complex interventions, such as a Social Return on Investment.[141] These are not usually considered to be standard tools for economic evaluation owing to theoretical weaknesses and their handling of outcomes, but they are becoming more commonly used in the area of complex interventions. Such approaches are not mutually exclusive and if considered a feasible approach to economic evaluation, a cost-utility analysis could be conducted and embedded in a wider social return on investment or cost-consequences analysis that provides data on a more comprehensive inventory of outcomes.[172] A cost-consequences approach or social return on investment could also facilitate the inclusion of other outcome measures, as indicated within the theory of change model, within the economic analysis, such as the impact on the NHS and social care system.

Future research could also consider utilising modelling approaches to understand to what extent improvements in short-term income and mental health, wellbeing and health-related quality of life can impact medium to long term outcomes. Such modelling could then be used to inform an economic evaluation over a lifetime horizon.

5.6 CONCLUSION

Existing published literature evaluating the impact of welfare advice services co-located in health settings has published evidence suggestive of improvements to financial security and to the health and wellbeing of participants in receipt of this intervention. However, no consensus has been achieved on the most appropriate measures for these outcomes, nor an appropriate time frame within which to follow-up participants, particularly in a diverse and deprived population.

This chapter demonstrated the feasibility of evaluating a welfare advice service co-located in primary care utilising the PHQ-8, SWEMWBS and EuroQol EQ-5D tools, as measures of mental health, wellbeing and health-related quality of life respectively. This chapter also highlights the importance of achieving adequate completeness of financial outcome measures, with respect to financial outcomes for participants and the associated costs for commissioners and service providers. These outcomes measures are important to fully understand the impact of the services on participant financial security and how these interplays with other factors, such as participant health and wellbeing. This chapter also highlights the importance of these outcome measures for a wider economic analysis and to improve the value of these calculations and analysis to researchers, the wider community and to commissioners.

Finally, this chapter provides further evidence of promise to support the hypothesis that the implementation of a welfare advice service co-located in a health setting can improve health and wellbeing.

The following chapter seeks to further explore the acceptability and feasibility of evaluating a welfare advice service co-located in health settings for mothers and their families. It explores how best to measure participant financial security, particularly those in an ethnically diverse population and specifically explores the feasibility and acceptability of utilising data linkage as a measure of financial security within the context of an evaluation of welfare advice services co-located in health settings for mothers and their families.

CHAPTER 6 EXPLORING ATTITUDES AND VARIATION BY SOCIODEMOGRAPHIC FACTORS IN CONSENT PROVIDED FOR FINANCIAL DATA LINKAGE

This chapter explores the feasibility and acceptability of establishing a data linkage pathway with government agencies as a means of obtaining information regarding participant income and financial security within the Born in Bradford Better Start (BiBBS) cohort. The chapter begins by describing the value and importance of having an accurate understanding of financial security in research. It goes on to discuss how data linkage can be used in health research to link individuals with their income and benefits data in order to better understand financial security for individuals and their communities. The chapter then explores the feasibility and acceptability of utilising income and benefits data linkage, as a measure of financial security, within the particular context of the BiBBS cohort study.

6.1 INTRODUCTION

Improving our understanding of household incomes and what constitutes financial insecurity for families can help us to better understand how financial insecurity is experienced and how this can change over time within and between individuals and populations.

Having an accurate understanding of financial insecurity can also help researchers, commissioners and policy makers to have a better understanding of what works to improve the financial security of individuals and communities and the impact this has on health and wellbeing and health inequalities. It can also improve our understanding of who needs financial assistance, who receives an intervention to improve financial security and thus improve our understanding of the reach of the service. Furthermore, validated financial outcome data can also facilitate and improve the accuracy of health economic analyses.

6.1.1 FINANCIAL SECURITY DATA

Information regarding financial security can be obtained from a variety of data sources. Often, participants are asked directly for a measure of their income and may be asked to provide a self-reported subjective measure of financial security. For example, BiBBS participants at the time of recruitment are asked “How would you say you are managing financially right now?”.[89] Answer options include: living comfortably; doing alright; just about getting by; finding it quite difficult; and finding it very difficult. Participants may also be asked for a broad measure of individual or household income, for example less than £600, more than £1000, and more than £2000 per month.[200] Participants may also be asked to declare if they are in receipt of state benefits and to provide an indication of the specific benefits to which they are entitled or receive. Financial outcome data can also be collected from third party sources, such as partners and other family members. These outcome measures are important measures required to improve our understanding of a person's subjective assessment of financial security and their experience of financial insecurity.

However, there are several limitations to using these approaches exclusively. Income and being eligible for or in receipt of financial benefits are often seen as sensitive issues to discuss and can feel stigmatising.[201-203] Some participants may not be willing to disclose such financial data or financial concerns. Furthermore, when reporting household financial circumstances, participants may feel uncomfortable providing information about their partner or other household financial circumstances, without their prior consent.[201-203] Given the sensitivities around the discussion and disclosure of financial circumstances, levels of income, financial security, debt or being in receipt of benefits may be over or under-estimated depending on the context.

It has also been reported that some participants, for example women from ethnic minority backgrounds, may be unaware of the details of household financial circumstances such as was found to be the case in the Born in Bradford Research Programme. During the development of pilot baseline questionnaire surveys for the Born in Bradford Research Programme, questions were initially included that asked participants directly what their household income was. It was found that these questions were poorly answered because the women, particularly from a Pakistani Heritage background, did not know their income. This question was therefore removed from the baseline questionnaire. In replacement, participants are now asked financially secure they feel. Gaining an in depth understanding of the financial security of participants and their families, can be challenging, particularly in certain groups, and it can therefore be difficult to accurately measure the impact of interventions and other internal and external factors on financial security and those effects over time.

Obtaining validated income and benefits data could be a useful method of overcoming some of the subjectivity and challenges inherent with other self-reported measures. Validated income and benefits data can be obtained through financial statements or payslips. Validated financial data can also be obtained through data linkage processes, acquiring validated income and benefits data from third party sources, such as the Department for Work and Pensions (DWP) and His Majesty's Revenue and Customs (HMRC).

6.1.2 DATA LINKAGE IN HEALTH RESEARCH

Data linkage is a method of bringing discrete data sources together into a single dataset.[204] Data linkage usually occurs at an individual level but can incorporate information held at a household, organisational and area level. Data held within discrete databases may belong to the same organisation but often is held by different external organisations and between different sectors.

Data linkage processes can create rich data sets that provide a detailed picture of individuals and their families, communities and populations. Such data can permit entire populations to be studied and reduces common follow-up problems encountered in survey-based research designs. Data linkage processes can be seen as less intrusive and costly than collecting bespoke data, and allows entire populations to be studied over longer periods of time.[205] Data sets created through data linkage processes are, however, limited by the quality and completeness of the original data sources and researchers have little ability to influence the data or quality of data collected from the various sources.

Data linkage in health research can provide an effective way of obtaining objectively measured outcome variables.[206] Although health data is regarded as personal and private, it appears acceptable to share in a trusted medical context. A recent narrative review of both quantitative and qualitative studies to explore predominant patient and public views and attitudes towards data sharing for health research identified that participants largely understood the benefits of sharing and linking data to improve health research and health outcomes.[201] The main concerns expressed related to confidentiality, data security, awareness about access and control, and the potential harms resulting from these risks. However, privacy protecting measures, such as data de-identification, use of secured databases, and improved transparency and information about data sharing processes and responsibilities increased willingness to share.[201] Research exploring the perceptions of people from ethnic minority communities have found that they are more concerned about health data linkage than other groups.[202] However, they have also described how they often do not see evidence of data on their race, ethnicity, culture, or religion often being considered and feel under-represented in research.[203] Data linkage for health and educational records in the Born in Bradford Better Start (BiBBS) cohort study is reported to be high; greater than 99% of participants consent to data linkage with health and educational records.[207]

6.1.3 FINANCIAL DATA LINKAGE IN HEALTH RESEARCH

The DWP is responsible for welfare, pensions and child maintenance policy in the UK.[50] They collect and hold personal and household data on benefits claimed and data on eligibility for benefits. HMRC is the tax, payments and customs authority of the UK government. It is responsible for collecting taxes, paying child benefits, enforcing tax and customs laws, and enforcing the payment of minimum wage by employers.[208] There are a number of cohort studies conducting health research that have already established data linkage pathways with the DWP and HMRC in order to better understand the impact of their research on the financial security of their participants.[209,210]

There are a number of longitudinal population studies conducting health research that have already established data linkage pathways with the DWP and HMRC in order to better understand the impact of their research on the financial security of their participants.[209,210] The English Longitudinal Study of Aging (ELSA) reports a 79% consent rate for linkage of participants to their benefits and income data through their national insurance number.[211] The Next Steps Age 25 Survey reports consent rates of 70% for data linkage with DWP and 65% for data linkage with HMRC.[212]For the Avon Longitudinal Study of Parents and Children (ALSPAC) and Project to Enhance ALSPAC through Record Linkage (PEARL) studies, the consent rates for data linkage are slightly lower at 59% for the DWP and 57% for HMRC.[209,213] Overall, the level of consent for data linkage in such longitudinal population studies remains higher for other records, such as educational and health records, than for financial records. Where done well data linkage can ameliorate research inequities through improvements in data completeness and representativeness. However, without careful design and implementation, information governance barriers and the potential for bias can risk exacerbating inequalities in longitudinal population studies utilising data linkage.

Furthermore, research has highlighted that some data uses and data linkage processes are more concerning for participants than others and that context is important. People trust the health sector, including health researchers, more than they trust other organisations, such as the DWP and HMRC.[214,215] Research also highlights that trust in the health sector could be at risk of being diminished by the involvement of less trusted parties.[202] It is also important to understand that the potential for financial data linkage in a study may affect the type of person willing to participate in a study and may exclude those most vulnerable to financial insecurity. Furthermore, the requirements for financial data linkage with UK governmental agencies are stringent, making the consent process seem more daunting for researchers and participants alike. It highlights the need to investigate this process further to test acceptability and feasibility of asking for consent to this data linkage given the impact this could have on participant recruitment, causing cohorts to become unrepresentative and damaging trust within communities.

6.1.4 CONSENT FOR FINANCIAL DATA LINKAGE

Individuals involved in health research are required to provide consent for participation and specifically for data linkage. If several data sources are of interest, participants are required to give consent specifically for each data source, meaning that multiple consent questions may need to be included in a single survey or study.

Approaches to obtaining consent for data linkage include collecting consent once collectively to permit data linkage with all specified data sources or separately for each discrete data source. Some research studies inform their participants of the intent to link their data and provide the participants with an opt-out approach to consent.

6.1.5 AIMS AND OBJECTIVES

In this chapter, I aim to explore the feasibility and acceptability of developing data linkage pathways with the Department for Work and Pensions (DWP) and His Majesty’s Revenue and Customs (HMRC) for BiBBS cohort participants, in order to obtain validated income and benefits data, to better understand the impact of a welfare advice service co-located in health settings for mothers and their families on the financial security of its participants and their families.

The objectives of the research reported in this chapter are:

a) To establish a working group alongside the DWP to ascertain the feasibility of data linkage with the DWP and HMRC for BiBBS participants.

b) To establish an approach to obtaining consent for data linkage with the DWP and HMRC for BiBBS participants that is acceptable to the DWP, BiBBS research team and its participants.

c) To pilot this approach within the BiBBS recruitment process to explore if attitudes towards consent for benefits and income data linkage vary between BiBBS participants in order to test if the established data linkage processes are feasible to implement in practice and are acceptable to participants and researchers.

6.2 METHODS

6.2.1 CO-PRODUCING AN APPROACH TO FINANCIAL DATA LINKAGE

In the first instance, I established a consultation group with representatives from the BiB Research Programme data management team and senior researchers from the BIBBS cohort research group. This group worked with representatives from the DWP to establish the feasibility of establishing a data sharing pathway between the BiB Research Programme and the DWP to facilitate data linkage between BiBBS participants and their income and benefits data, held by the DWP and HMRC.

To permit financial data linkage, I developed a participant information sheet and consent form, in consultation with the BiBBS research and recruitment teams and the CRAG. The DWP were consulted in the final iterations of the design to ensure it met governmental and legal requirements for consent for such data linkage. Once a final draft had been approved by the research team and the DWP, the information sheet and consent form was sent for ethics approval, as an amendment to the existing BiBBS cohort study ethics approval. Once approval was received, a standard operation procedure and associated training was developed and conducted with recruitment coordinators. The new consent standard operation procedure was then piloted within the BiBBS cohort study recruitment processes. During the pilot process, the Born in Bradford CRAG were consulted again on the acceptability of the current and alternative approaches to obtaining consent for financial data linkage within the BiBBS cohort.

6.2.2 PILOT OF CONSENT PROCESS FOR FINANCIAL DATA LINKAGE

Participants were recruited into the BiBBS cohort study, following the usual BiBBS recruitment processes.[89] Following recruitment to the BiBBS cohort study, participants were provided with the financial data linkage participant information sheet, see Appendix A.5.1, and asked if they would be willing to provide consent for further data linkage with the DWP and HMRC.

6.2.3 DATA COLLECTION

Participants were coded as having provided consent or having declined to consent to data linkage with the DWP and HMRC. Participants who did not wish to provide consent for financial data linkage were asked for their reason for not wishing to providing consent. Their response was entered as a free text response. Where it was not feasible for recruitment coordinators to obtain consent, for example because a participant became unwell during the recruitment process or lack of administrative time, participants were coded as having declined consent and a reason was documented to explain the reason why.

Participant sociodemographic data was taken from the BiBBS baseline cohort study questionnaires.[89] The key domains used in this analysis were: ethnicity; socioeconomic security; language; relationships; and health and wellbeing.

Ethnicity was coded using Census 2011 categories as ‘White British’, ‘Pakistani Heritage’ and ‘Other’. There were small numbers of non-White British and non-Pakistani Heritage mothers from multiple ethnic groups who were grouped and categorised within the ‘Other’ category.

To establish financial insecurity, the surveys employed the question: ‘How well would you say you are managing financially right now?’. Answer options included: ‘living comfortably’; ‘doing alright’; ‘just about getting by’; ‘finding it quite difficult’; and ‘finding it very difficult’. The latter two options were grouped and categorised as indicating financial insecurity. Participants were also asked: ‘Compared to a year ago, how would you say you (and your partner) are doing financially?’. Answer options included: ‘better off’; ‘about the same’; and ‘worse off’. Residential address, as at 31st March 2019, was linked to the 2019 Index of Multiple Deprivation.[160] Participants were also asked their employment status and the employment status of their partner, where relevant.

The relationship status of the participants was recorded and whether the baby’s father lived with the mother. If a partner, friend or relative was present with the mother at the time of the survey, this was also coded.

Language was coded as ‘English’, ‘Punjabi’, ‘Urdu’, ‘Pashto’, ‘Bengali’ or ‘Other’. There were small numbers of non-British, Punjabi, or Urdu speaking mothers who were grouped and categorised within the ‘Other’ category. First language was further grouped into ‘English’ and ‘Language other than English’. Where English was not the first language, participants were asked how well they could read, write and speak English. Answer options included: ‘not at all’; ‘a little bit’; ‘some’; ‘quite well’; and ‘very well’. The latter two options were grouped and categorised as indicating comprehension of the English language for each domain.

The general health and wellbeing of participants was measured using several tools. Participants were asked for a self-reported measure of their general health: ‘How would you describe your health generally?’. Answer options included: ‘Excellent’; ‘Very good’; ‘Good’; ‘Fair’; and ‘Poor’. The first three options were grouped and categorised as good health, with the latter two options being grouped as indicating poor self-reported general health.

Mental health was measured using the PHQ-8 questionnaire, described previously in Chapter 4.2.4. Standard categorisations were employed for the scores: 0 to 4 indicating no depression; 5 to 9 mild depression; 10-14 moderate depression; and 15-24 severe depression.[100] Clinical depression was defined as those with moderate to severe depression.

Wellbeing was measured using the SWEMWBS questionnaire, described previously in Chapter 5.3.4.5.[216] SWEMWBS scores were further categorised into low (7-19.5), average (19.6-27.4) and high (27.5-35) wellbeing groups. The health-related quality of life of participants was measured using the EQ-5D-5L questionnaire, described previously in Chapter 5.3.4.5.[107]

6.2.4 DATA ANALYSIS

Descriptive statistics were used to identify the overall proportion of BiBBS participants who consented to data linkage with the DWP and HMRC and their sociodemographic characteristics are reported. Multiple logistic regression models were used to explore associations between provision of consent and key explanatory variables, including: ethnicity; socioeconomic security; language; relationships; and health and wellbeing. Missing data on measures was small for most variables and was not adjusted for in the analyses. All statistical analyses were carried out using Stata 15.[162]

Free text responses explaining the reason for declining consent were coded and analysed using a thematic analysis to explore reasons participants did not wish to provide consent for data linkage with the DWP and HMRC.[127] Qualitative analysis was conducted using NVivo10.[217]

6.2.5 ETHICS

This study involved human participants and was approved by the HRA and Bradford/Leeds Research Ethics Committee (15/YH/0455). This protocol was submitted and approved as an amendment to the existing BiBBS cohort study ethics approval (amendments to BiBBS 15/YH/0455).

6.2.6 DATA MANAGEMENT

In order to obtain access to the required data, I submitted an Expression of Interest form to the Born in Bradford Executive Committee, see Appendix A.5.2. Following approval of the Expression of Interest application, a Data Sharing Agreement was established between myself and the Bradford Institute of Health Research, see Appendix A.5.3. Once approved, the required data were extracted by the BiB Data Manager and transferred via the Cisco Registered Envelope Service for the secure transmission of encrypted data. The received data were stored on the University of York drive accessible via a password protected computer in a secure location on the University campus. The requirement of the University of York's Data Management Policy to evidence ownership and rights in respect to the data and research conducted is satisfied by the BiB Collaboration Agreement.[163]

6.3 RESULTS

6.3.1 APPROACHING FINANCIAL DATA LINKAGE

Representatives from the BiB Research Programme data management team and senior researchers from the BiBBS research group worked with representatives from the DWP to establish the feasibility of establishing a data sharing pathway between the BiB Research Programme and the DWP to facilitate data linkage between BiBBS participants and their income and benefits data, held by the DWP and HMRC. It was understood that the DWP and HMRC were keen to actively grow and diversify their external engagement with academia, to maximise the impact of their research in order to be prepared to meet future challenges.[218]

Meetings were held regularly between September 2019 and September 2022 to work towards establishing the most appropriate route for data linkage. Historically, financial data linkage between the DWP and HMRC and other research collaborations[209,210] had been established on a case-by-case basis and at the level of each research collaboration. Moving forward, the DWP were keen to establish a more routine and accessible method for establishing and approving data linkage pathways with research collaborations, using BiB Research Programmes as a trial research collaboration for this new process. It was important that this would be an appropriate and legal method for the safe linkage and transfer of data that was acceptable to both the DWP and the Born in BiB Research Programme.

The discussions and work conducted during these meetings cumulated with an approach to data linkage agreed between the BiB Research Programme and DWP, which received approval from the Secretary of State for Work and Pensions. Income and benefits data from the DWP and HMRC will be repurposed and held by the Office for National Statistics, with onward sharing to the UK Longitudinal Linkage Collaboration (UK LLC).[219] The UK LLC was established to bring together information from longitudinal study participants with their routine records in a secure way to help researchers work to improve health and wellbeing throughout and beyond the COVID-19 pandemic.[219] As an established partner study of the UK LLC, the BiB Research Programme could then safely link their survey data to benefits and income data through the UK LLC for participants who have consented to this.

6.3.2 DEVELOPMENT OF A CONSENT PROCESS FOR FINANCIAL DATA LINKAGE

To permit financial data linkage, a participant information sheet and consent form was developed, in consultation with the BiBBS research and recruitment team. There were concerns from the BiBBS research team that requesting consent for financial data linkage may impact upon overall recruitment to the BiBBS cohort study. For this reason, it was decided that the safest approach to financial data linkage in the first instance, was to pilot the introduction of the consent process as a separate, additional and optional process, following the usual recruitment to the BiBBS cohort study. Thereby, the potential impact on BiBBS recruitment rates could be explored without any real detriment to recruitment rates for the study.

I designed a participant information sheet and consent form, ensuring it remained in line with existing BiBBS consent procedures in terms of content, format and style to facilitate integration with existing recruitment processes. Feedback was received iteratively from the BiBBS research group until it reached approval. The final approved participant information sheet and consent form, see Appendix A.5.1, was then shared with the DWP to ensure it met their legal and other governmental requirements for data sharing. Following approval by the DWP and after receiving ethics approval for use of the participant information sheet and consent form, the process was piloted as a separate, additional and optional process, following the usual recruitment to the BiBBS cohort study.

6.3.3 PILOT OF A CONSENT PROCESS FOR FINANCIAL DATA LINKAGE

6.3.4 STUDY POPULATION

The pilot study ran from the 1st October 2021 to 27th February 2023. A total of 662 participants were recruited into the BiBBS study and were asked if they were willing to provide consent for financial data linkage, see Figure 12. As BiBBS is an ongoing cohort, an interim data extraction was completed for the purposes of this analysis. As a result, only questionnaires which were completed online during the pilot study were available, providing linked sociodemographic data for 295 participants, see Table 29.

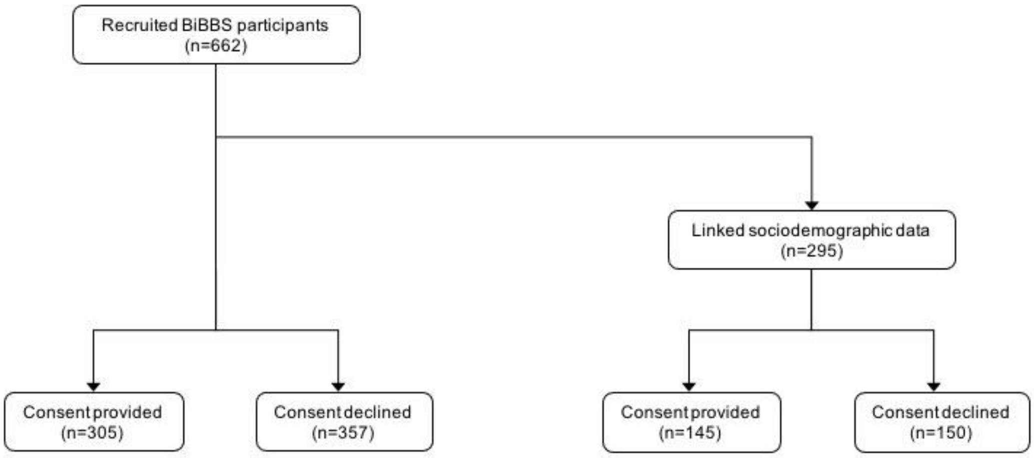

Figure 12 Consort diagram for the evaluation of trends and attitudes towards consent for income and benefits data linkage in the Born in Bradford Better Start cohort

Participants with linked sociodemographic data available were ethnically diverse: 177 (60%) were of Pakistani heritage; 25 (8%) were White British; and 93 (32%) comprised of mothers from other ethnic groups. The majority of participants lived in the first (91%) most deprived IMD decile in England, with the remainder living in the second (22%) most deprived IMD decile. Most participants were employed (62%). Participants were more likely to report that they were living comfortably (26%), doing alright (37%) or just about getting by (25%). Some participants reported that they were finding it quite (8%) or very difficult (4%) to manage financially.

Most participants (82%) reported that they were married or in a relationship with the father of their child but not married (11%). A small proportion of participants reported that they separated or divorced (5%) or have never been in a relationship with the father (2%). 42 (14%) mothers were single parents. Where relevant, most participants reported that their partners were employed (62%).

The first language reported by participants varied across the study population: 109 (37%) reported English was their first language; 79 (27%) Punjabi; 35 (12%) Urdu; 21 (7%) Bengali; 15 (5%) Pashto; and 36 (12%) participants reported having ‘Other’ first language. Where English was not a participant’s first language, most participants reported that they could understand spoken English very well (46%) or quite well (26%).

Participant’s self-reported health varied across the study population. The majority of participants felt that they had good health (48%). Similar proportions of participants felt that their general health was very good (20%) and fair (21%). Overall across the study population, the mean PHQ-8 score was 13.8 (95% CI 13.3, 14.4) with 50% of participants falling within the mild depression category and 34% of participants falling within the no depression category. The majority of participants had moderate (44%) to high (45%) wellbeing scores. The mean SWEMWBS score for the study population was 26.7 (95% CI 26.0, 27.4) falling towards the higher end of the moderate wellbeing category. The mean EQ-5D utility score for the study population was 0.117 (95% CI 0.99, 0.135).

Participants were representative of the Bradford population in terms of ethnicity and levels of deprivation.[30]

Table 29 Sample characteristics of the study population with linked sociodemographic data available

	Number (n=295)	Frequency (%) (95% CI)
Ethnicity		
White British	25	8 (6, 12)
Pakistani	177	60 (54, 65)
Other	93	32 (26, 37)
Missing	0	
IMD 2019 decile		
IMD 1 (most deprived)	91	81 (73, 88)
IMD 2	21	19 (12, 27)
IMD 3-10 (least deprived)	0	0 (0, 0)
Missing	183	
Employment status		
Employed	183	62 (56, 67)
Not employed	112	38 (33, 44)
Missing	0	
Financial security		
Living comfortably	72	26 (21, 31)
Doing alright	104	37 (32, 43)
Just about getting by	71	25 (21, 31)
Finding it quite difficult	22	8 (5, 12)
Finding it very difficult	11	4 (2, 7)
Missing	15	
Relationship status		
Married	242	82 (77, 86)
In a relationship but not married	32	11 (8, 15)
Separated or divorced	15	5 (3, 8)
Never been in a relationship with father	6	2 (3, 8)
Partner has died	0	0 (0, 0)
Missing	0	
Single parent		
Yes	42	14 (11, 19)

Table 29 Sample characteristics of the study population with linked sociodemographic data available

	Number (n=295)	Frequency (%) (95% CI)
No	253	86 (81, 89)
Missing	0	
Partner employment status		
Employed	228	62 (56, 67)
Not employed	37	38 (33, 44)
Missing	30	
Person present at recruitment		
None	171	58 52, 65)
Partner	60	3 (2, 6)
Family member	9	1 (0, 3)
Friend	<5	4 (3, 7)
Other	<5	
Missing	<5	
First language		
English	109	37 (32, 43)
Punjabi	79	27 (22, 32)
Urdu	35	12 (9, 16)
Pashto	15	5 (3, 8)
Bengali	21	7 (5, 11)
Other	36	12 (9, 16)
Missing	0	
Where English is not first language: how well can understand verbal communication in English		
Not at all	<5	2 (1, 6)
A little bit	26	14 (10, 20)
Some	22	12 (8, 17)
Quite well	49	26 (20, 33)
Very	85	46 (39, 53)
Missing	9	
Self-reported general health		
Excellent	15	5 (3, 8)
Very good	57	20 (15, 25)
Good	140	48 (43, 54)
Fair	62	21 (17, 26)

Table 29 Sample characteristics of the study population with linked sociodemographic data available

	Number (n=295)	Frequency (%) (95% CI)
Poor	16	6 (3, 9)
Missing	5	
PHQ-8 score		
PHQ-8 mean score	13.8 (95% CI 13.3, 14.4)	
PHQ-8 Category		
No depression	90	34 (29, 40)
Mild depression	133	50 (44, 56)
Moderate depression	41	16 (12, 20)
Severe depression	0	0 (0, 0)
Missing	31	
Clinically relevant symptoms of depression		
No clinically relevant symptoms of depression	223	84 (80, 88)
Clinically relevant symptoms of depression	41	16 (12, 20)
Missing	31	
SWEMWBS score		
SWEMWBS mean score	26.7 (95% CI 26.0, 27.4)	
SWEMWBS Category		
Low wellbeing	33	11 (8, 16)
Moderate wellbeing	125	44 (38, 49)
High wellbeing	129	45 (39, 510
Missing	8	
EQ-5D utility score		
EQ-5D mean utility score	0.117 (95% CI 0.99, 0.135)	

6.3.5 CONSENT RATES FOR FINANCIAL DATA LINKAGE

Consent rates for financial data linkage are reported overall for the study population and separately for participants with linked sociodemographic data available. Of the 662 participants overall, 46% (95% CI 41%, 50%) provided consent for financial data linkage and 54% (95% CI 49%, 58%) declined consent for financial data linkage. For participants where linked sociodemographic data was available, 49% (95% CI 43%, 55%) provided consent for financial data linkage and 51% (95% CI 45%, 57%) declined consent for financial data linkage.

Overall, participants were equally likely to decline consent to financial data linkage. Given the overlap of confidence intervals between each consent group, the difference is not statistically significant. However, the overlap is small and therefore there is some evidence to suggest that perhaps with a larger sample size, there may be evidence to suggest that participants are more likely to decline to consent to financial data linkage.

6.3.6 VARIATION IN CONSENT RATES FOR FINANCIAL DATA LINKAGE

Multiple logistic regression models were used to explore associations between provision of consent and key explanatory variables, including: ethnicity; socioeconomic security; language; relationships; and health and wellbeing, see Table 30.

Measures of socioeconomic security were associated with being more likely to provide consent for financial data linkage. Participants who were not employed were more likely to provide consent for financial data linkage (OR 1.49 95% CI 0.93, 2.40), although this was not statistically significant. Participants who were more financially insecure were more likely to provide consent for data linkage than those who reported that they were living comfortably. Participants who were finding it quite difficult to get by were most likely to provide consent for data linkage than those who reported that they were living comfortably (OR 4.30 95% CI 1.54, 11.91). Overall, participants who were more financially insecure were more likely to provide consent than those who were financially secure (OR 1.85 95% CI 1.14, 3.93).

Relationship factors such as relationship status and whether the participant is a single parent were not associated with whether a person is likely to provide consent for financial data linkage. Similarly, the employment status of the participant’s partner and whether and the type of person present at recruitment were not associated with the provision of consent.

Ethnicity was not a factor that was associated with consent for data linkage. However, there were several indicators that factors relating to language spoken and the comprehension of the English language were associated with the probability of providing consent for financial data linkage. Overall, where the participant’s first language was a language other than English, participants were less likely to provide consent for data linkage (OR 0.65 95% CI 0.39, 0.98). At the level of individual languages, this association persisted and was significant for participants who spoke Punjabi (OR 0.59 95% CI 0.33, 0.98) and Urdu (OR 0.46 95% CI 0.21, 0.94) compared to participants who spoke English as their first language. This association was not significant for those who spoke Pashto (OR 0.39 95% CI 0.13, 1.23), Bengali (OR 1.05 95% CI 0.41, 2.69) or another language (OR 0.98 95% CI 0.46, 2.10) as their first language, which is likely to be related to the smaller participant numbers in these groups. However, where English was not the participants first language, how well a participant could understand verbal communication in English (OR 0.85 95% CI 0.48, 1.52) was not associated with whether a participant was likely to provide consent for financial data linkage.

There was no association found between measures of general health, mental health, wellbeing and health-related quality of life and the provision of consent for financial data linkage.

Table 30 Odds ratios (95% CI) from unadjusted logistic regression model for the probability of providing consent.

	OR	95% CI
Ethnicity (Reference: White British)		
Pakistani	0.76	0.33-1.76
Other	1.17	0.48-2.84
Employment status (Reference: Employed)		
Not employed	1.49	0.93-2.40
Financial security (Reference: Living comfortably)		
Doing alright	2.43	1.30-4.53
Just about getting by	2.44	1.24-4.80
Finding it quite difficult	4.30	1.54-11.91
Finding it very difficult	2.40	0.66-8.67
Financial security (Reference: Financially secure)		
Financial insecurity	1.85	1.14-3.93
Relationship status (Reference: Married)		
In a relationship but not married	1.40	0.66-2.93
Separated or divorced	2.17	0.72-6.54
Never been in a relationship with father	0.22	0.03-1.89
Single parent (Reference: Not single parent)		
Single parent	1.16	0.60-2.24
Partner employment status (Reference: Employed)		
Not employed	1.86	0.91-3.79
Person present at recruitment (Reference: None)		

Table 30 Odds ratios (95% CI) from unadjusted logistic regression model for the probability of providing consent.

	OR	95% CI
Partner, family or friend	0.73	0.45-0.96
First language (Reference: English)		
Punjabi	0.59	0.33-0.98
Urdu	0.46	0.21-0.94
Pashto	0.39	0.13-1.23
Bengali	1.05	0.41-2.69
Other	0.98	0.46-2.10
First language (Reference: English)		
Language other than English	0.65	0.39-0.98
Where English is not first language: how well can understand verbal communication in English (Reference: Not well)		
Well	0.85	0.48-1.52
Self-reported general health (Reference: Good health)		
Poor health	1.31	0.78-2.20
PHQ-8 score		
PHQ-8 mean score	1.00	0.95-1.06
PHQ-8 category (Reference: Mild depression)		
Moderate depression	0.97	0.48-1.95
Severe depression	1.04	0.50-2.18
Clinically relevant symptoms of depression (Not clinically depressed)		
Clinically relevant symptoms of depression	1.00	0.51-1.94
SWEMWBS score		
SWEMWBS mean score	0.98	0.94-1.02
SWEMWBS Category (Reference: Low wellbeing)		
Moderate wellbeing	1.09	0.50-2.34
High wellbeing	0.75	0.35-1.60
EQ-5D utility score		
EQ-5D mean utility score	1.00	1.00-1.00

6.3.7 ATTITUDES TOWARDS CONSENT

All participants (n=357) who declined to consent to financial data linkage were asked why they chose not to provide consent for data linkage. Of participants who declined to consent to financial data linkage, a reason for choosing to decline consent was not documented for

21 (6%) of participants. Some participants gave more than one reason. The explanations for choosing not to give consent were coded, analysed and are documented in Table 31.

Table 31 Reasons for choosing to decline to consent to financial data linkage given by BiBBS participants

Reason given	Number	Frequency (%)
Not interested in taking part	139	39%
Does not feel comfortable sharing this sort of information	68	19%
Need to seek permission from partner prior to providing consent	24	7%
Partner deals with finances	24	7%
Participant is not in receipt of benefits and therefore did not understand the need to share financial data	23	6%
Partner, friend or other family member present during recruitment process and declined consent	12	6%
Did not understand the need to share financial data	19	5%
Participant does not understand finances	8	2%
Participant is already in receipt of benefits and therefore did not understand the need to share financial data	6	2%

Most participants explained that this aspect to the research programme was not something that they were interested in taking part in (39%). Some participants explained that they did not feel comfortable sharing this sort of information given the nature of the information (19%).

"I don't like it"

Participant

Many reasons given by participants for not wishing to consent to financial data linkage related to a lack of understanding of the need to do so. In some cases, this was stated as the reason with no further explanation given (5%). Some participants were already in receipt of benefits and felt they were already aware of their entitlement and therefore could not see how they would personally benefit from sharing such data (2%). Conversely, some participants who were employed and were not in receipt of benefits did not understand the need to share financial data (6%).

“Husband deals with it and he's working full time so might not get anything”

Participant

Several participants explained that they did not understand finances or their financial circumstances (2%) or did not manage household finances (7%) and therefore felt unable to discuss any aspects of financial data sharing.

“[my] husband deals with all that. [I don’t] know anything”

Participant

Other participants stated that they would be unable to provide consent without the permission of their partner (7%). On occasion, the participant’s partner, friend or another family member (6%) were present during the recruitment process and decline to consent on behalf of the participant.

“[I] need to ask [my] husband…can’t decide on [my] own”

Participant

In some circumstances, recruitment coordinators were unable to seek consent from participants for financial data linkage. These reasons were coded, analysed and are documented in Table 32.

Table 32 Reasons documented by recruitment coordinators for being unable to ask participants for their consent to financial data linkage

Reason documented	Number	Frequency (%)
Only recently moved to UK	10	3%
No national insurance number	9	3%
Other (including language barrier, immigration status, lack of time, illness)	<5	<2%

Some of the reasons documented by recruitment coordinators for not being able to seek consent for financial data linkage involved the participant not having lived in the country long (3%), not having a national insurance number (3%) and being a refugee or asylum seeker (<5%).

“Recently moved to UK. Not familiar with culture”

Recruitment coordinator

Some recruitment coordinators documented language barriers (<5%) as being a reason for being unable to seek consent, despite the presence of translators in many circumstances. Being physically located in a health setting, participants were sometimes called for healthcare appointments (<5%) or became unwell (<5%) before or during the process of seeking consent.

6.3.8 REVIEW OF THE CONSENT PROCESS FOR FINANCIAL DATA LINKAGE

Six months into the pilot of consent process for data linkage within the BiBBS cohort study, we sought feedback on the process from the BiBBS recruitment team.

The BiBBS recruitment team understood the need and the utility of financial data linkage for research purposes, however they felt that the process of obtaining consent for financial data linkage in the manner of the pilot was onerous and cumbersome. The recruitment team feedback anecdotally that requesting consent for financial data linkage as a distinct process made the act of providing consent for financial data linkage a more daunting process for participants. The consent process stood out as a distinct part of the recruitment process and seemed to give the participants cause to pause and perhaps feel more wary about being asked to consider this separately. They felt that provision of consent for financial data linkage may be greater and less cumbersome for the team and participants if it was better integrated into the existing BiBBS recruitment process.

The existing BiBBS recruitment process involves obtaining consent from participants for data linkage with a number of other agencies, including health, education and the local authority, see Appendix A. 5.4.1, Section 1d. There are a number of other research projects, previously discussed,[209,210] that use financial data linkage to better understand their communities and the impact of their research on these communities. These research projects all use different approaches to obtain consent for financial data linkage, including: opt-out processes; obtaining consent collectively for data linkages to all agencies; and obtaining explicit and separate consent for data linkage to financial data.

I consulted with the BiBBS Community Research Advisory Group with the aim of ascertaining the acceptability of the current and alternative potential approaches to financial data linkage within the BiBBS cohort. I arranged to meet with the CRAG and circulated preparatory material ahead of the meeting to make the group aware of our progress with the pilot so far and the possible options moving forward, see Appendix A.5.2.

The CRAG meeting was informative and insightful. The CRAG understood the utility of income and benefits data for understanding the financial security of families within the local community and for the planning, design, implementation and evaluation of BiBBS interventions. They also recognised the sensitivity around data sharing and data linkage and how this might be further heightened by the particularly sensitive and potentially stigmatising nature of financial data. The CRAG felt that it was ultimately a choice that should be made at an individual level. For this reason, it was felt that transparency should be a priority. An opt-out approach to consent was not considered to be transparent. The CRAG also felt that integration of consent for financial data linkage into the existing BiBBS recruitment consent form could be missed and was therefore not as transparent as the existing separate approach to consent. Despite this option being the most onerous and cumbersome for the BiBBS recruitment team and potentially the most daunting for participants, it was still considered to be the most appropriate approach given the sensitive nature of the data concerned and thus the priority of maintaining transparency.

Some other concerns were raised by a small number of individuals during the CRAG meeting with how data shared by BiBBS with the DWP would be used by the DWP, with whom there was little trust. There were also concerns raised with the legitimacy of consent provided by mothers for financial data linkage, which ultimately might disclose the financial circumstances of other household members who have not provided their consent for data linkage.

6.4 DISCUSSION

6.4.1 SUMMARY OF KEY FINDINGS

6.4.2 FEASIBILITY OF FINANCIAL DATA LINKAGE PROCESSES

Following establishment of a working group and several years of discussions, a pathway was successfully established to facilitate data linkage between Born in Bradford Research Programme and DWP and HMRC. Income and benefits data from the DWP and HMRC will be repurposed and held by the Office for National Statistics, with onward sharing to the UK LLC, and onto the Born in Bradford Research Programme.

Discussions with the DWP and research teams, highlight that there is a perceived and accepted utility to sharing financial data that meets the vision and objectives of both research arms. Discussions with the community research advisory groups confirmed that they understood the value of having a better understanding of financial insecurity for research purposes and the potential benefit this could have for participants and the wider community. However, there was much hesitation regarding the nature of the data shared, how this would be used and the transparency of the methods used to obtain consent for data linkage.

6.4.3 ACCEPTABLE APPROACHES FOR OBTAINING CONSENT FOR FINANCIAL DATA LINKAGE

Developing an approach to obtaining consent from BiBBS participants for data linkage with the DWP and HMRC required input and thoughtful consideration from all parties involved with the process. Initially there was significant uncertainty regarding the requirements for consent from the perspective of the DWP and HMRC. Therefore the model of consent was developed from existing, approved models of consent used by other cohort studies with established data linkage pathways with the DWP an HMRC. [209,210] Balanced against the desire for a separate consent process from the BiB research team to existing BiBBS recruitment procedures, the design for the participant information sheet and consent form emerged and ethics approval received for use. However, the recruitment coordinators felt that this led to a particularly long and onerous consent process that was daunting for coordinators and participants involved. Balanced against other approaches to consent, this approach remained the preferred option given a strong desire from the research team and community research group to prioritise transparency throughout the process and to protect recruitment into the existing BiBBS cohort.

6.4.4 FACTORS ASSOCIATED WITH CONSENT FOR FINANCIAL DATA LINKAGE

Of the 662 participants overall, 46% (95% CI 41%, 50%) provided consent for financial data linkage and 54% (95% CI 49%, 58%) declined consent for financial data linkage. For participants where linked sociodemographic data was available, 49% (95% CI 43%, 55%)

provided consent for financial data linkage and 51% (95% CI 45%, 57%) declined consent for financial data linkage.

There were some factors relating to socioeconomic security and language spoken found to be associated with the decision to consent to financial data linkage. Measures of socioeconomic security were associated with being more likely to provide consent for financial data linkage. Participants who were not employed (OR 1.49 95% CI 0.93, 2.40) and were more financially insecure (OR 1.85 95% CI 1.14, 3.93) were more likely to provide consent for financial data linkage.

However, there were several indicators that language spoken was associated with the probability of providing consent for financial data linkage. Overall, where the participant's first language was a language other than English, participants were less likely to provide consent for data linkage (OR 0.65 95% CI 0.39, 0.98). However, where English was not the participants first language, how well a participant reported that they could understand English was not associated with whether a participant was likely to provide consent for financial data linkage. Ethnicity was also not found to be a factor that was associated with consent for financial data linkage.

Furthermore, the choice of consent for financial data linkage was not associated with: relationship factors, such as relationship status and whether the participant is a single; employment status of the participant's partner; person present at time of recruitment; and measures of health, such as general health, mental health, wellbeing and health-related quality of life.

6.4.5 ATTITUDES TOWARDS CONSENT FOR FINANCIAL DATA LINKAGE

For participants who chose not to provide consent for financial data linkage, a number of varied explanatory reasons were provided. Most participants reported feeling that they were simply not interested in taking part in research involving financial data sharing and did not feel comfortable sharing such sensitive data. Some participants highlighted that they did not understand the need for sharing financial data and related this to being financially secure or already being in receipt of benefits. In some circumstances, participants felt that because they did not understand their finances or because their partner organised the household financial circumstances, they felt unable to participate or to provide consent to participate and would need their partner's permission to do so. In a few situations, a partner or family member was present during the recruitment process and declined to consent on behalf of the participant.

In some circumstances, recruitment coordinators were unable to seek consent from participants for financial data linkage. Commonly, this related to language barriers, or the participant becoming unwell or needing to go to a health appointment prior to or during the process of obtaining consent. Sometimes recruitment coordinators documented that they were unable to seek consent because the participant had not been in the country long or did not have a national insurance number.

6.4.6 LIMITATIONS

The pilot of the chosen approach to obtaining consent for financial data linkage was subject to a number of limitations. Nearly half of participants did not have linked sociodemographic data available. This was related to delays in the processing of BiBBS recruitment data and should be available at a later date. However, the omission of these participants in the analysis, may have implications on the analysis and subsequent interpretation of the results.

A number of sociodemographic variables were collapsed to support the analysis owing to small sample sizes within each strata across survey timepoints. For example, financial insecurity was defined as those 'finding it quite difficult' and 'finding it very difficult' to manage financially. Families 'living comfortably', 'doing alright' and 'just about getting by' were considered financially secure. Such categorisations are conservative and several mid-point categories could be considered true for either categorisation. This is likely to have underestimated the measure of association for these groups.

Finally, the reasons documented for declining consent were often simple and the wording similar between participants. This perhaps reflected a lack of administrative time and the confidence and understanding of the recruitment coordinators with respect to seeking consent for data linkage and discussing sensitive information. Furthermore, it was unclear to what degree the reason for declining consent documented was in the participant's own words and the degree to which the reason given was understood and interpreted by the recruitment coordinators prior to documentation. This highlights the need to understand the reflexivity of the recruitment coordinators involved to better understand the effect of this on the results and the possible introduction and extent of bias involved.

6.4.7 IMPLICATION OF FINDINGS

Financial information is widely regarded as sensitive data and being financially insecure and being in receipt of benefits can be stigmatising. This can lead to challenges in discussing financial circumstances for the purposes of research and may mean financial insecurities are under or overestimated. For some people, financial circumstances are simply not known or fully understood. This chapter highlights the potential for the use of data linkage as a means to obtain objective, validated financial data to improve the accuracy and understanding of financial circumstances and insecurity in research. However, the utility of such financial data as objective and validated measures of financial circumstances as used in health research is not yet fully understood and requires further research. It is understood that such data will provide clarity of income and receipt of benefits, which may give some indication to benefit entitlement, uptake of advice for those who are eligible and outcomes for those who access intervention to improve financial security. However, the information obtained may not be sufficient to capture all individuals who are eligible and who may not claim benefits. The lack of this information may also disproportionally impact vulnerable groups who are likely to have disengaged with the benefits system, such as homeless people or refugees, and still not have found work or be consistently in work. Furthermore, the definition of financial security may need to be re-examined and not taken in totality to represent household income and the presence or absence of debt. Measures of financial resilience need to be captured and further reinforces the need to supplement any objective data received with important subjective self-reported measures of financial security. This reflects the need to conduct further research into how such subjective measures reflect the experience of financial resilience and security for individuals and their families.

This chapter improves our understanding of the impact of the use of financial data on recruitment rates for cohort studies used in health research. This falls in line with existing research, highlighting the complex nature of utilising data linkage in health research and the interplay of other agencies in this. Further entwining of financial data linkage consent pathways into the existing BiBBS recruitment process may impact upon the relationship and trust the research group have built with the participants and its community, which has been reflected in other health research studies.

This study further improves our understanding of the most appropriate approaches for improving uptake of consent for financial data linkage whilst maintaining the values and priorities considered most important by researchers, participants and the community. Through this research and co-production processes, it has emerged that transparency and accountability are considered priorities for researchers and the community alike. This transparency extends from the request to link participant data with their financial data linked with the DWP and HMRC to the rationale for doing so. Highlighting more clearly the utility of this research, and where financial data fits in with this, for participants and the wider community has been highlighted as an important component for researchers and participants and failure to do so can impact upon consent rates, particularly for those who may be more vulnerable and less willing to participate. Finally, when approaching consent for financial data linkage, further consideration needs to be given to the role of the partner and other family members in the process. Notably, whether the provision of consent from other members of the household is a necessary part of the consent process, given that some benefit eligibility, such as Universal Credit, is calculated based on household income and not at the level of the individual participant.

Furthermore, research has highlighted that some data uses and data linkage processes are more concerning for participants than others and that context is important. People trust the health sector, including health researchers, more than they trust other organisations, such as the DWP and HMRC.[214,215] Research also highlights that trust in the health sector could be at risk of being diminished by the involvement of less trusted parties.[202] It is also important to understand that the potential for financial data linkage in a study may affect the type of person willing to participate in a study and may exclude those most vulnerable to financial insecurity. Furthermore, the requirements for financial data linkage with governmental agencies are stringent, making the consent process seem more daunting for researchers and participants alike. It highlights the need to investigate this process further to test acceptability of asking for consent to this data linkage given the impact this could have on participant recruitment, causing cohorts to become unrepresentative and damaging trust within communities.

This research improves our understanding of the impact of the use of financial data on recruitment rates for cohort studies used in health research. The consent rates found in this study were lower for this study (46%) than for other published consent rates for other longitudinal population studies of 79% for the ELSA study, of 70% (DWP) and 65% (HMRC) for the Next Steps Age 25 Survey and 59% (DWP) and 57% (HMRC) for the ALSPAC and PEARL studies.[212,213] This may reflect differences in consent methodology between the studies. Some interstudy variation was reported for the Next Steps, ALSPAC and PEARL studies with respect to method of communication when obtaining consent, with face-to-face and telephone communication achieving higher rates if consent than online methods.[212,213] This highlights the complex nature of utilising data linkage in health research and the interplay of consent and communication methodology with this. Furthermore, the differences in consent rates between these studies may reflect inherent differences within the population group. The BiBBS population group represent a young and pregnant population in an ethnically diverse and deprived population.

This research further improves our understanding of the interplay of socioeconomic demographics on the provision of consent for financial data linkage. It suggests that adapting consent procedures in light of these findings may improve rates of consent, in particular for the most vulnerable and marginalised groups. However, further research needs to be conducted with larger sample sizes to fully understand some of the reported associations, particularly with certain marginalised groups, where sample sizes are inherently smaller. Particularly, there needs to be more research conducted specifically to understand how attitudes towards financial data sharing relates to language spoken and how best to overcome this. However, the research suggests that those experiencing financial insecurity overall are more likely to consent to data linkage and as such, it is possible that data linkage would be achieved for those most likely to need welfare advice.

Finally, this chapter reinforces the value and importance of genuine co-production and shared learning throughout every stage of the research process. To facilitate improved acceptance and effectiveness of the implementation of a financial data sharing process representatives from the DWP and HMRC, research staff, recruitment coordinators, participants and relevant health professionals should be consulted and involved in the co-production process.

6.5 CONCLUSION

Improving our understanding of what constitutes financial insecurity can help us to better understand how financial insecurity is experienced and how this can change over time within and between individuals and populations. Having an accurate understanding of financial insecurity can also help researchers, commissioners and policy makers to have a better understanding of what works to improve the financial security of individuals and communities and the impact this has on health and wellbeing and health insecurity.

Any approach to obtaining financial data from participants needs to be sensitive and considered. It should be acceptable to all agents involved and meeting ethical requirements of governmental and research institutions. Pragmatic, imaginative and flexible approaches are needed if research using data linkage is to successfully realise its potential for public good without undermining trust in the research process.

This chapter sets out a successful and broadly acceptable approach to obtaining validated income and benefits data, as a measure of financial security, within the particular context of the BiBBS cohort study. It highlights considerations for future approaches to co-production, implementation and further research in this area.

The next and final chapter will detail the relevance of the findings to the thesis as a whole, addressing the overarching theoretical and methodological issues as they relate to the research and will consider the broader research and policy implications of the research before making a series of recommendations to conclude the thesis.

CHAPTER 7 COMPLEX INTERVENTION METHODOLOGY AND RESEARCH

Chapter 7 provides a reflective account of the key considerations of the development and evaluation of a universal welfare advice service co-located in health settings for mothers and their families, as a complex intervention, compiled using the Medical Research Council (MRC) and National Institute of Health Research (NIHR) complex intervention research framework. It considers the application of the evidence and learning associated with each of these elements as an intervention in a typical health setting for mothers and their families and specifically to the setting of Bradford to the core elements of this framework.

7.1 DEVELOPING AND EVALUATING A COMPLEX INTERVENTION

Complex interventions are widely used in the health service, in public health practice, and in areas of social policy that have important health consequences. Complexity of an intervention is considered to arise from the property of the intervention itself, the context in which the intervention is delivered and the interaction between the two.[172,220] Interventions become more complex with: increasing numbers of interventions and the interactions between them; the range of behaviours and skills required by those delivering or receiving the intervention; the number of groups, organisational levels or settings targeted by the intervention; and the level of flexibility of the intervention that is permitted.[172]

Welfare advice services co-located in health settings for mothers and their families should be considered a complex intervention. The nature and scope of welfare advice are wide ranging and complicated to effectively deliver. Whilst the intervention in question is being delivered to mothers and their families, this group is not homogenous in nature. The Bradford population is diverse, with mothers from different backgrounds, cultures, and socioeconomic groups, adding further complexity to this intervention. The co-located nature of this service within health settings for mothers and their families, adds a final layer of complexity to this intervention. Several physical settings may be involved in the delivery of this intervention and will require involvement from a variety of health professionals.

7.1.1 COMPLEX INTERVENTION RESEARCH FRAMEWORK

In 2006, the Medical Research Council published guidance for developing and evaluating complex interventions,[221] building on a framework published in 2000.[222] In 2021, the NIHR and MRC launched a new complex intervention research framework building upon this previously published guidance.[172] The new framework provides an updated definition of complex interventions, highlighting the dynamic relationship between the intervention and its context. It aims to improve the design and conduct of complex intervention research to increase its utility, efficiency and impact. Consistent with the principles of increasing the value of research and minimising research waste, the framework: emphasises the use of diverse research perspectives and the inclusion of research users, clinicians, patients and the public in research teams; and aims to help research teams prioritise research questions and choose and implement appropriate methods.[172]

The MRC and NIHR complex intervention research framework will support the implementation of the evidence assimilated from this research towards the development and evaluation of a welfare advice service co-located in health settings for mothers and their families generally and more specifically to the setting of Bradford. This framework was chosen for its systematic and transparent approach to developing and evaluating complex interventions, improving the likelihood of the validity and replicability of results.

The MRC and NIHR complex intervention research framework describes six core elements and four main phases to complex intervention research, see Figure 13**Error! Reference source not found.**.[172] Complex intervention research incorporates four main phases of intervention research: development; feasibility; evaluation; and implementation. Each phase of intervention research is also connected to a set of core elements considering: context; developing and refining programme theory; identifying and engaging stakeholders; identifying key uncertainties; refining the intervention; and economic considerations.[172]

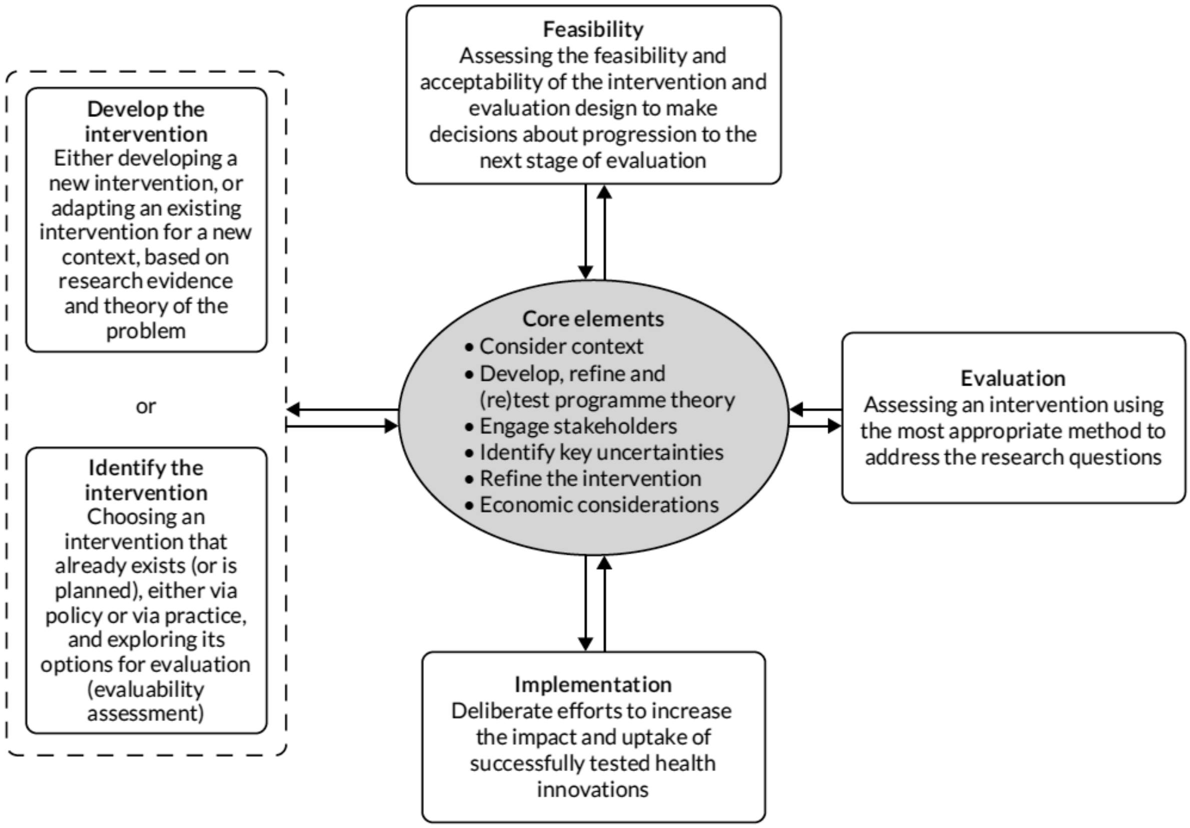

Figure 13 Main phases and core elements of complex intervention research, taken from NIHR and MRC framework for developing and evaluating complex interventions.[172]

7.2 CORE ELEMENTS OF COMPLEX INTERVENTION RESEARCH

The MRC and NIHR complex intervention framework identifies six core elements that require consideration throughout all phases of complex intervention research: context; developing and refining programme theory; identifying and engaging stakeholders; identifying key uncertainties; refining the intervention; and economic considerations.[172] I will now consider each of these elements with respect to welfare advice services co-located in a health setting for mothers and their families generally and with particular respect to Bradford.

7.2.1 CONTEXT

Context is defined as any feature of the circumstances in which an intervention is conceived, developed, implemented and evaluated, for example social, political, economic and geographical contexts.[223] Context is dynamic and multidimensional and contextual factors are intervention specific and may be difficult to anticipate. The degree to which contextual factors could affect how an intervention achieves its outcomes should be examined at all phases of the research development and evaluation. As well as being influenced by context, many 'interventions work to change the context within which health is produced and become part of the context for future health behaviours, interventions and outcomes'.[223]

It is hoped that taking context into account will assist with: anticipating and understanding barriers to and facilitators of implementation, and scaling up and scaling out of interventions; in the development phase to make it more likely that the intervention is effective and implementable among the target population and setting; at the evaluation phase, to understand how interventions work with respect to how they interact with their context; and in the reporting of research, to help decision-makers understand whether or not the intervention will work and for whom in the context for which they are responsible.[172] Ultimately, it allows interventions to be dynamic and to be developed, refined and adapted so that they fit with the contexts in which they are implemented.

The PESTLE framework is a tool devised to assist individuals and organisations in identifying and analysing situational context, in order to maximise opportunities and minimise threats. These factors include: political, economic, social, technological, legal and environmental factors.[224] The PESTLE framework was designed and most commonly used for business management and marketing, however its use has become more widespread in strategic management and project planning in sectors, such as the health sector, in recent years. A modification has been made to the PESTLE framework in order to adapt the framework for health and public health purposes. This includes the addition of demographic and ethical (DEPESTLE) factors to the original PESTLE framework to support a fuller analysis of the full scope of the context of a health intervention.[225] Table 33 presents an analysis of the context of a welfare advice service co-located in health settings for mothers and their families using the DEPESTLE framework for a general health setting for mothers and their families and specifically within the setting of Bradford. I assimilated the information table based on the knowledge I gathered during an initial scoping review into the relationship between financial insecurity and health and wellbeing outcomes, and based upon my own reflections from the knowledge I gained conducting the iterative process working through the core elements of the complex intervention framework.

Table 33 Analysis of the general and Bradford specific context for a welfare advice service co-located in health settings for mothers and their families, as a complex intervention, utilising the DEPESTLE framework

Factor	General maternal and child health setting	Bradford setting
Demographic	The ongoing cost of living crisis, owing to rising inflation and soaring food and energy prices, in the midst of the recovery from a national pandemic, has led to more families and children struggling financially and living in poverty.[15,26,27] Furthermore, there is evidence of widening health and social inequalities.[23]	Whilst also experiencing the same general contextual factors, Bradford has several population specific demographic factors to consider. Bradford is the fifth largest metropolitan district in England and has a young, ethnically diverse population with high levels of deprivation and health inequalities. Health and financial literacy levels are also low.[79]
Ethical	It is important to ensure that the service is inclusive and accessible to all mothers and their families, regardless of background, ethnicity and language spoken, and socioeconomic status. Financial and welfare concerns are often considered sensitive topics and are potentially stigmatising. Furthermore, people experiencing financial or other welfare problems are vulnerable. Therefore care and consideration is needed to ensure physical settings to provide welfare advice interventions are safe, secure and confidential.	Given the diversity of the city with respect to ethnicity, languages spoken, and levels of socioeconomic security, it is especially crucial to take measures to ensure that the service is fully accessible to all mothers and their families with respect to these factors.
Political	Overall, there is a political willingness to support research into how financial insecurity is affecting families and how welfare advice services can support families across the United Kingdom.[218] The previous three years have seen huge political and economic instability internationally and domestically given the onset and recovery of the COVID-19 pandemic, the Russian invasion of Ukraine, with its subsequent impacts on gas and oil prices, the impact of Brexit and rising inflation. Furthermore, there has been a period of significant domestic political instability and uncertainty, with several recent changes to significant political leadership positions,	Commissioning for welfare advice services across Bradford is due to be renewed in the summer of 2023. A priority has been established by the council has been for the expansion of welfare services into other settings, including maternity, postnatal and child health services, which serves an important opportunity for political investment in this intervention, and a potential source of commissioning.

Table 33 Analysis of the general and Bradford specific context for a welfare advice service co-located in health settings for mothers and their families, as a complex intervention, utilising the DEPESTLE framework

Factor	General maternal and child health setting	Bradford setting
	with further changes probable within the next twelve months. Such domestic political instability may influence national and regional priorities and public policy. This may affect political willingness to support such interventions and research and may lead to significant changes to public policy affecting the delivery and funding for welfare advice services.	
Economic	As previously discussed, the last three years have seen huge political and economic instability internationally and domestically given the onset and recovery of the COVID-19 pandemic, the Russian invasion of Ukraine, with its subsequent impacts on gas and oil prices, the impact of Brexit and rising inflation. Long periods of political instability and uncertainty may lead changes to political priorities. This may result in sudden and unpredictable changes to funding available for public spending and particular interventions. Specifically, over recent years, during significant periods of austerity and rising inflation, council budgets and public spending have been cut, leading to a reduction in funding for welfare advice services.	Over recent years, there has been an overall reduction in funding to councils for public spending. This has had a significant impact on the provision of welfare advice services in Bradford, seeing many services cut, in particular many specialist services and services co-located in health settings. Following the removal of public funding for welfare advice services co-located in health settings, Bradford City CCG commissioned a new welfare advice programme co-located in primary care delivered as a community alliance programme, as part of their Reducing Inequalities in Communities programme. This introduces new potential avenues of funding for welfare advice services co-located in health settings. However, the fragmentation of funding and provision of services poses challenges for collaboration and shared learning and risks duplication of efforts and watering down of potential benefits of services. Commissioning for the provision of welfare advice services locally in Bradford is due for renewal in 2023 and is expected to remain stable compared to the previous five-year service funding. However, the rising cost of living and rising inflation may place additional pressures on this already constrained budget to deliver

Table 33 Analysis of the general and Bradford specific context for a welfare advice service co-located in health settings for mothers and their families, as a complex intervention, utilising the DEPESTLE framework

Factor	General maternal and child health setting	Bradford setting
		greater and more sophisticated services, in an area with great and ever-growing need.
Social	Financial insecurity is widely considered to be a sensitive topic and being in receipt of benefits is often stigmatising. However, given a longstanding period of austerity, the recovery from the COVID-19 pandemic and worsening economic climate and cost of living crisis, more families are experiencing poverty and financial security than ever before and the ability of families to be resilient to further changes to the financial climate or to personal financial needs is likely to be significantly impaired. As a result, it is possible that the way families perceive financial insecurity may have changed, with more families being willing to discuss their financial insecurities and more willing to ask for and be in receipt of financial assistance.	Financial insecurity is widely considered to be a sensitive topic and being in receipt of benefits is often stigmatising, particularly so for ethnic minority groups. Whether changes to political and economic factors will have an effect on the attitudes and perceptions towards financial insecurity and being in receipt of financial support for ethnic minority groups remains unclear and should be examined. Alternative sources of financial support may be more preferable to ethnic minority groups and should be explored in any research into supporting local communities in Bradford. Families from ethnic minority groups may have different financial help seeking behaviour. For example, families from Pakistani Heritage communities in Bradford, have a long standing history of forming informal rotating savings and credit associations (ROSCA), as a means to establishing financial resilience for families.[193] These ROSCAs are often referred to as committees, pronounces ‘kaametees’ and are seldom spoken of outside of the committees in the community.[193]
Technological	The DWP and HMRC have established research as a priority for the organisations.[218] Within this they have clarified their willingness and desire to engage with academic institutions to facilitate data sharing to better understand the financial circumstances of people in the United Kingdom and interventions which can alleviate financial insecurity.[218] Data linkage solutions with such organisations can improve the efficiency	The majority of welfare advice services delivered within Bradford City district have predominately been delivered via face-to-face appointments by walk-in or on an appointment basis. Some services, particularly follow-up services, have been delivered by telephone. However, the council and public health teams are exploring technological solutions to expand the reach and efficiency of services. For example, the use of tablets as means to

Table 33 Analysis of the general and Bradford specific context for a welfare advice service co-located in health settings for mothers and their families, as a complex intervention, utilising the DEPESTLE framework

Factor	General maternal and child health setting	Bradford setting
	and readiness of objective and validated financial outcome data. Where welfare advice services have been physically located within health settings, there has been a desire from researchers for the linkage of medical and welfare data to improve the care of patients and to facilitate analysis of the impact of welfare advice services on the health sector. This provides an opportunity to further enhance research outcomes but remains an important potential threat to the trust of participants in academic and health organisations.	triage potential clients in welfare advice centre waiting rooms and in libraries.[97] Existing datasets such as the Connected Bradford Dataset with the BiBBS cohort study could be used to capture population baseline characteristics to support an evaluation of a welfare advice service co-located in health settings. Through the Connected Bradford Dataset, participant data could also be linked with routine health service use data to facilitate an assessment of longer-term health outcomes and impact on the NHS. A data linkage pathway has been established between the Born in Bradford Research Programme and the DWP and HMRC, see Chapter 6. This provides validated income and benefits data for participants who consent to financial data linkage.
Legal	There have been concerns raised regarding the requirement for consent from partners or other adult household members for financial data linkage, where this may affect benefits eligibility. Entitlement to Universal Credit is calculated based upon combined household income and therefore eligibility for this benefit could inadvertently disclose details about the nature of another adult's income. The DWP and HMRC have clarified that the provision of participant consent will be sufficient but this may change in time. Welfare advice services are regulated and delivered by approved advisors. In the provision of welfare advice services, safe and confidential spaces need to be established.	
Environmental	Physical co-location of services within health settings seems to improve trust of welfare service advisors, may normalise	In Bradford, there is willingness from maternity services, health visiting and child health centre teams to support a co-

Table 33 Analysis of the general and Bradford specific context for a welfare advice service co-located in health settings for mothers and their families, as a complex intervention, utilising the DEPESTLE framework

Factor	General maternal and child health setting	Bradford setting
	access to welfare advisors and reframe services as important to health. The geographical location and physicality of the co-located welfare advice services is also important in improving the accessibility of the services and ensuring the most vulnerable mothers and families have access to services. Challenges to accessing services for the most vulnerable could be overcome through the use of technology or outreach services where required. Financial assistance for attending clinics could also be considered. Where there are significant challenges with mothers and their families being able to access services, greater consideration could be given to home-based services, such as home visiting services.	located service. The provision of a universal glucose tolerance test in Bradford at the 20-week anomaly scan provides a significant opportunity in time for such an intervention. Children's health settings, such as community paediatric clinics, particularly for vulnerable children and children with neurodevelopmental difficulties, could also be an area to explore. As previously discussed, Bradford City Council have highlighted their appetite for expansion of existing welfare advice services into such health settings.

7.2.2 PROGRAMME THEORY

Programme theory describes how an intervention is expected to lead to a set of specified outcomes and under what conditions.[172] It should be developed at the outset as a collaborative process involving researchers and stakeholders and is an iterative process, that should be tested and refined at all stages and used to guide the identification of uncertainties, research questions and evaluation outcomes. It articulates: the key components of the intervention and how they interact; the mechanisms of the intervention; the features of the context that are expected to influence those mechanisms; and how those mechanisms may influence the context.[226]

An overarching theory of change was developed as part of the systematic review process and used as an analytical framework against which to assess the evidence and explain how the intervention works, why and for whom, see Figure 3. The theory of change explored how co-located services may work to improve health and wellbeing through measures to address social determinants of health and how the services may provide benefits to the health service.

The theory of change model has been amended based on the findings from this thesis, see Figure 17. This theory of change builds upon the theory of change developed throughout the systematic review and highlights where evidence to this theory of change is contributed to by this thesis. The model also highlights the areas, indicated by the asterisks, where evidence is contradictory.

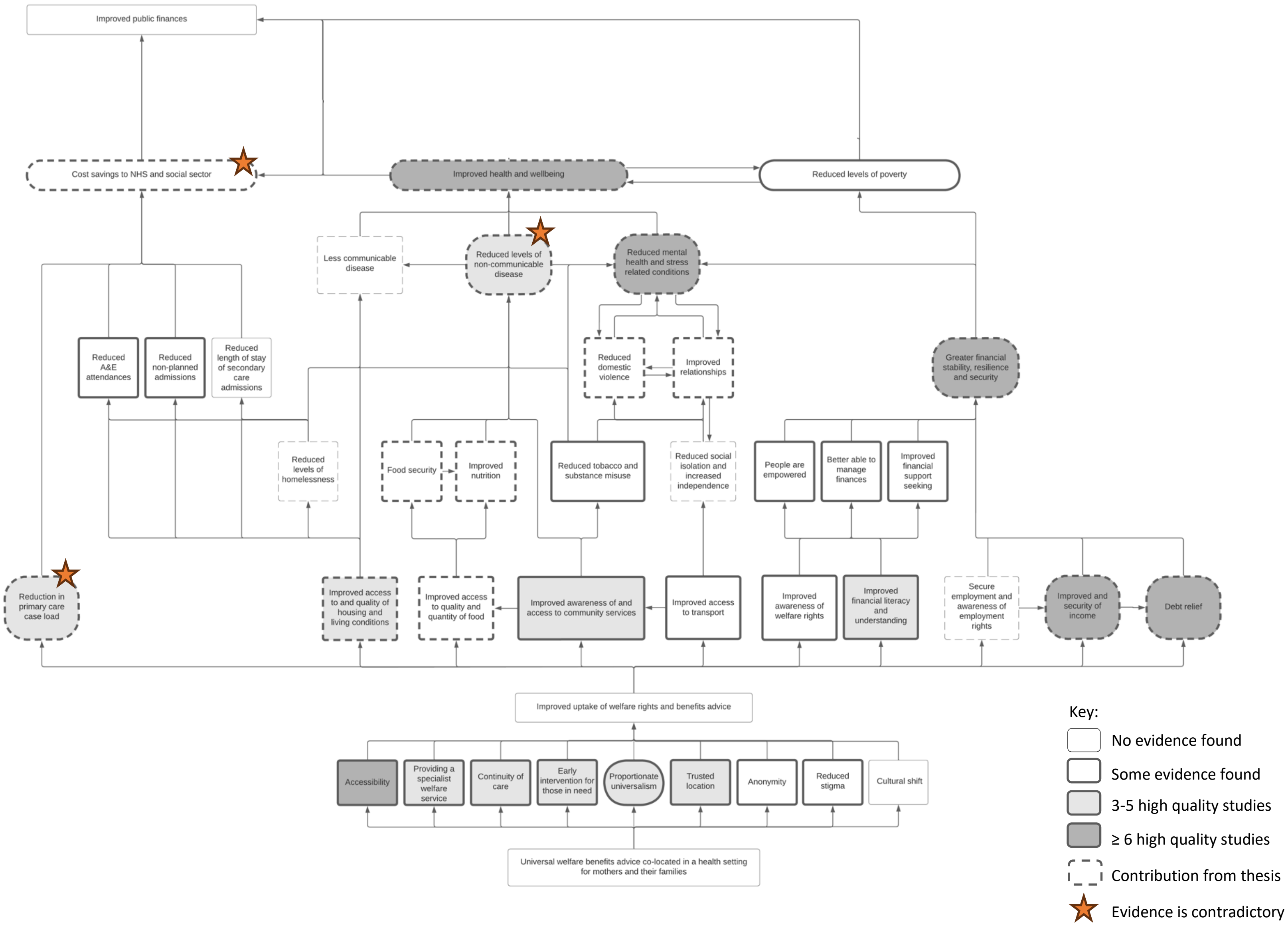

Figure 14 Revised and concluding theory of change model for universal welfare advice services co-located in health settings for mothers and their families

There are several mechanisms through which welfare advice services co-located in health settings for mothers and their families this thesis proposes this intervention operates to improve uptake of advice, compared to welfare advice services offered in a conventional setting, owing to the nature of its co-location. Being nested within such health settings, the services are considered by patients to be more accessible and anonymous. Due to the connection between welfare advice services and health professionals, the services are perceived by patients to be more trustworthy, less stigmatising and better able to identify and provide early intervention to those most in need of help. The services are thought to offer, by welfare advisors and patients alike, a more enhanced, specialist service, tailored to the needs of those specifically with long-term health and mental health conditions, with better follow-up and continuity of care, compared to conventional services. Overall, some welfare services co-located in health settings report adopting a proportionate universalism approach, distributing resources to favour the disadvantaged, by increasing resources to meet the needs of some of society's most vulnerable people, enabling it to have a greater impact on health inequalities.[131-133]

Access to these services and uptake of the welfare advice provided, improves financial security and stability for individuals through increased household income and support with debt relief. Improved financial literacy and an awareness of their welfare rights, help individuals feel more empowered and better able to manage their finances and improves their financial support seeking when they are in need of financial assistance in the future, instead of relying on overdrafts, credit cards and loans. This breaks the cycle of spiralling financial insecurity and ultimately reduces levels of poverty. These impacts on financial security improve physical health and wellbeing, through reduced levels of mental health and stress-related conditions.

Accessing co-located welfare services could also improve health and wellbeing through measures to address other social determinants of health more directly. The services provide advice and support to improve housing conditions, access to nutritional food and transport, reducing the risk of communicable disease transmission and improving physical health, as well as mental health and wellbeing. Services also raise awareness of and promote access to community services, improving and encouraging appropriate use of health services to improve health and wellbeing generally. This also reduces levels of tobacco and substance misuse directly, where relevant, improving personal relationships and reducing levels of domestic abuse, all improving health and wellbeing.

Finally, improved access to welfare services may also provide benefits to the NHS. Improved uptake of welfare advice services may lead to a reduction in primary care appointments and improved use of secondary health services, particularly mental health services, resulting in significant cost savings for the NHS.

As highlighted, there are some areas where there is contradictory evidence regarding the components of the theory of change model. There is evidence as demonstrated by this thesis, through the results of the systematic review and the results of Chapter 5, that co-located welfare advice services work to improve health and wellbeing for participants. However, some studies have found no evidence of effect. The evaluation of a welfare advice service co-located in a primary care setting presented in Chapter 5 demonstrated small improvements in wellbeing and quality of life but found no effect on mental health. Furthermore, the systematic review, presented in Chapter 3, presented evidence of improvements to primary care workload and as such, cost savings to the National Health Service. However, there were some studies that reported mixed findings in this area, with some primary care workers finding that there were no improvements in workload as a result of this intervention.

7.2.3 STAKEHOLDERS

Genuine stakeholder engagement is required throughout the research process to maximise the likelihood that the research addresses relevant questions that leads to changes in practice or policy.[172] Stakeholders are individuals or groups who are targeted by the intervention or policy, involved in its development or delivery, or more broadly those whose personal or professional interests are affected.[227,228] This includes patients and members of the public, as well as those linked in a professional capacity. The goal should be the development of collaborative relationships that continue throughout the phases of development, evaluation and implementation. The nature of stakeholder involvement should be transparent, with upfront and agreed terms of references and processes for declaring conflicts of interest.[172]

I conducted a stakeholder analysis for a universal welfare advice service co-located in health settings for mothers and their families, see Table 34. This analysis identifies important stakeholder groups for the development and evaluation of this complex intervention and provides an example of a representative from each stakeholder group from the setting of Bradford. Their role is described as singular or a combination of roles, including: commissioners, those who pay the organisation to do things; collaborators, those with whom the organisation works to develop and deliver products; contributors, those from whom the organisation acquires content for products; channels, those who provide the organisation with a route to a market or customer; commentators, those whose opinions of the organisation are heard by customers and others; consumers, those who acquire and use the product; champions, those who believe in and will actively promote the project; and competitors, those working in the same area who offer similar or alternative services.[227,228]

I constructed a topic guide for use with each stakeholder for the purposes of the stakeholder analysis, see Appendix A.1.1. In development of the topic guide, the most appropriate way to obtain the required information was considered, given the cultural context. Open questions were preferred to provide the stakeholders with time to consider and respond fully to the question. Direct follow-up questions were asked as required to elicit specific required information from stakeholders.

Following each interview, I reviewed and refined the topic guide where there may have been confusion or lack of understanding of the wording of any questions. The topic guide proved a suitable length and was easy to follow for the stakeholders. Stakeholders were all comfortable with the questions and overall topic guide.

Following completion of interviews with the stakeholders, I assessed and documented the relative power of each stakeholder, with respect their ability to influence and affect the development, implementation or evaluation of the intervention, and the likely impact of the change instigated by the intervention on the individual stakeholder. Furthermore, I recorded each stakeholder's interest in the intervention, their position with regards to the implementation of the intervention and their key priorities for the intervention. Dotted arrows indicates where I considered it possible and important to invest resources to shift the position of the stakeholder.

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	**Bradford representative example**	**Stakeholder role**	**Power**	**Impact**	**Interest**	**Support**			**Stakeholder priorities**
						For	**Neutral**	**Against**	
Patients	Patients of relevant health services	▪ Consumer ▪ Collaborator through co-production process ▪ Potential champions	High	High	High	X			▪ Consultation events were held with local parents in Bradford in the development of the UK PRP ActEarly consortium.[96] ▪ These consultation events identified poverty as a key barrier to engaging in a wide range of parenting interventions. ▪ Local parents and workers identified tackling financial vulnerability as a way to enable parents to engage in other activities beyond day-to-day 'survival'. ▪ However, financial vulnerabilities were also seen as stigmatising and asking for help as unacceptable in some local cultures.
	BiBBS Participants	▪ Consumer ▪ Collaborator through co-production process ▪ Potential champions	High	High	Medium	◀┈┈┈┈	X		▪ BiBBS participants have not formally been consulted in the stakeholder analysis as they were represented in the above consultation exercises and through the CRAG below.
Community groups	Bradford Community	▪ May contain consumers of	High	Low	Medium	X			▪ The CRAG were in support of interventions to improve the financial

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	Bradford representative example	Stakeholder role	Power	Impact	Interest	Support			Stakeholder priorities
						For	Neutral	Against	
	Research Action Group	the intervention. ▪ Collaborator through co-production process ▪ Commentator being elected representatives of BiBBS community. ▪ Potential champions							resilience of families in Bradford, including a welfare advice co-located in a maternity setting.
Healthcare professionals	Midwifes	▪ Collaborator ▪ Channel ▪ Commentator ▪ Potential champions	High	Medium-High	High	◄·······	X··		▪ Historically, interventions have been implemented in the BiBBS cohort study during antenatal appointments, in particular at the 20-week antenatal appointment. These have been welcomed and successful. ▪ Concerns were raised about the impact of any new intervention implemented on the already stretched and strained capacity of the midwifery team. Priority

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	Bradford representative example	Stakeholder role	Power	Impact	Interest	Support			Stakeholder priorities
						For	Neutral	Against	
									should be given to the provision of patient care in the first instance. ▪ The midwifery team also raised concerns about the sensitivity of the timing of some antenatal appointments, such as the 20-week appointment, where mothers may have been given bad news. This would need to be taken into consideration in the establishment of any intervention.
	Health visiting team	▪ Collaborator ▪ Channel ▪ Commentator ▪ Potential champions	High	Medium-High	High		X		▪ The health visiting team have also hosted other public health interventions historically and with success. ▪ There are concerns regarding the knowledge and the skills of the health visitors to co-host such an intervention. ▪ Health visitors also highlighted the importance of ensuring that any co-located intervention did not interfere with patient care.
	Screening co-ordinators	▪ Collaborator ▪ Channel ▪ Commentator	Low	Low	Low	Not formally assessed			▪ Not approached during this stakeholder analysis.

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	Bradford representative example	Stakeholder role	Power	Impact	Interest	Support			Stakeholder priorities
						For	Neutral	Against	
		▪ Potential champions							
	Community paediatricians	▪ Collaborator ▪ Channel ▪ Commentator ▪ Potential champions	High	Medium-High	Medium	X			▪ Community paediatricians from Bradford were not formally approached during this stakeholder analysis. ▪ However, consultation exercises were conducted within the ActEarly livelihoods theme, in preparation for a bid for the development of a welfare advice service co-located in children's hubs in London. These consultation exercises highlighted the desire of community paediatricians to move towards welfare advice services co-located within community paediatrician clinics. Families with children with neurodisabilities were highlighted by paediatricians as being particularly financially vulnerable and in need of financial assistance.
Welfare advice services	VCS Alliance welfare advisors	▪ Potential collaborator ▪ Contributor	High	High	High	◄·······	X··		▪ Welfare advisors were keen to expand their services where possible.

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	Bradford representative example	Stakeholder role	Power	Impact	Interest	Support			Stakeholder priorities
						For	Neutral	Against	
		▪ Channel ▪ Potential champions ▪ Competitors							▪ A priority is to establish secure funding for services. Recently, funding and services have been cut and commissioning is often short-term. This prevents any meaningful development of services. ▪ A confidential physical space dedicated for such services needs to be established and dedicated for the welfare advisors to use should a co-located service be established. ▪ Effective collaboration and integration within the clinical team is also a priority.
	Translators	▪ Collaborator ▪ Channel	▪ Collaborator Channel	Medium-High	Medium-High	Not formally assessed			▪ This stakeholder group has emerged during the latter stages of the development of the intervention and requires further engagement and evaluation.
Commissioners	Bradford City Council public health	▪ Potential commissioners ▪ Collaborators	High	Low	High	X			▪ Highlighted the challenges of delivering an effective city-wide welfare service

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	**Bradford representative example**	**Stakeholder role**	**Power**	**Impact**	**Interest**	**Support**			**Stakeholder priorities**
						For	**Neutral**	**Against**	
		▪ Commentator ▪ Potential champions							during periods of austerity and constrained funding. ▪ Recognised the needs and particular vulnerabilities of young families in the community and the role of such vulnerability as a social determinant of health. ▪ Would like to establish new services for mothers and their families.
	CCG	▪ Commissioners ▪ Potential collaborator ▪ Potential contributor if could facilitate data sharing. ▪ At present a competitor, offering a similar service through RIC VCS WBA programme	High	Low	Medium	Not formally assessed			▪ Not approached during this stakeholder analysis. ▪ Currently commission a welfare service co-located in primary care in Bradford, as part of the CCG RIC programme, which is described and evaluated in Chapter 5. It is unclear whether this funding may still be available for further developments in co-located services in the future and could be explored.

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	Bradford representative example	Stakeholder role	Power	Impact	Interest	Support			Stakeholder priorities
						For	Neutral	Against	
Academia and academic support	BIHR Bradford Inequalities Research Unit	▪ Collaborator ▪ Channel ▪ Champion	Low-Medium	Low	High	X			▪ Not approached during this stakeholder analysis. ▪ Bradford City CCG have commissioned BIRU to support the design and delivery of the RIC programme. ▪ Their support may be available for any future research programmes should they be financially supported by the RIC programme.
	ActEarly	▪ Collaborator ▪ Channel ▪ Champion	Low-Medium	Low	High	X			▪ The ActEarly livelihoods theme and wider ActEarly consortium can offer evaluation and wider support to any new such intervention. ▪ Establishing welfare services co-located in health settings has already been established as a priority for the Healthy Livelihoods theme. Bids are being prepared and have already been submitted for such services in East London in children's hubs.
	Born in Bradford Better Start	▪ Collaborator ▪ Channel ▪ Consumer	Low-Medium	Low	High	X			▪ Preliminary interest and support has been expressed for a welfare advice

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	Bradford representative example	Stakeholder role	Power	Impact	Interest	Support			Stakeholder priorities
						For	Neutral	Against	
		▪ Champion							service co-located in a setting for mothers and their families. ▪ Any such service would need to be carefully and considerately implemented in a culturally sensitive way that is acceptable to mothers, the BiBBS research team and existing health services.
	Healthy Wealthy Families	▪ Collaborator ▪ Channel ▪ Champion	Low	Low	High	X			▪ Healthy Wealthy Families are a new international research collaboration, consisting of researchers from England, Scotland, Sweden and Australia. ▪ The collaboration provides an opportunity for shared learning and future collaboration.
	Translators	▪ Collaborator ▪ Channel	Medium-High	Medium-High	High	Not formally assessed			▪ This stakeholder group has emerged during the latter stages of the development of the intervention and requires further engagement and evaluation.
Third sector	VCS Alliance	▪ Commissioner ▪ Potential collaborator	High	Low	High		X		▪ Currently co-ordinate a welfare service co-located in primary care in Bradford, as part of the CCG RIC programme.

Table 34 Stakeholder identification and analysis for setting of Bradford and identification of need for change to support for intervention

Stakeholder group	Bradford representative example	Stakeholder role	Power	Impact	Interest	Support			Stakeholder priorities
						For	Neutral	Against	
		▪ Channel ▪ Competitor							▪ The Alliance are keen to continue the delivery of their service and would consider expansion with secured funding. ▪ Longer term funding would be a priority, including buy-in from the welfare advisors.
Policy makers	DWP and HMRC	▪ Collaborator ▪ Contributor ▪ Channel ▪ Potential champions	Low-Medium	Low	Medium	X			▪ There is a political willingness to support research into how financial insecurity is affecting families and how welfare advice services can support families across the United Kingdom. ▪ Financial data sharing pathways already established.

Eight out of twelve representatives from stakeholder groups, whose support fort the intervention was assessed, were broadly in support of this intervention. Four out of twelve stakeholders were neither in support nor against the implementation of the intervention. However, all of these representatives were interested in the intervention and keen to explore the potential for the intervention. Their neutrality potentially reflects the complexity and unfamiliarity of the intervention and therefore their trepidation in providing initial support for the intervention without further knowledge and time to consider the complexities. Notably, health professionals and welfare advisors were of neutral position in this stakeholder analysis. This may be reflective of their apprehension and unfamiliarity with integrating two such services in this manner. As professionals are key to delivering the intervention, they are important stakeholders for which the intervention would require support should it be delivered. Therefore it is crucial that they are fully engaged with the development of the intervention to improve its likelihood of success. There were no stakeholder group representatives who opposed the intervention.

Figure 15**Error! Reference source not found.** presents a graphical representation of the specific stakeholders identified for the context of Bradford with respect to their respective stakeholder power and impact. I prioritised stakeholders according to their respective potential power and impact for this proposed intervention. Where multiple stakeholders were classified within the same power and impact e.g., high power, high impact, I examined the power and impact of each stakeholder relative to each other and positioned stakeholders accordingly on the position map.

Figure 15 Bradford stakeholder power and impact analysis position map

The stakeholder power and impact analysis facilitates the categorisation of stakeholders into four groups. These groups can be used to prioritise the order in which stakeholders are approached for engagement with the research process.[227,228] Stakeholders who have high power and high impact with respect to the intervention are crucial to the successful development and implementation of the intervention. These stakeholders should be meaningfully engaged throughout the research process through communication and consultation and should be managed closely.[172] For this intervention, this includes welfare advisors crucial to delivering the intervention. This group also includes health professionals, including midwives, health visitors and community paediatricians. Translators are not often considered to have such high power and impact within complex intervention settings.

However, the importance and challenge of engaging individuals from ethnic minority groups, particularly those whose first language is not English, has already been highlighted. For this reason, translators offer a crucial insight and service to play in the delivery of these services. Stakeholders who have high power but are likely to be less affected by any change effected by the intervention are a group that should be understood. They are usually opinion formers and it is important to keep them satisfied by keeping them informed of what is happening and regularly reviewing their position and interest with respect to the interest. As commissioners, Bradford City Council public health team and the Bradford City CCG lie within this group. Specialist patient groups, including the Bradford CRAG also have been afforded similar power and opportunity to contribute their voices to this and other interventions but are likely to have little impact directly from the intervention. Stakeholders with low power and high impact should be considered throughout the research process and generally kept informed of any progress. Patients often fall into this group, and for this intervention, BiBBS participants also lie within this group. They are traditionally considered to have low power as they have a low natural ability to influence the implementation or effectiveness of the intervention, despite being the consumers of the intervention. However, they are important stakeholders, as they are expected to be one of the groups most impacted by the intervention. Therefore, steps should be considered to increase the influence and power of these stakeholders by taking active consultative work. The final group includes those stakeholders who have low power and low impact. These stakeholders should be monitored for change in position or interest and should be kept informed. Should resources be significantly limited, it is thought that this group of stakeholders could be ignored. For this intervention, this would include antenatal screening coordinators, who are unlikely to have significant ability to affect the implementation or effectiveness of the intervention or to be impacted by the intervention.

7.2.4 UNCERTAINTIES

This section considers the key uncertainties that the research aims to address. Understanding which outcomes are important and measurable may help prioritise the focus of future research in this area. A PICOSS (population, intervention, comparator or control, outcome, setting, study design) framework was used to classify the main uncertainties emerging for this intervention,[118] see **Error! Reference source not found.** 35.

Table 35 Main uncertainties identified for the development and implementation of a welfare advice service co-located in a setting for mothers and their families as a complex intervention, classified according to the PICOSS Framework[118]

PICOSS item	Key uncertainties
Population, or participants and conditions of interest	▪ Whether and to what extent fathers should be actively involved with the intervention?
Interventions or exposures	▪ The nature and extent of the intervention: whether the intervention should involve a triage; a partial or full welfare advice service; and the nature of any follow-up required? ▪ Who should deliver the intervention: a legal advisor; a qualified welfare advisor; or a trained administrator? ▪ How much time to allocate to each participant for the delivery of the intervention? ▪ How to ensure accessibility and equity of access to the intervention?
Comparisons or control groups	▪ Where should participants for the control group be sourced from? ▪ If some BiBBS participants were to be used as a control group, how should the intervention be allocated to ensure randomisation and to minimise cross over? ▪ What should be ratio of participants to controls?
Outcomes of interest	▪ Does a universal offer of welfare advice in health settings for mothers reduce stigma, improve uptake of welfare advice and lead to a cultural shift? ▪ To what degree does access to welfare advice services improve financial resilience and reduce overall levels of poverty? ▪ To what degree do objective measures of financial security reflect lived experience of financial insecurity and resilience? ▪ The utility of linked validated financial data in health research. ▪ Lack of a sophisticated understanding of how families from ethnic minority groups experience financial insecurity and seek to improve their financial resilience, the ability to withstand and recover from financial shocks or hardship. ▪ How first language spoken affects the provision of consent for financial data linkage and how best to overcome this? ▪ What perspective should be adopted for an economic evaluation that captures all relevant outcomes? ▪ How and when to measure outcome measures relating to other social determinants of health, including employment, education and housing outcomes? ▪ How can impact of the services on healthcare professionals be feasibly evaluated given existing time pressures on already stretched health services? ▪ Which measures are available from routine linked data and what additional follow-up data may be needed? ▪ What is an appropriate length of time to measure outcomes to detect a meaningful change?

Table 35 Main uncertainties identified for the development and implementation of a welfare advice service co-located in a setting for mothers and their families as a complex intervention, classified according to the PICOSS Framework[118]

PICOSS item	Key uncertainties
	▪ How should the sample size be powered to detect change?
Setting	▪ Which setting would offer the most appropriate, feasible and acceptable universal offer of a welfare advice service?
Study designs	▪ Which of a randomised controlled trial, a trial within a cohort or quasi-experimental designs would be the most suitable and feasible method of evaluation? ▪ Would key demographics be balanced across potential clusters? ▪ Are people willing to participate in a study on this potentially sensitive issue and how might this be affected by the study design?

7.2.5 INTERVENTION REFINEMENT

This core element of the development and evaluating of complex intervention framework involves the development and subsequent refinement of the intervention. The PICOS framework was used to classify the main characteristics of the proposed intervention,[229] see Table 36.

Table 36 A welfare advice service co-located in a setting for mothers and their families, as a complex intervention, for the setting of Bradford classified according to the PICOS Framework

PICOS Item	Description
Population, or participants and conditions of interest	▪ New BiBBS participants attending their 20-week antenatal appointment at Bradford Royal Infirmary.
Interventions or exposures	▪ Welfare advice triage appointment by a qualified welfare advisor with provision of initial advice and arrangements made for follow-up as required.
Comparisons or control groups	▪ New BiBBS participants attending their antenatal or postnatal appointment on alternate days to provision of intervention. Control participants will receive a pamphlet of written financial advice.
Outcomes of interest	▪ Health and wellbeing outcomes: general health; mental health; and health-related quality of life. ▪ Social outcomes: educational; employment and housing outcomes. ▪ Participant financial outcomes: number of contacts; number and type of welfare issues resolved; length of caseload; and detail of benefits received and debt relieved. ▪ Economic evaluation: cost of intervention; staff salaries; cost of room hire; and total of participant financial outcomes. ▪ Implementation fidelity: uptake of welfare advice; variation of uptake of welfare advice by key sociodemographic factors;

Table 36 A welfare advice service co-located in a setting for mothers and their families, as a complex intervention, for the setting of Bradford classified according to the PICOS Framework

PICOS Item	Description
	provision of consent for financial and other data linkage for the purposes of intervention evaluation. ▪ Feasibility and acceptability: to participants; welfare advisors; and midwives and health visitors.
Setting	▪ 20-week antenatal appointment at Bradford Royal Infirmary where all pregnant women are attending for their routine and universal anomaly scan and glucose tolerance test.

7.2.6 ECONOMIC CONSIDERATIONS

Nearly all complex interventions will be costly to implement and will impose costs on a range of populations and organisations. Economic evaluation, the comparative analysis of alternative courses of action in terms of both costs and consequences, for those people and organisations affected should be a core component of all phases of intervention research.[172] Early identification of the potential costs and outcomes help with the setting of research questions and the design of an appropriate economic evaluation. Inclusion of economists, including health economists, in research teams from the early stages of research development ensures that economic considerations are fully incorporated in all important decisions about intervention and evaluation design. Inclusion of economic considerations in the programme theory will help with the understanding of the problem and shape the design of future feasibility and evaluation studies. Consideration should also be given to the research perspective. It may be appropriate in complex intervention research to adopt a broad rather than a narrow perspective, such as a societal rather than health service, to the scope of economic considerations included.[172]

Based upon the work conducted in the systematic review describing existing welfare advice services co-located in health settings, I comprised a table of economic considerations for a welfare advice service co-located in a setting for mothers and their families as a complex intervention, see Table 37.

Table 37 Economic considerations for a welfare advice service co-located in a setting for mothers and their families as a complex intervention

Perspective	Costs	Consequences
Participant	▪ Transport costs ▪ Childcare costs ▪ Potential loss of earnings in time invested in service	▪ Benefits received ▪ Additional income gained ▪ Debt relieved ▪ Secure employment achieved
Commissioners	▪ Salary of welfare advisors ▪ Room hire ▪ Equipment and materials required	
NHS	▪ Any loss of healthcare professional time to engaging with new service ▪ Potential loss of physical space to new co-located service	▪ Reduction in workload relating to social circumstances of participant ▪ Improved health and wellbeing of participants leading to reduced health burden on NHS
Wider society		▪ Reduced levels of poverty ▪ Reduced inequalities

A particular challenge for this intervention is determining and evaluating the outcomes of interest and the perspective from which to consider these outcomes. It is also theorised that the full range of the outcomes will be achieved in the medium and longer term, which impose challenges for researchers on monitoring these outcomes and evaluating causality. Consideration would need to be made to these challenges in the context of the wider research project to ensure all meaningful outcomes are accurately and meaningfully captured and analysed.

CHAPTER 8 DISCUSSION

This final chapter offers an overview of the key findings from the research and considers the overarching theoretical and methodological issues in the thesis as a whole. It considers the limitations of the research before outlining the strengths and contributions of the findings to the broader research and policy context. A series of recommendations based on the research and a final conclusion ends the thesis.

8.1 INTRODUCTION

This thesis explores whether co-location of universal welfare advice in health settings for mothers and their families, as a cost-effective measure to improve health and wellbeing, is acceptable and feasible to deliver and evaluate.

In this chapter, first I describe the main findings from my research and knowledge of the literature presented in this thesis in relation to the thesis research questions, originally depicted in Chapter 1.9:

a) How could universal welfare advice co-located in health settings improve health and wellbeing?

b) What are the health, social and financial impacts of welfare advice services co-located in health settings?

c) How has the COVID-19 pandemic and subsequent public health and welfare measures affected levels of financial security for mothers and their families in Bradford and what impact did this have on maternal health and wellbeing?

d) Would universal welfare advice co-located within health settings for mothers and their families be acceptable and feasible to deliver and evaluate?

I will then discuss other important contributions made by the results of my thesis and the limitations of the thesis overall, before moving on to a discussion of the implications of my research for practice and research.

8.2 MAIN FINDINGS AND CONTRIBUTIONS

8.2.1 RESEARCH QUESTION 1: HOW COULD UNIVERSAL WELFARE ADVICE CO-LOCATED IN HEALTH SETTINGS IMPROVE HEALTH AND WELLBEING?

An overarching theory of change was developed in the development process of my systematic review and was used as an analytical framework against which to assess the evidence emerging from the systematic review for this thesis. It explained how the intervention might work, why and for whom, see Figure 3. Following the completion of my systematic review, the emerging evidence was mapped against the theory of change model, see Figure 5, demonstrating the spread of evidence across the model, highlighting areas with a greater evidence base and areas where evidence was limited or lacking.

The original theory of change model has since been updated and refined in light of the emerging evidence conducted throughout this research, see Figure. Amendments to the theory of change model developed during the systematic review process are represented graphically in Appendix A.6.1.

The theory of change model now focuses on the implementation of a welfare advice service that is universal and specifically co-located in health settings for mothers and their families, rather than in a general health setting. It builds upon some of the foundational relationships understood between the mechanisms by which these services work to improve health and wellbeing. It goes further to explain some of the longer-term impacts of this intervention on the broader socioeconomic landscape, should the intervention be more widely rolled out. The theory of change model also highlights where the research contributes to this overall theory of change model and body of evidence.

This thesis argues and concludes that a universal offer of welfare advice, through co-location in health settings for mothers and their families, could overcome, to some extent, the stigma and cultural issues associated with financial vulnerability and receiving help by normalising access to welfare advice and re-framing financial security as an issue important to the health of the mother and their family.

These services could thereby increase the uptake of welfare advice, particularly in under-served populations, and improve financial security for families. Furthermore, this theory of change proposes that the implementation of a universal welfare advice service in health settings for mothers and their families results in cost savings to the NHS and social sector, improves public finances.

There are several additional mechanisms through which welfare advice services co-located in a healthcare setting for mothers and their families might operate to improve uptake of advice, compared to welfare advice services offered in a conventional setting, owing to the nature of its co-location. Being nested within a health setting, the services are considered more accessible and provide a greater degree of anonymity to individuals accessing them. Due to the connection between welfare advice services and health professionals, the services are perceived to be more trustworthy, less stigmatising and better able to provide early intervention to those most in need of help. The services are thought to offer a more enhanced, specialist service, tailored to the needs of those specifically with long-term health and mental health conditions, with better follow-up and continuity of care, compared to conventional services. These services can be further tailored to address the specific needs of mothers and young families, such as maternity and employment rights and support for domestic abuse. Overall, welfare services co-located in a healthcare setting adopt a proportionate universalism approach, distributing resources to favour the disadvantaged, by increasing resources to meet the needs of some of society's most vulnerable people, enabling it to have a greater impact on health inequalities.[131] This approach is strengthened with the provision of a universal offer of welfare advice in a universally provided health service, where there is near universal uptake.

This programme theory proposes that access to these services and take up of the welfare advice provided, improves financial security and stability for individuals through increased household income and support with debt relief. Improved financial literacy and an awareness of welfare rights, help individuals feel more empowered, improve financial resilience and improve their financial support seeking when they are in need of financial assistance in the future, instead of relying on overdrafts, credit cards and loans. This breaks the cycle of spiralling financial insecurity and ultimately reduces levels of poverty. These impacts on financial security improve physical health and wellbeing, through reduced levels of mental health problems and stress-related conditions.

Accessing co-located welfare services could also improve health and wellbeing through measures to address other social determinants of health more directly. The services provide advice and support to improve housing conditions, access to nutritional food and transport, reducing the risk of communicable disease transmission and improving physical health, as well as mental health and wellbeing. Services also raise awareness of and promote access to community services, improving and encouraging appropriate use of health services to improve health and wellbeing generally. This also reduces levels of substance misuse directly, improving personal relationships and reducing levels of domestic abuse, all improving health and wellbeing.

Finally, improved access to welfare services may also provide benefits to the NHS and subsequently improves public spending. Improved uptake of welfare advice services lead to a reduction in primary care appointments and improved use of secondary health services, particularly mental health services, resulting in significant cost savings for the NHS and freeing up the resources needed to address those most in need.

8.2.2 RESEARCH QUESTION 2: WHAT ARE THE HEALTH, SOCIAL AND FINANCIAL IMPACTS OF WELFARE ADVICE SERVICES CO-LOCATED IN HEALTH SETTINGS?

A systematic review, published in 2006, of welfare advice delivered in health settings found that there was evidence that this approach resulted in financial gains but at that time there was limited high quality evidence to determine whether this resulted in improved uptake of welfare advice or measurable health and social benefits.[62] Furthermore, none of the included studies considered variation in uptake between ethnic groups. Allmark et al. developed a theory of change model, building upon this review with a synthesis of evidence published to 2010, to demonstrate the possible theoretical causal pathways linking co-located welfare services and health benefits.[63]

I conducted a narrative systematic review, building upon the previously published systematic review and theory of change model, to assess the health, social and financial impacts of co-located welfare services in the UK and to explore the effectiveness of and facilitators and barriers to successful implementation of these services. I searched Medline, EMBASE and other literature sources, from January 2010 to November 2020, for literature examining the impact of co-located welfare services in the UK on any outcome. The review identified 14 studies employing a range of study designs, including: one non-randomised controlled trial; one pilot randomised controlled trial; one before-and-after-study; three qualitative studies; and eight case studies. All studies demonstrated improved financial security for participants, generating an average of £27 of social, economic and environmental return per £1 invested. Some studies reported improved mental health for individuals accessing services. Several studies attributed subjective improvements in physical health to the service through action on key social determinants of health.

Importantly, several studies highlighted challenges in conducting evaluations of welfare services of relevance to future studies conducted in this area. Many struggled to recruit sufficient participants or were unable to follow-up sufficient numbers to achieve reasonable statistical power. Several studies reported challenges in identifying suitable effectiveness and implementation outcome measures, resulting in significant heterogeneity in reported outcomes across the included studies. The challenge of recruiting minority groups was also raised as a particular concern in many studies. Furthermore, given the overall, generally poor scientific quality of the studies, care must be taken in drawing firm conclusions about the impact of co-located services on health, social and financial outcomes from both systematic reviews of the existence evidence base in this area.

I conducted a feasibility evaluation of a welfare advice service co-located in a primary care setting in Bradford to investigate whether the proposed evaluation tools and processes were acceptable and feasible to implement and where permitting, whether they were able to detect any evidence of promise for this intervention on the health, wellbeing and financial security of participants in an ethnically diverse and deprived population. This evaluation demonstrated further evidence of promise for improvements in measured wellbeing and health-related quality of life for participants accessing services in a highly ethnically diverse population. There were small improvements in group mental health, as indicated by PHQ-8 scores, however this study was not powered sufficiently to detect any meaningful change in PHQ-8 scores. Given that no control group was included for this study, it is not clear whether these associations are causal and the role of chance cannot be excluded. There is also a significant risk of selection and reporting bias given the use of welfare advisors for the recruitment of participants and data collection. This evaluation also demonstrated clear financial gains for participants and a small return on investment for commissioners, with an estimated return of investment of £0.35 for participants for every £1 invested. The financial outcomes for participants of this study are lower in value in comparison to other published studies, however the completeness of this outcome measure was poor.

Overall, this thesis brings together the existing evidence base to support the theory of change model and hypothesis that welfare advice services co-located in a health setting improve health, social and financial outcomes for participants. This thesis also offers further evidence of promise to build upon this evidence base. However, given the limitations discussed there remains a need for more high-quality research, using experimental methods and larger sample sizes, to further build upon this evidence base and to measure the strength of the proposed theoretical pathways in this area. Greater homogeneity of outcome measures in reported studies facilitating meta-analysis of synthesis evidence will also further support and build the understanding of the direction and magnitude of impact of co-located services on health, social and financial outcomes.

8.2.3 RESEARCH QUESTION 3: HOW HAS THE COVID-19 PANDEMIC AND SUBSEQUENT PUBLIC HEALTH AND WELFARE MEASURES AFFECTED LEVELS OF FINANCIAL SECURITY FOR MOTHERS AND THEIR FAMILIES IN BRADFORD AND WHAT IMPACT DID THIS HAVE ON MATERNAL HEALTH AND WELLBEING?

The emergence of the COVID-19 pandemic and subsequent implementation of public health measures during the conduct of this thesis had unintended consequences on socioeconomic security and health inequalities, having the greatest impact on the most vulnerable groups. A longitudinal study was conducted with the aim to explore the medium to long-term impacts of the COVID-19 pandemic and subsequent public health measures on financial security for families living in the deprived and ethnically diverse city of Bradford. Data were collected at four time points before and during the pandemic from mothers who participated in one of two prospective birth cohort studies in Bradford, BiBBS and BiBGU.

The findings of this study demonstrated that the risk of experiencing financial insecurity for mothers rose sharply during the pandemic and had not returned to pre-COVID-19 baseline levels towards the end of the pandemic. Several individual characteristics were found to be possible predictors of financial insecurity, including homeowner status, free school meal eligibility and not working. Several protective factors against financial insecurity were identified, including: living in more affluent areas; greater levels of educational attainment; and families with two or more adults in the household. Notably, families of Pakistani Heritage were found to have the greatest risk of experiencing financial insecurity throughout the pandemic. Furthermore, this study demonstrated that there were strong associations between financial insecurity and maternal health and wellbeing outcomes, with mothers experiencing financial insecurity being more likely to report unsatisfactory general health and clinically relevant symptoms of depression and anxiety.

The findings of this study highlighted that the impact of financial insecurity experienced by mothers and their families throughout the pandemic was severe, wide ranging and affected the most vulnerable. However, the results need to be considered alongside the main limitations of the study. There was a notable risk of selection bias owing to the low response rates to the initial survey and subsequent follow-up surveys. Furthermore, it was not possible from this analysis to establish temporality and thus determine causality for these associations. However, the study has highlighted the direction and magnitude of these relationships for this population, emphasising the need to address all health, social and economic factors to support families to recover holistically, with targeted support to those most vulnerable.

The results of this study emphasise the need for intervention to provide greater financial support for families in order to build financial security and resilience in the wake of the pandemic and emerging cost of living crisis to prevent further widening of existing health and social inequalities. Identified as a priority from community co-production work for the ActEarly consortium research proposal, the provision of welfare advice services co-located in health settings for mothers and their families could help to address these issues.

8.2.4 RESEARCH QUESTION 4: WOULD UNIVERSAL WELFARE ADVICE CO-LOCATED WITHIN HEALTH SETTINGS FOR MOTHERS AND THEIR FAMILIES BE ACCEPTABLE AND FEASIBLE TO DELIVER AND EVALUATE?

This section assimilates the evidence presented by this thesis and provides a narrative for the implementation of this evidence to the development and evaluation of a universal welfare advice service co-located in health settings for mothers and their families. This section highlights the remaining considerations for the development of this complex intervention and the potential impact of this intervention for future research and policy.

The evidence presented by this research is assimilated and presented according to the four phases of complex intervention development and evaluation as presented by the MRC and NIHR complex intervention research framework: developing or identifying the intervention; feasibility testing; evaluation; and implementation.[172] This section provides an overview of these phases and considers the application of the evidence and learning associated with each of these elements as a generic adaptable intervention and specifically to the setting of Bradford.

8.2.4.1 INTERVENTION DEVELOPMENT

The intervention development phase of a complex intervention involves either the development of a new intervention or the adaptation of an existing intervention for a new context, based on research evidence and the theory of the problem.[230] This thesis considers the adaptation of an existing intervention in a new setting and applied in a different manner. It considers welfare advice services co-located in health settings offered universally to mothers and their families.

The stakeholder consultation exercises conducted found that eight representatives from stakeholder groups in Bradford were broadly in support this intervention, with four stakeholders neither in support nor against the implementation of the intervention. One group who were in support of the intervention were the council who currently commission welfare advice services across Bradford. They had established a service for mothers and their families as a priority for the next funding round and were keen to deliver this intervention. The neutrality of some stakeholders may have reflected the complexity and unfamiliarity of the intervention and therefore the trepidation of stakeholders in providing initial support for the intervention without further knowledge and time to consider the complexities. One significant cluster of stakeholders with neutral positions were health professionals and welfare advisors. This may be reflective of their apprehension and unfamiliarity with integrating two services in this manner. As both professional groups are key to delivering the intervention, they were identified as important stakeholders for which the intervention would require support should it be delivered. Therefore, it is crucial that they are fully engaged with the development of the intervention to improve its likelihood of success. There were no stakeholder group representatives who opposed the intervention.

In order to further explore intervention feasibility, implementation and evaluations of interventions conducted specifically within the context of a health setting for mothers and their children have been specifically considered. Launched in November 2010, Healthier, Wealthier Children is a continuing partnership approach to tackle child poverty across NHS Greater Glasgow and Clyde. By creating information and referral pathways between the NHS early years workforce and welfare advice services, it was envisaged that staff, such as midwives and health visitors, would strengthen the identification of need for advice among pregnant women and families, thereby mitigating the impact of child poverty. Evidence for the effectiveness of the Healthier, Wealthier Children was promising,[110,111] and the model is now being evaluated in England, Sweden and Australia, as part of an international academic collaboration, Healthier Wealthier Families.[231,232] Similar welfare advice services have been co-located in children's hospitals, such as Great Ormond Street Hospital, however their effects have not been formally evaluated and reported.[233] There are no known interventions that currently offer a universal offer of welfare advice within existing services.

8.2.4.2 FEASIBILITY

This section explores the feasibility of the intervention and evaluation design to underpin decisions about whether or not and how to progress to evaluation.[172] Alongside the consideration of the feasibility of the intervention and evaluation design, the feasibility phase also evaluates key economic considerations. This may include identifying and measuring key resource use and outcomes for the purposes of designing a full economic evaluation.[234]

With respect to evaluation design, a feasibility study should assess key aspects of research design, which may include: recruitment, including time frames, willingness of participants to be randomised, capacity of those involved to recruit participants and effective recruitment strategies; retention, including follow-up rates and reasons for attrition; sample size; outcomes, including choice of outcome measures, data collection tools and duration of follow-ups; analysis; and unintended outcomes, for example, potential harms or the impact of the intervention on inequalities.[172,234]

I conducted a feasibility evaluation of a welfare advice service co-located in a primary care health setting in practice, which sought to investigate whether the proposed evaluation tools and processes were acceptable and feasible to implement and, where permitting, whether they were able to detect any evidence of promise for this intervention on the health, wellbeing and financial security of participants in an ethnically diverse and deprived population.

Overall, this evaluation found that there were low participant recruitment rates into the study. Inter-provider variability in recruitment rate was observed suggesting that there may be individual provider level factors affecting the ability or willingness of providers and the associated welfare advisors to engage with the evaluation. Therefore, recruitment should be conducted by an independent researcher and recruitment offered to all potential participants in a standardised manner to minimise recruitment bias. Where possible, follow-up data collection should also be performed by an independent researcher to minimise observer and reporting bias.

The calculated retention rate (69%) was high and comparable to similarly conducted evaluations, which could be explained by the use of financial incentives, comparable to other similar published interventions utilising financial incentives.[64] Overall, the majority of key outcome measures were well completed, indicating participant acceptability of these outcome measures, data collection tools and processes, and length of follow-up in this population. Financial gains outcomes were not well completed in comparison to other outcome measures, which limited the ability of the evaluation to report accurate financial outcome data and to conduct meaningful economic analyses, however these data was collected and reported by the VCS Alliance. This highlights the need to ensure complete and accurate financial outcomes are achieved for participants to support economic evaluations of such interventions.

This study offered evidence of acceptability and utility of the proposed evaluation tools to evaluate the impact of this intervention on the health, wellbeing and financial security of participants with respect to completeness of outcome measures and their ability to detect potential change in outcome measures for the intervention in this population. Chosen measures of mental health, wellbeing and health-related quality of life were extremely well completed and could be considered acceptable for use in the evaluation of this intervention in this setting and within this unique and diverse population.

Chapter 6 specifically demonstrates the feasibility of obtaining validated benefits and income data, as an objective measure of financial security, to support evaluations of such interventions and the acceptability of this to mothers and their families. This research highlights the potential for the utility of data linkage as a means to obtain objective, validated financial data to improve the accuracy and understanding of financial circumstances and insecurity for participants in research. As highlighted from the feasibility evaluation of the VCS Alliance welfare advice programme, such validated financial outcome measures are also useful in supporting accurate economic evaluations of such interventions and supporting other analytical approaches to avoid regression to the mean.

However, the utility of such financial data as objective and validated measures of financial circumstances as used in health research are not yet fully understood and require further research. It is understood that such data will provide clarity of income and receipt of benefits, which may give some indication to benefit entitlement. However, the information obtained may not be sufficient to capture all individuals who are eligible and who may not claim benefits. The lack of this information may also disproportionally impact vulnerable groups who are likely to have disengaged with the benefits system, such as homeless people or refugees, who still not have found work or been consistently in work. Furthermore, the definition of financial security may need to be re-examined and not taken in totality to represent household income and the presence or absence of debt. Measures of financial resilience need to be captured and this further reinforces the need to supplement any objective data received with important subjective self-reported measures of financial security. This reflects the need to conduct further research into how such subjective measures reflect the experience of financial resilience and security for individuals and their families.

This research also further improves our understanding of the impact of the use of financial data on recruitment rates for cohort studies used in health research. The results fall in line with existing research, highlighting the complex nature of utilising data linkage in health research and the interplay of other agencies in this. Further entwining of financial data linkage consent pathways into the existing BiBBS recruitment process may impact upon the relationship and trust the research group have built with the participants and its community, which has been reflected in the experience of other health research studies.

Furthermore, this research further improves our understanding of the interplay of socioeconomic demographics on the provision of consent for financial data linkage. It suggests that adapting consent procedures in light of these findings may improve rates of consent, in particular for the most vulnerable and marginalised groups. However, further research needs to be conducted with larger sample sizes to fully understand some of the reported associations, particularly with certain marginalised groups, where sample sizes are inherently smaller. Particularly, there needs to be more research conducted specifically to understand the perception of people from ethnic minority groups towards financial data sharing, how this relates to language spoken and how best to overcome this.

8.2.4.3 EVALUATION

According to the complex intervention framework, evaluation enables judgements to be made about the value of an intervention. It assesses whether an intervention works in achieving its intended outcomes, theorising how the intervention works, and taking into account how the interventions interacts with the context and system in which it is implemented.[172]

Existing evidence has also highlighted the challenges in demonstrating the effectiveness of co-located welfare advice interventions and further research requires a robust evaluation to assess effectiveness. Evidence acquired through this thesis also demonstrates evidence of promise for the improvement of health and wellbeing for recipients of welfare advice, warranting further investigation. With this in mind, it seems appropriate to proceed to a full effectiveness evaluation. Effectiveness evaluations assess whether interventions work in pragmatic real-world settings. The principal focus is to identify an unbiased estimate of the average effect of the intervention in a heterogeneous context that is representative of the scenarios in which the intervention will be applied in practice.

Existing literature in this area has also highlighted that successful implementation of the intervention is crucial to ensuring that there is an intervention and service available for evaluation. This intervention is affected by a complex interplay of several individual, societal, structural and system factors and as such it would be difficult to conduct an efficacy evaluation. This complexity highlights the importance and need for evaluating the intervention in a real-world setting, where these factors can be measured and assessed in order to better understand how to improve the chances of successfully implementing the intervention, whilst also measuring and understanding the impact of the intervention on its purported outcome measures. Therefore it is important that any effectiveness evaluation of this intervention is accompanied by a suitable process evaluation to assess the acceptability, equity and fidelity of the intervention.

Choice of evaluation outcomes

The choice of outcome measures is a crucial aspect of the design of an evaluation to demonstrate evidence of change.[172] There are several approaches to the choice of appropriate outcome measures. A good theoretical understanding of the intervention, derived from careful development work, is key to choosing suitable outcome measures. It is also important to consider this alongside which outcomes are most important for stakeholders, to improve the utility and relevance of any outcome data achieved.

Most existing published literature has reported evidence suggestive of improvements to financial security and to the health and wellbeing of participants in receipt of this intervention, leading to potential reductions in health inequalities. Some literature also reports potential benefits to health services with respect to greater job satisfaction and to cost savings for the health service and wider society through its action on wider determinants of health. However, no consensus has been achieved on the most appropriate measures for these outcomes nor an appropriate time frame within which to follow-up participants.

The proposed theory of change model and associated logic model highlights the potential range of short- and long-term outcomes and pathways to impact for this intervention. The stakeholder analysis highlights the importance and relevance of each outcome to stakeholders. The assimilation of existing published literature in this area, demonstrated in Chapter 3, with further feasibility work published in Chapter 5 and Chapter 6, suggests a number of effectiveness outcomes. Table 38 details the proposed effectiveness outcomes measures for this complex intervention. The table also maps the proposed outcomes against existing national outcomes frameworks and core outcome sets: the NHS Outcomes

Framework (NHSOF)[235]; Public Health Outcomes Framework (PHOF)[236]; and the COS-EY Core Outcome Set.[197] Demonstrative alignment of effectiveness outcome measures against published national outcome frameworks and other published core outcome measures improves the relevance of the outcomes for stakeholders, particularly commissioners, policy makers and other researchers.

Table 38 Welfare advice services co-located in health settings for mothers and their families proposed effectiveness evaluation outcomes.

Outcome set	Outcome name	Outcome measures	Potential data sources	Outcomes framework mapping
Poverty and inequality	▪ Poverty	▪ Income	▪ Self-reported via participant questionnaire ▪ Data linkage	▪ COS-EY Set 6: Poverty and inequality[197]
	▪ Financial security and resilience	▪ Self-reported financial security ▪ Additional benefits received ▪ Additional income gained ▪ Debt relieved ▪ Financial literacy and understanding ▪ Financial support seeking ▪ Worry about paying for rent or mortgage ▪ Worry about eviction ▪ Ability to pay bills	▪ Self-reported via participant questionnaire ▪ Data linkage	▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
	▪ Food security	▪ Whether food lasted ▪ Ability to eat a balanced meal ▪ Needing to skip a meal ▪ Feeling hungry	▪ Self-reported via participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236]
	▪ Secure and fulfilling employment	▪ Secure employment achieved	▪ Self-reported via participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236]
	▪ Safe and secure housing	▪ Homeowner status ▪ Presence of damp and mould in the home	▪ Self-reported via participant	▪ COS-EY Set 6: Poverty and inequality[197]

Table 38 Welfare advice services co-located in health settings for mothers and their families proposed effectiveness evaluation outcomes.

Outcome set	Outcome name	Outcome measures	Potential data sources	Outcomes framework mapping
		▪ Number of adults per household ▪ Number of children per household ▪ Number of bedrooms per household	questionnaire	▪ Public Health Outcomes Framework[236]
Physical health and health behaviours	▪ Parental general health	▪ Self-reported general health	▪ Self-reported via participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
Mental health and quality of life	▪ Parental mental health	▪ PHQ-8[101]	▪ Validated research tool	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
	▪ Parental quality of life	▪ EQ-5D-5L[107]		▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
Social environment	▪ Family and social relationships ▪ Domestic violence ▪ Loneliness and isolation ▪ Access to community services ▪ Parenting skills	▪ Relationship status ▪ Single parent ▪ Loneliness ▪ Relationship quality ▪ Quality of communication in relationship ▪ Arguments within relationships ▪ Conflict within relationship	▪ Self-reported via participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236]

Table 38 Welfare advice services co-located in health settings for mothers and their families proposed effectiveness evaluation outcomes.

Outcome set	Outcome name	Outcome measures	Potential data sources	Outcomes framework mapping
Health service impact	▪ Healthcare professional burden	▪ Reduction in workload relating to social circumstances of participant ▪ Improved health and wellbeing of participants leading to reduced health burden on NHS	▪ Qualitative tools: questionnaires; interviews; and focus groups.	▪ Public Health Outcomes Framework[236]

The majority of the proposed effectiveness outcome measures are derived from self-reported measures via a tailored participant questionnaire. This approach has been chosen based on the demonstrable success of these measures with the Born in Bradford Research Programme, as they are embedded within the BiBBS participant questionnaire and COVID-19 study.[30,89] This approach was also trialled successfully within the evaluation of the community alliance welfare advice service in primary care, as additional questions embedded within the questionnaire as part of the feasibility evaluation. The PHQ-8 tool did not demonstrate meaningful change, however the sample size was not sufficiently powered to detect any meaningful change should there be one. The PHQ-8[101] and EQ-5D-5L[107] tools were also chosen based on their successful use within the Born in Bradford Research Programme and as part of the feasibility evaluation of this thesis. Furthermore, these tools have been validated for use in several different languages pertinent to the setting of Bradford and other relevant settings.

A priori sample size calculations are made to ensure that there is enough statistical power to detect a meaningful target difference in the outcome between the intervention and the comparison groups and ideally will be sufficient to detect a meaningful change in all specified candidate outcomes, as previously described.[172] For this complex intervention, PHQ-8, SWEMWBS and EQ-5D-5L measures could all be used to estimate sample sizes based on the desired significance level and power.

Utilising the effect sizes generated by the community alliance welfare advice evaluation, for a full effectiveness evaluation it is estimated that 296 participants per arm would be required to have 90% power to detect a clinically meaningful difference in the primary outcome of quality of life, measured as 0.133 in EQ-5D-5L health index score between groups for 5% two-sided alpha t-test. A sample size of 505 participants per arm would be required to have 90% power to detect a clinically meaningful difference in all quality of life (difference of 0.113 in mean group health index score), wellbeing (difference of 1.27 in SWEMWBS score) and mental health measures (difference of 1in PHQ-8 score) collectively at 3 months follow-up for 5% two-sided alpha t-test.

Understanding processes

Process evaluation is a critically important component of the evaluation of complex interventions and is an essential adjunct to the study designs. Process evaluations can use a mixed methods approach for process data to answer questions around: fidelity; quality of implementation; mechanisms of change; and context.[172] Process evaluations in an effectiveness perspective would be used to inform findings, for example to provide insight into why an intervention fails unexpectedly or has unanticipated consequences, or why a successful intervention works and how it can be optimised.[172,234]

In order to ensure that a full and holistic process evaluation is conducted of this complex intervention, a process evaluation is recommended for future evaluations, integrated within an effectiveness evaluation, such as the RE-AIM framework..[237-239]

Economic evaluation

Obtaining a cost of the overall intervention is simple to obtain and measure, as reported through published literature and as demonstrated through feasibility work conducted during this thesis, see Chapter 5. However, identifying the costs per participant is more challenging to establish. Participant outcome measures relating to additional income gained, through additional benefits received and one-off payments, and debt relieved has been relatively simple to obtain when in receipt of an intervention. This has been demonstrated in the published literature, however, was technically challenging to obtain though the community alliance welfare advice programme evaluated in Chapter 5. This data could be easier to obtain with more dedicated administrative resources to obtain this follow-up data, or through utilisation of data linkage pathways established, for example with HMRC and the DWP.

Utilising the available data, in the feasibility evaluation it was relatively straight forward to calculate and report a simple return on investment for participants per unit of investment for commissioners. This is in keeping with reported economic analyses in previously published evaluations as highlighted in my systematic review. However, a more complex economic evaluation has yet to be conducted and reported in full. The ability to measure improvements in health and health-related quality of life facilitates a cost benefit and cost utility analysis respectively. However, this does not capture the full range of outcomes measured or theorised in the programme theory for this complex intervention.

Given that complex interventions typically have effects across a wide and diverse range of outcomes, recent guidance emphasises the use of a broad framework, such as a CCA or CBA. A CCA has the intuitive appeal of providing data across a range of outcomes, with which decision makers are likely to be concerned when making a policy decision. This allows the analyst to adopt a broad public sector or societal perspective that is appropriate to many complex interventions. There are also a number of emerging methodologies that can lend themselves to economic evaluations of complex interventions, such as a Social Return on Investment.[141] These are not usually considered to be standard tools for economic evaluation owing to theoretical weaknesses and their handling of outcomes, but they are becoming more commonly used in the area of complex interventions. It is also important to note, that the different frameworks are not mutually exclusive and that cost-benefit and cost-utility analyses can be carried out and embedded in a wider CCA or social return on investment that provides data on a more comprehensive inventory of outcomes.[172]

8.2.4.4 IMPLEMENTATION

Within the context of the design, implementation and evaluation of complex interventions framework, implementation is considered to be a deliberate effort to increase the impact of successfully tested health innovations so as to benefit more people and to foster policy and programme development on a lasting basis. Even after interventions have demonstrated effectiveness, long term successful implementation and integration into routine care remains challenging and rare.[172]

Consideration of the implementation of this complex intervention has been a key priority throughout this thesis. A key aim of the systematic review reported in Chapter 3 was to identify and explore the relationships between reported facilitators and barriers to implementation, to understand how and why particular barriers and enablers to implementation operate. Overall, co-production throughout all research phases was seen as an essential factor for the successful implementation of the service. Co-production was felt to promote a more sustainable approach and built trust between the NHS and welfare advice services.

With the published literature concerning co-located services relying almost exclusively on referral pathways, the inclusion of healthcare professionals in the co-production process was found to be crucial, in order to raise awareness of the service amongst healthcare professions and thus improve appropriate referral rates. Even with a universal offer, this is likely to come from health professionals and thus they remain key to the successful implementation of the intervention. Several studies also reported the importance of higher-level strategic buy-in to facilitate effective leadership and strategic working relationships.

Most studies reported the importance of effective collaboration, communication and integration of the services, with genuine co-production throughout. Where working relationships were nurtured and created a welcoming, close and trusted relationship, the integrated services thrived. These relationships were facilitated through the provision of dedicated physical space and resources for welfare advisors within the health setting. Some studies also reported organisational barriers with NHS information sharing protocols which made referral processes more challenging and caused unnecessary delays. Embedding an evaluation within an existing cohort with established data linkage pathways, particularly with health services and the NHS, should hopefully negative some of these technical issues.

Finally, there was a strong sense that shared values of co-production, collaboration, communication, confidentiality, flexibility, holistic care and trust between all involved with the services was important for a successful and effective service.

It is important to note that only two of the included studies in the review included welfare advice services co-located in health settings for mothers and their families and that all of the studies relied on referrals to access the service, none included a universal offer. However, most of the implementation factors are considered important to include in the consideration of the implementation of this complex intervention.

Stakeholder inclusion has been a key priority from the outset of the thesis. From the inception of the complex intervention, genuine co-production and stakeholder involvement was a priority. Unfortunately, given the onset of the COVID-19 pandemic, the original service design group planned for the development of this intervention was considered not appropriate at this time but could be established based on the work of this thesis moving forward.

The ongoing need for such a service has been assessed continuously throughout this thesis, through ongoing consideration of the wider contextual issues, and ongoing engagement with stakeholders. Chapter 4 explores the medium to long-term impacts of the COVID-19 pandemic and subsequent public health measures on financial security in vulnerable families in Bradford and the resultant impact on maternal health and wellbeing. This chapter serves to highlight that the impact of financial insecurity experienced by mothers and their families throughout the COVID-19 pandemic was severe, wide ranging and affected the most vulnerable, with significant impact to the physical and mental health of mothers. Although there were indications that severe financial insecurity was recovering towards the end of the pandemic, the subsequent cost of living and energy crisis likely means that the recovery from the effects of the pandemic will be short lived and further threatens the health, wellbeing and socioeconomic security of vulnerable families. The need for policy makers and commissioners to act to support vulnerable families remains urgent and critical to prevent further financial, fuel and food debt, homelessness, poor health and widening existing health and social inequalities. This complex intervention may serve to address some of these needs.

The implementation evaluation has been fully considered through the development of the intervention design, implementation and evaluation considered in this chapter. The proposed effectiveness implementation hybrid study, incorporating the RE-AIM implementation tool, will consolidate and provide a framework for the collection and reporting of key implementation factors relevant to this complex intervention.

8.2.4.5 SUMMARY OF MAIN FINDINGS

In this chapter, I have described the main findings from my research and knowledge of the literature presented in this thesis in relation to the thesis research questions. The assimilation of this knowledge presents a general approach for consideration in the development, implementation of a welfare advice service co-located in health settings for mothers and their families. This research has been assimilated and utilised to produce a suggestive protocol for the specific delivery and evaluation of a universal welfare advice service co-located in health settings for mothers and their families in Bradford, see Appendix A.6.2.

8.3 LIMITATIONS

The NIHR and MRC framework for the development and evaluation of complex interventions provides a useful tool for approaching the development and evaluation of universal welfare advice co-located in health settings for mothers and their families. However, the framework itself is a tool and not a comprehensive guide to the development and evaluation of complex interventions. It does not provide detailed methodological guidance but rather acts as a signposting document where this is available elsewhere. Therefore it was important to incorporate other methodologies and approaches to developing each component of the development and evaluation of the intervention.

Furthermore, the framework draws upon and brings together many novel and, in some cases, limited methodologies, which should be used with caution. For the development and evaluation of this complex intervention, care has been taken to consider a range of approaches and to establish decision making in the evidence base and on the feasibility work presented in this thesis, alongside the guidance in the complex intervention framework.

There also remain inherent challenges in adopting an approach to evaluation that balances an efficacy versus an effectiveness perspective, whilst also fully incorporating important evaluation outcomes. Pursuing a hybrid experimental design appears to maximise upon these approaches, however it has implications for resource use and demands specific research expertise. Nonetheless, in the setting of Bradford, many of these challenges could be overcome through the establishment of a trial within a cohort. The BiBBS experimental birth cohort provides an opportunity to embed complex interventions, maximising upon the existing use of established data sharing pathways and expansive research infrastructure. The research expertise of the research programme, in addition to the established relationships of the research programme within the community provides opportunities to overcome and indeed maximise upon these expertise to benefit the implementation and evaluation of this complex intervention.

There remain several potential limitations of the intervention itself. Whilst a universal offer of welfare advice at a time of change and a known opportune teaching moment is hoped to address many of the previously identified barriers to uptake of these services, it not without its limitations. The intervention assumes that a universal offer of welfare advice in a universal service such as a maternal health setting, will reach all if not the majority of pregnant women. However, unequal access to health services remains an issue.

As has previously been described, it is well understood that there is a perverse relationship between the need for healthcare and the actual utilisation of it. The inverse care law states that the availability of good medical care tends to vary inversely with the need for it in the population served.[241] Conversely, those with least need of healthcare tend to use health services more, and more effectively. Given the close relationship between lower socioeconomic status and ill health, one could argue that simply co-locating welfare advice services within health settings may not be sufficient to reach those most in need for this reason. Furthermore, a mistrust of health services has been also highlighted by certain communities, for example the Roma community in Bradford. Their engagement with maternity services may therefore be more limited for this reason.

Consideration should be given to ensuring variation in the provision of the intervention with respect to geographical location and time points across the antenatal and postnatal period. It is important to ensure that the approach to the development and evaluation of such interventions should be incorporating elements of proportionate universalism and perhaps giving consideration in future development of the intervention to the use of targeted outreach for those most in need, for example: homeless people; refugee populations; in drug and alcohol clinics; obstetric clinics; and community paediatric clinics.

Many of the studies have relied on data linkage and the proposed method of conducting a hybrid effectiveness implementation trial within a cohort relies on data linkage. This offers opportunities for collecting long-term outcomes with relatively little ease to researchers and participants and therefore improves retention rates but presents challenges in relation to the quality of these data and the data linkage processes. Long term follow-up data may also be incomplete. As previously demonstrated, for some types of data linkage where this involves sensitive data, such as that for financial data, this may impact upon initial recruitment rates and indeed introduce elements of selection bias.

This thesis focuses on mothers as the primary recipient of the intervention and considers the impacts of receipt of the intervention on maternal health and wellbeing. The role of fathers, other co-parents and guardians, and children have not been formally considered in this thesis. It is likely that improvements to maternal financial security will have positive contributions to household financial security and therefore will offer potential benefit to the health and wellbeing of other members of the household. It has also been proposed that improvements to maternal mental health and wellbeing have the potential to improve parenting outcomes and thus improve outcomes for children in the short and long-term.

Engagement with fathers has been historically challenging in birth cohort studies.[85,206] It is felt that this reflects the lack of opportunities to approach men, who for the most part do not attend antenatal clinics and are not in the house during home visits to the family.[85] In the Born in Bradford Family Cohort Study, where fathers were able to be approached for recruitment, greater than 90% of fathers consented to participate.[85]

In considering the generalisability of the findings from this thesis based in Bradford to other populations, it is important to consider the population profile of Bradford, with its high levels of poverty and ethnic diversity. Although there are similarities with some other UK cities and with cities with high levels of ethnic minority and immigrant communities across the world, where these results can be easily applied, care needs to be taken in transferring these results to the wider population.

However, the cohort contains populations of particular interest and importance for health research, given the high levels of diversity and deprivation, who represent a group in particular need of such services and are a seldom researched and understood group within this context. Furthermore, whilst conventional measures of socioeconomic position, such as income and employment, show an unequal distribution for many health outcomes in the general population, these measures do not always display the same social gradients in health for ethnic minorities. Therefore, socially diverse datasets with a sufficiently large sample of ethnic minorities are required to detect such differences.

It is also important to note, that the findings of the systematic review and as such, the theory of change model, are based upon the literature based in the United Kingdom. Therefore these findings can be more generalised to the wider population in the United Kingdom, but conversely may not represent some underrepresented groups, such as ethnic minority groups, as highlighted in Chapter 3.

8.4 IMPLICATIONS OF FINDINGS

Through the application of this protocol and the implementation of this intervention, one would expect improvements in financial security for mothers, particularly the most vulnerable, with associated improvements in maternal mental health, health-related quality of life and longer-term physical health. Benefits would be seen for health professionals, with a reduced need to assist with social problems and through action on wider determinants of health, an overall medium to long-term reduction in service burden and therefore cost burden to the NHS would be expected. Implementation of this protocol will also generate evidence and an improved understanding of the factors affecting the uptake of benefits advice, providing explanations for the differences observed in existing literature, in addition to a better understanding of factors affecting the successful implementation of these services, particularly for a diverse and deprived population.

Successful demonstration of this intervention in the setting of Bradford could produce robust evidence that can be used to build upon and refine the existing programme theory and evidence base for this intervention. Furthermore, this thesis highlights the direction of implementation research required to establish a consensus on the most appropriate evaluation methodology for this intervention.

Embedding this evidence base and learning within the newly established Healthier Wealthier Families international collaboration provides further unique opportunities to disseminate this learning, refine the evidence base and to improve the impact and translation of research into policy at a national and international level. ActEarly has developed a number of core partnerships nationally to support wider national spread and translation of research that could also be utilised within the setting of Bradford and Tower Hamlets to disseminate generated evidence.

Embedding an effectiveness trial within a cohort, specifically the BiBBS cohort, has a number of strengths. The BiBBS cohort is incredibly diverse. This provides the opportunity to study the interplay of deprivation, ethnicity, migration and cultural characteristics, and their relationship to health and wellbeing. Recruitment for the BiBBS cohort has been successful since its inception and the cohort population is representative of the population of Bradford, indicating minimal selection bias. The establishment of detailed and routine data linkage for the cohort, with health, educational, local authority, and more recently governmental agencies providing information on income and benefits entitlement and receipt as established through the work of this thesis, provides a unique opportunity for clinical and public health translational research on maternal and perinatal health and developmental origins of health and wellbeing. The BiBBS cohort and wider BiB Research Programme also benefits from established and successful community participation and engagement. This community support and engagement infrastructure provides important opportunities for co-production of any trial within a cohort and thus improving the appropriateness, quality and successful implementation of the intervention and improving the successful implementation of the evaluation processes.

8.5 RECOMMENDATIONS FOR POLICY AND PRACTICE

Funding and dedicated commissioning for welfare advice services is increasingly under pressure. The service is often considered a preventative service and with fewer tangible outcomes than others. Services are not statutory and provision and commission is considered discretionary for local councils, therefore provision can vary significantly between local areas. Consequently, welfare advice services often face a double pressure. In the recovery of the COVID-19 pandemic and emerging cost of living crisis and global recession, there has been an increased demand for welfare advice services, with more people being made redundant, falling into debt and more people in food, energy and housing crises. However, simultaneously sources for funding for welfare advice services are diminishing, particularly in areas where there may be greater need for welfare provision. It is therefore imperative that commissioned welfare services are able to robustly evaluate their services to demonstrate the value of their services for clients and wider society.

Performing an evaluation of services is now often a requirement of funding and those commissioning and implementing welfare services co-located in healthcare settings should therefore consider investing additional funds and securing the appropriate skills to conduct a robust, and preferably independent, evaluation of service implementation and effectiveness, guided by the findings of this review. Given the current economic climate and need to support families to prevent further widening of health and social inequalities, as demonstrated by this thesis, investment should be made to pilot universal welfare advice services for mothers and their families, to determine the strength of impact of these services for families.

Inconsistencies in measured outcomes of evaluations of co-located welfare services makes synthesis and meta-analysis of available evidence more difficult. Given the need and urgency to demonstrate the effectiveness of this intervention and to make the case for more dedicated commissioning for such services for families, action by researchers is recommended to facilitate this. A core outcome set for co-located welfare advice services should strongly be considered for future research and development in this area. The recent development of the Healthier Wealthier Families international collaboration and rapid development of further research in this area on an international scale offers a unique expert group and opportunity to collaborate and consort on the development and use of a core outcome measures set for the evaluation of welfare advice services co-located in a health setting. This network should also be utilised not only to harmonise research produced in this area but to also provide an international platform for dissemination of research, driving policy adaptation and implementation to better support families globally through this global financial crisis.

8.6 FINAL CONCLUSION

This research first offers a novel theory of change describing the mechanisms by which universal co-located welfare advice services could improve financial security, improve health and wellbeing, and reduce the burden on the National Health Service, thereby reducing health inequalities and improving public sector finances.

Bringing together the extant body of evidence in the area, this research updates and improves the understanding of the links between co-located welfare advice and financial security and health and wellbeing. For the first time, this research also brings together the evidence regarding the barriers and facilitators to the successful implementation of co-located welfare services.

The results of this work also improve understanding of the methodology most feasible to evaluate such services in a real world setting to best demonstrate effectiveness and implementation outcomes for researchers, policy makers and commissioners alike. It improves the understanding of the utility of routine data linkage in this setting to improve the ability of researchers to robustly demonstrate effectiveness outcomes resulting from access to these services.

Finally, the thesis culminates in a methodological approach to most effectively explore the effectiveness of a welfare advice service co-located in health settings for mothers and their families based on the knowledge and evidence assimilated in this thesis. It recommends how to develop future research in this area to strengthen the quality and build the body of evidence for the effectiveness of this intervention.

With a high cost of living, energy prices and inflation since the pandemic, the ability of families to recover from the effects of the pandemic is untenable without intervention. The need for policy makers and commissioners to act to support vulnerable families is now urgent and critical to prevent further financial, fuel and food debt, homelessness, poor health and widening existing health and social inequalities. This research advocates for greater research collaboration to harmonise evaluation methodology to facilitate an improved understanding of the magnitude and direction of impact of welfare advice services in health settings on mothers and their families. Finally, this research offers a call to policy makers to consider the establishment of welfare advice services co-located in health settings for mothers and families as a statutory service to establish longer-term funding provision for welfare advice services and to facilitate and support robust evaluations of commissioned services.

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APPENDICES

APPENDIX 1 FURTHER INFORMATION FOR CHAPTER 3

A.1.1 A STAKEHOLDER ANALYSIS INTERVIEW TOPIC GUIDE

1. What is of importance to you in a welfare advice service co-located in a maternal and child health setting?
2. What should be the priority of such a service?
3. What would a successful co-located service achieve?
4. How could this service be funded?
5. How should the service be delivered to ensure it is acceptable to those involve and feasible to implement?
    a. When would be the best time to deliver the service?
        i. 20-week scan *(prompt for discussion)*
        ii. Community antenatal clinics *(prompt for discussion)*
        iii. Health visitor appointments *(prompt for discussion)*
    b. Where would be the best place for the intervention be located?
        i. Home visits *(prompt for discussion)*
        ii. Community clinics *(prompt for discussion)*
        iii. Routine screening appointments *(prompt for discussion)*
        iv. Functional link *(prompt for discussion)*
    c. What should initial contact with a welfare advisor involve?
        i. Triage appointment *(prompt for discussion)*
        ii. Full benefits and welfare assessment *(prompt for discussion)*
        iii. An alternative approach *(prompt for discussion)*
    d. Are there any impacts of the COVID-19 pandemic on how this intervention should be delivered?
6. What improvements (if any) would be achieved:
    a. For participants?
    b. For welfare services?
    c. For healthcare professionals?
    d. For society?
    e. For commissioners?
7. How could these improvements be measured in your experience?

APPENDIX 2 FURTHER INFORMATION FOR CHAPTER 4

A.2.1 PRISMA-P CHECKLIST

Table A 1 PRISMA-P checklist for reporting systematic reviews and meta-analyses

Section and topic	**#**	**Checklist item**	**Reported on page #**
ADMINISTRATIVE INFORMATION			
Identification	1a	Identify the report as a protocol of a systematic review	n/a
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	47
Registration	2	If registered, provide the name of the registry, for example PROSPERO, and registration number in the Abstract	n/a
AUTHORS			
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	n/a
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	n/a
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
SUPPORT			
Sources	5a	Indicate sources of financial or other support for the review	20
Sponsor	5b	Provide name for the review funder and/or sponsor	20
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	20
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	46
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	47
METHODS			
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	48

Table A 1 PRISMA-P checklist for reporting systematic reviews and meta-analyses

Section and topic	#	Checklist item	Reported on page #
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	49
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	49
STUDY RECORDS			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	50
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	50
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	51
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	274
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	274
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	51
DATA			
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	53
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall’s tau)	53
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	53
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	53

Table A 1 PRISMA-P checklist for reporting systematic reviews and meta-analyses

Section and topic	#	Checklist item	Reported on page #
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	53
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed e.g., GRADE	53

A.2.2 EXAMPLE SEARCH STRATEGY

Table A 2 Search strategy for Medline via Ovid using keywords

Concept	**Search terms**
Social rights advice	*1. ((welfare adj3 (advice or advis$ or counsel$)) or (welfare adj2 right$) or (welfare adj2 (assess$ or eligibl$ or entitle$)) or (welfare adj2 (benefit$ or claim$ or unclaim$)) or (welfare adj2 consultat$) or (welfare adj2 (eligib$ or entitle$))).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *2. ((benefit$ adj2 (claim$ or unclaim$)) or (benefit$ adj2 (eligib$ or entitle$))).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *3. (underclaim$ or under-claim$ or ((debt$ or money) adj3 (advice or advis$ or counsel$))).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *4. (citizen$ advice or (CABHO or (CAB adj (advice or advis$ or staff or health outreach)))).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *5. (((improv$ or increas$ or maximis$ or assist$ or help$ or support$) adj3 (access$ or uptake or apply$ or application$) adj3 welfare) or ((improv$ or increas$ or maximis$ or assist$ or help$ or support$) adj3 (access$ or uptake or apply$ or application$) adj3 benefit$) or (income security adj3 (intervention$ or program$ or promotion$))).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *6. ((housing adj3 (advice or advis$ or counsel$)) or (homeless$ adj3 (advice or advis$ or counsel$)) or (housing adj3 (advice or advis$ or counsel$))).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *7. ((employment adj3 (advice or advis$ or counsel$)) or (employment adj2 right$)).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *8. ((immigration adj3 (advice or advis$ or counsel$)) or (immigration adj2 right$)).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *9. ((family adj3 (advice or advis$ or counsel$)) or (family adj2 right$)).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *10. Social Welfare/* *11. Social Security/* *12. Public Assistance/* *13. Counseling/* *14. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13*
Healthcare setting	*15. (NHS or health service$ or healthcare or health-care or health care or medical service$ or medical care or (patient$ adj2 care) or (patient$ adj2*

Table A 2 Search strategy for Medline via Ovid using keywords

Concept	Search terms
	health) or (care adj3 delivery) or care pathway$).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt] *16. (primary care or primary healthcare or primary health or general practice$ or family practice$).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *17. (secondary care or secondary healthcare or secondary health or hospital$).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *18. (emergency care or urgent care or hospice$).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *19. social prescri$.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *20. (health center or health centre or medical center or medical centre).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *21. ((matern$ adj3 care) or (matern$ adj3 service) or (midwi$ adj3 care) or (midwi$ adj services)).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt* *22. 15 or 16 or 17 or 18 or 19 or 20 or 21*
Restricted to UK studies	*23. exp Great Britain/* *24. (national health service* or nhs*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *(gb or britain$ or british$ or uk or uk or united kingdom$ or england$ or english$ or northern ireland$ or northern irish$ or scotland$ or scottish$ or wales or welsh$)* *25. 23 or 24*
Excluding animal studies	*26. (animal or animals or rat or rats or mouse or mice or rodent or rodents or swine or porcine or murine or sheep or lamb or lambs or ewe or ewes or pig or pigs or piglet or piglets or sow or sows or rabbit or rabbits or cat or cats or kitten or kittens or dog or dogs or puppy or puppies or monkey or monkeys or horse or horses or racehorse or donkey or donkeys or elephant or elephants or foal or foals or equine or dairy or cow or cows or bovine or calf or calves or cattle or heifer or heifers or hamster or hamsters or chicken or chickens or chick or chicks or hen or hens or poultry or broiler or broilers or livestock or wildlife or panda or pandas or buffalo$ or baboon$ or penguin$).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, ox, px, rx, an, ui, sy, pt]* *27. exp animals/ not humans/* *28. 25 or 26*
	29. 14 and 22 and 25 *30. 29 not 28*

The $ symbol indicates truncation

A.2.3 DATA EXTRACTION PROFORMA

Table A.3 Data extraction proforma

Data extraction proforma
Study details
Author
Title
Publication Type
Study funding sources
Possible conflicts of interest for study authors
Aim
Aim of study
Research questions
Sampling and recruitment
Setting
Health setting
Nature of co-location
Nature of welfare service provider
Welfare assistance provided
Length of appointment
Follow-up arrangements
Aims and objectives of service
Funding and costs of service
Governance arrangements
Method
Design methodology
Method of recruitment of participants
Participants
Population description
Inclusion criteria
Exclusion criteria
Incentives offered
Analysis
Data analysis
Results
Total number of participants
Effectiveness
Reported health outcomes
Reported social outcomes
Reported financial outcomes (from participant perspective)

Table A.3 Data extraction proforma

Data extraction proforma
Reported financial outcomes (from a commissioner perspective)
Reported financial outcomes (from healthcare perspective)
Reported impacts on healthcare provider
Implementation
Factors facilitating implementation
Barriers to implementation

A.2.4 EXAMPLE OF A TEXTUAL SUMMARY

Reference

Charlotte W, et al. Co-located welfare advice in general practice: a realist qualitative study. Health and Social Care in the Community. 2017;25(6):1794-804.

Setting

The study was conducted in two urban primary care general practices in England.

Intervention

The provision of co-located welfare advice services varied across locality. Co-located services in locality 1 provided specialist casework advice on welfare benefits and debt. They offered a walk-in "first-come-first-served" service that was open to all residents. In locality 2, the co-located welfare service offered booked appointments and casework advice on a broader range of issues e.g., housing and employment.

Aim of study

To develop an initial programme theory for how the provision of co-located advice supports specific practice outcomes, and to identify salient barriers and enabling factors.

Sampling and recruitment

GPs, practice managers, GP receptionists and advice staff from intervention practices in both localities invited to participate. Sampling aimed to include representatives from each job role as well as from both the advice and comparison groups. Further sampling also aimed to include a greater number of GPs.

Study design

Twenty-four semi-structured interviews were conducted with general practice staff, advice staff and service funders between January and July 2016. This study is nested within a mixed-methods evaluation described elsewhere.[50] Interviews were chosen rather than focus groups both due to practical difficulties of bringing together practitioners at the same time and to enable individuals in different roles within the same practices to speak freely.

Data analysis

Data were thematically analysed and a modified Realist Evaluation approach informed the topic guide, thematic analysis and interpretation. The topic guide was built on a formative evaluation covering experiences, attitudes and expectations of the co-located advice service.

Results

Two outcomes are described linked to participant accounts of the impact of such non-health work on practices: reduction of GP consultations linked to non-health issues and reduced practice time spent on non-health issues. It was found that individual responses and actions influencing service awareness were key facilitators to each of the practice outcomes, including proactive engagement, communication, regular reminders and feedback between advice staff, practice managers and funders. Facilitating implementation factors were not limiting access to GP referral and offering booked appointments and advice on a broader range of issues responsive to local need. Key barriers included pre-existing sociocultural and organisational rules and norms largely outside of the control of service implementers, which maintained perceptions of the GP as the “go-to location”.

APPENDIX 3 FURTHER INFORMATION FOR CHAPTER 5

A.3.1 BORN IN BRADFORD EXPRESSION OF INTEREST APPLICATION

Expression of Interest

Collaborator's request to access data and/or biological samples from the Born in Bradford study

1. Details of lead applicant

Title	Forename	Surname	Affiliation	Email
Dr	Sian	Reece	University of York	Sian.reece@hyms.ac.uk

2. Name(s) of co-applicant(s)

Title	Forename	Surname	Affiliation	Email
Dr	Brian	Kelly	Born in Bradford	Brian.kelly@bthft.nhs.uk
Dr	Josie	Dickerson	Born in Bradford	Josie.dickerson@bthft.nhs.uk

3. Title of project (less than 30 words)

Assessing the impact of the COVID-19 pandemic, and subsequent public health measures, on levels of financial security and exploring factors associated with increased financial insecurity during the COVID-19 pandemic.

4. Brief description of project

Background

There is growing concern that the ongoing public health measures to control the spread of the COVID-19 pandemic, implemented locally and nationally since March 2020, have had unintended consequences, including an impact upon household socioeconomic security. The detrimental impacts of the pandemic to the UK and other national and global economies are well documented.[1,2] Several studies since the COVID-19 pandemic began have documented the socio-economic challenges faced by households and families as a result of the pandemic and its subsequent social isolation measures. Studies conducted within the UK were cross-sectional and focused on changes to household consumption or policy measures implemented to address financial insecurity and instability.[3,4]

The Born in Bradford research programme provides in-depth longitudinal information on the demographics and socioeconomic and health status of participants before the pandemic and at two time points during the pandemic. This offers a unique opportunity to assess the impact of the pandemic longitudinally in a deprived and ethnically diverse population. Data published from phase one of the COVID-19 survey[5] found that economic insecurities were frequently reported, with more than one-third reporting financial insecurity. Financial insecurity was predicated by previous financial security, employment status and ethnicity. There were strong associations between financial insecurity and poor family relationships, mental health and negative health behaviours.

This piece of work seeks to explore in further depth, the financial impact of the COVID-19 pandemic on families and households in Bradford over time. It builds upon the existing work published on the early effects of the pandemic on families in Bradford.[5] We will also work in conjunction with Alexandra Dalton and her team, who are looking at the impacts of the COVID-19 pandemic on food insecurity, to ensure these papers are aligned.

Research Objectives

1. Has economic insecurity changed over time as a result of COVID-19 and subsequent public health measures?
2. What individual factors are associated with changes to economic security?
3. Does changing levels of economic security predict mental health outcomes?

Methods

Data:

A longitudinal study collected data at two time points before and during the March-June 2020 COVID-19 lockdown from mothers who participated in one of two prospective birth cohort studies in Bradford: Born in Bradford's Growing Up (BiBGU) study with parents of children currently aged 9-13 and Born in Bradford's Better Start (BiBBS) with parents of children currently aged 0-4.

This data will be used alongside existing Born in Bradford and Better Start pre-COVID-19 baseline data for this cohort, to provide descriptive statistics of the impacts of the COVID-19 pandemic, and subsequent isolation measures, on levels of economic security broken down by key demographics.

For financial insecurity, the COVID-19 phase one and two data employ the question: “How well would you say you are managing financially right now?”. Answer options are: living comfortably, doing alright, just about getting by, finding it quite difficult, finding it very difficult. The latter two options will be grouped and categorised as indicating current financial insecurity.

Analysis:

We will carry out descriptive cross-sectional analysis of level of financial insecurity at each pre-COVID-19 and COVID-19 lockdown survey. We will analyse levels of financial insecurity over time, as well as the association between previous financial status, employment status and ethnicity at each time period.

Data will be modelled to explore whether changes in financial security over time predict key outcomes, including mental health outcomes (moderate to severe depression (PHQ8>9) and moderate to severe anxiety (GAD7>9)), partner relationship quality/conflict and social capital and isolation.

Appendix 1 indicates the sample size for each cross-sectional data collection of financial insecurity questions and the potential sample size for longitudinal data. Though this sample would be smaller at each time point, this longitudinal data would allow us to construct simple models looking at factors associated with the change in individual financial insecurity status.

Results from the open text questions asked in the questionnaire have been coded and analysed. A further detailed in-depth analysis within the finance theme will be conducted to explore sub-themes within this area.

Planned outputs

The results will be submitted for publication in a relevant peer reviewed journal.

Timescales

We hope to have paper completed before the end of the Summer 2021.

References

1. Coronavirus and the economic impacts on the UK: 22 October 2020: Office for National Statistics, 2020.

2. Harari D, Keep M. Coronavirus: Economic impact. Briefing paper. Number 8866.; 2021.

3. Brewer M, Gardiner L. The initial impact of COVID-19 and policy responses on household incomes. Oxford Review of Economic Policy 2020; 36(Supplement_1): S187-S99.

4. How has Covid-19 affected the finances of UK households?: Bank of England, 2020.

5. Dickerson J, Kelly B, Lockyer B, et al. Experiences of lockdown during the Covid-19 pandemic: descriptive findings from a survey of families in the Born in Bradford study [version 2; peer review: 1 approved, 1 approved with reservations]. Wellcome Open Research 2021; 5(228).

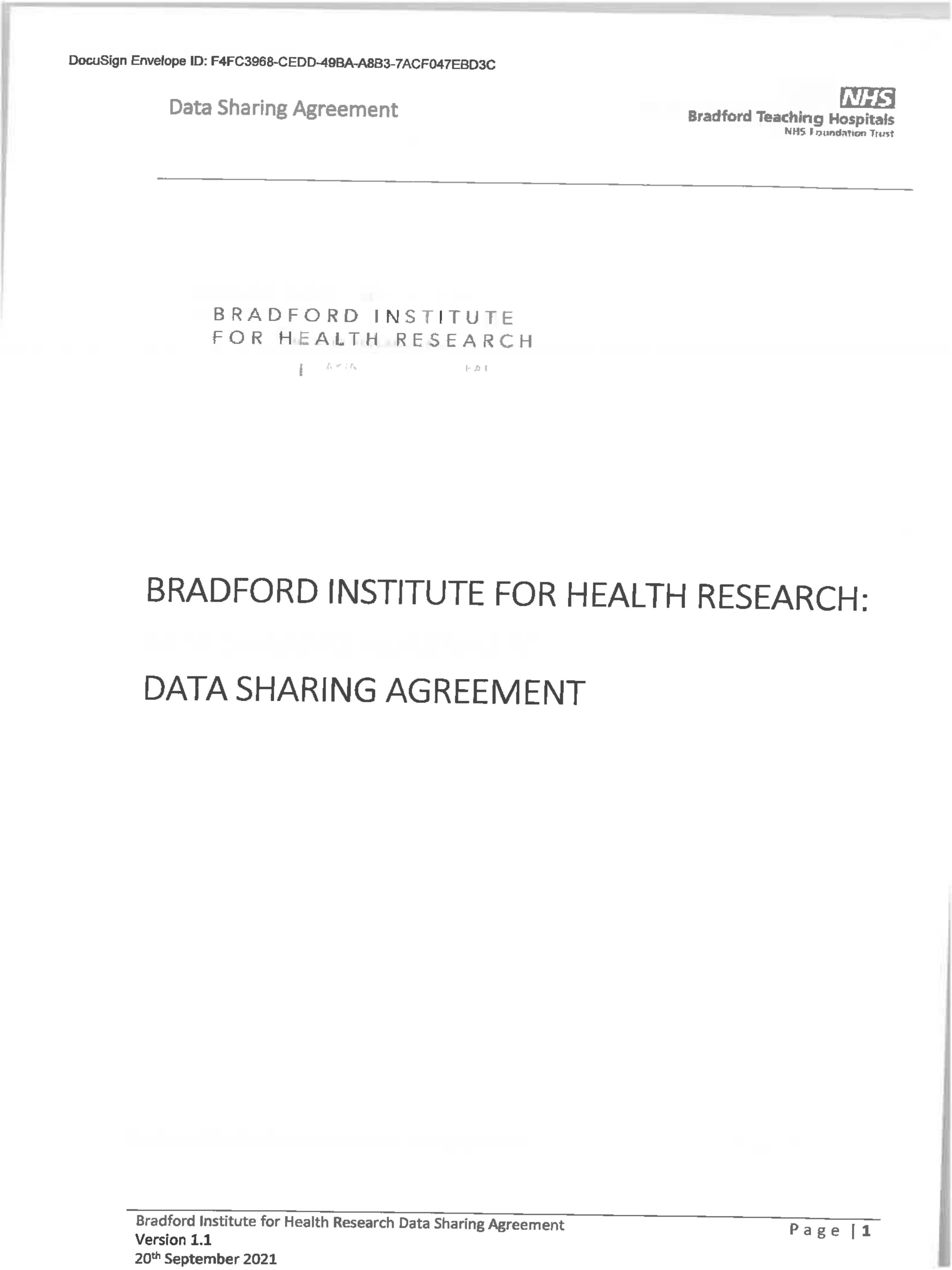
Thank you very much for completing this form.

Please send via email to borninbradford@bthft.nhs.uk and we will contact you as soon as we can.

Appendix One

	BiBGU	BiBBS	Total
Baseline (pre-COVID-19)	5038	2553	7591
COVID-19 Survey Phase 1	1581	563	2144
COVID-19 Survey Phase 2	631	136	767
Number with all 3	569	80	649

A.3.2 DATA SHARING AGREEMENT



DocuSign Envelope ID: F4FC3968-CEDD-49BA-A8B3-7ACF047EBD3C

Data Sharing Agreement

NHS
Bradford Teaching Hospitals
NHS Foundation Trust

BRADFORD INSTITUTE
FOR HEALTH RESEARCH

BRADFORD INSTITUTE FOR HEALTH RESEARCH:

DATA SHARING AGREEMENT

Bradford Institute for Health Research Data Sharing Agreement
Version 1.1
20th September 2021

Page | **1**

This Data Sharing Agreement 'Agreement' is subject to the terms and conditions set out in the Bradford Institute for Health Research Data Sharing Contract [https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Contract.docx]

The Data Sharing Contract 'Contract' must be signed in advance of entering into the Agreement. In the event of any conflict between the terms in the two documents, the terms of the Contract will prevail.

Each party to this Agreement must have signed up to these terms and conditions before any Data can be shared.

1. Title and Reference Code

BIHR Project	Assessing the impact of the COVID-19 pandemic, and subsequent public health measures, on levels of financial security, and exploring the factors associated with increased financial insecurity during the COVID-19 pandemic
Reference	SP478

2. Parties to the Agreement

Receiving Organisation (s)	University of York Heslington York YO10 5DD
Providing Organisation	Bradford Institute for Health Research Bradford Teaching Hospitals NHS Foundation Trust Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ

3. Additional Terms of the Agreement

Start Date	The date of last signature
End Date	31/01/2023
Cost	£0

4. Data Details

Purpose for Sharing	Please see attached expression of interest form. Expression-of-interest-proforma-v3_23.01.2
Personnel to have access to the Data	Sian Reece
Details of the Data to be shared	Please see attached expression of interest form
Details of how the Data will be shared	Data will be transferred in Stata files using encrypted email to the recipients named above.
Details of access / storage and destruction	See Terms and Conditions in the Data Sharing Contract BIHR Data Sharing Contract - York (FULL
Frequency	Once

5. Re-Identification Controls

Details of Controls to be put in place to minimise the risk of re-identification of patients or service users	Records are de-identified by removing personal identifiers and replacing with pseudonymous study ID codes. Dates of birth and death are degraded to month and year only. Residential information is removed and replaced with postcode sector and/or LSOA. Clinical letters, images and free text are removed from health records.

Signature Page

Parties to the Data Sharing Agreement (add as required)

Signed for and on behalf of Receiving Organisation	**University of York**
Name	**Amanda Selvaratnam**
Role / Job Title	**Associate Director (Enterprise Services)**
Signature	DocuSigned by: Amanda Selvaratnam 37F1EFD374FB4E9...
Date	09.11.2021

Lead Applicant Signed for and on behalf of Receiving Organisation	
Name	**Sian Reece**
Role / Job Title	**NIHR Doctoral Research Fellow**
Signature	DocuSigned by: 9372ED90616F4C1...
Date	09.11.2021

Signed for and on behalf of Providing Organisation	**Bradford Teaching Hospitals NHS Foundation Trust** **Bradford Royal Infirmary** **Duckworth Lane** **Bradford** **BD9 6RJ**
Name	Professor John Wright
Role / Job Title	Director of Research
Signature	
Date	10/11/2021

APPENDIX 4 FURTHER INFORMATION FOR CHAPTER 6

A.4.1 HYMS ETHICS COMMITTEE APPROVAL

Hull York Medical School

Hull
University of Hull
Hull, HU6 7RX, UK

York
University of York
York, YO10 5DD, UK

T 0870 1245500
info@hyms.ac.uk
www.hyms.ac.uk

2nd August 2021

Ms Sian Reece
PhD Student
Hull York Medical School

Dear Sian,

21 42 – Co-locating a community welfare advice alliance in primary care to reduce health inequalities: a service evaluation

Thank you for submitting your application to the HYMS Ethics Committee. The application has been reviewed on behalf of HYMS Ethics Committee with respect to the documents received on 21st July 2021.

I am pleased to inform you that I do not have any HYMS specific ethical concerns and am happy to confirm HYMS Ethics approval.

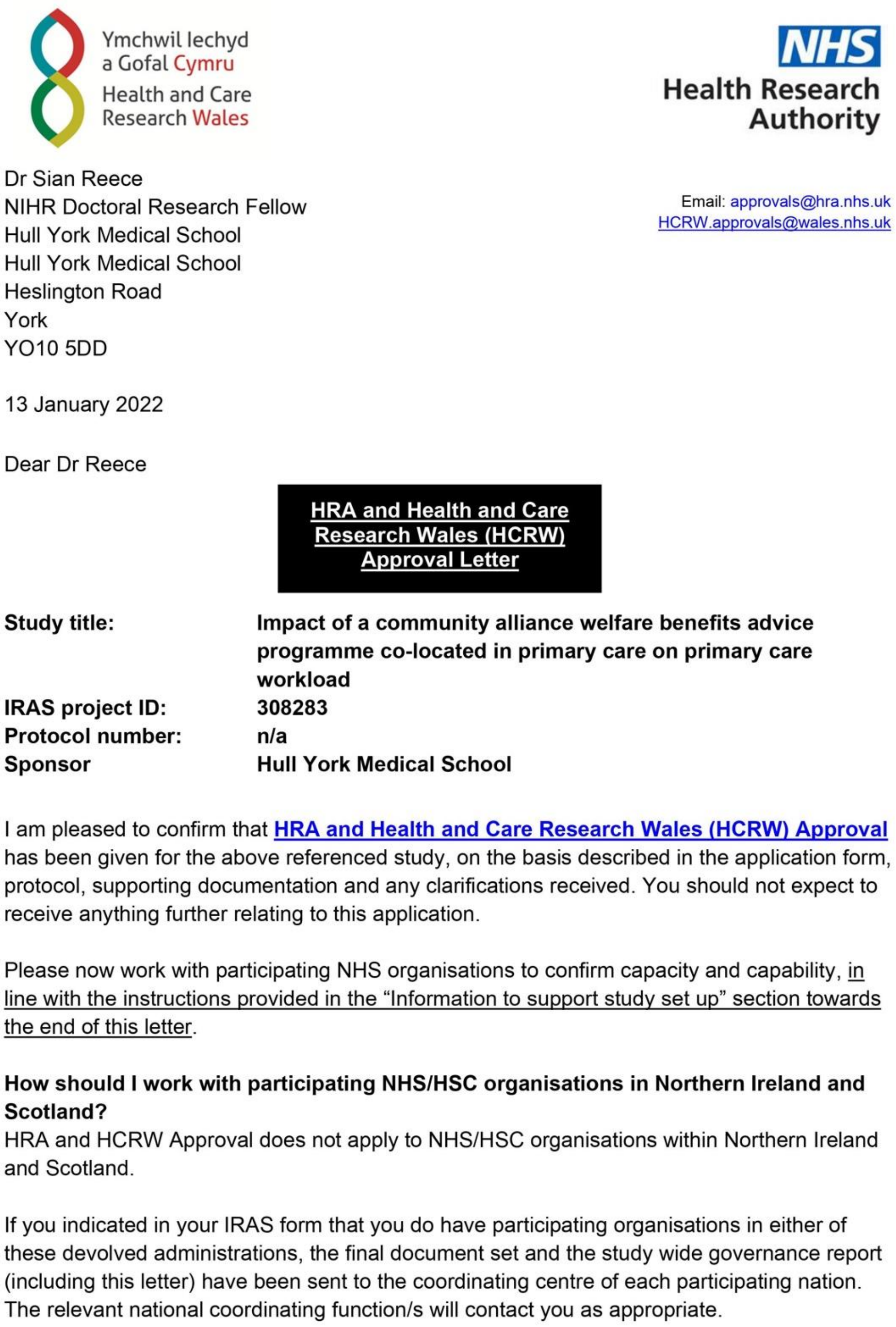
On behalf of the Ethics Committee, we wish you success with this study.

Kind regards

Yours sincerely

Professor Thozhukat Sathyapalan
Chair
HYMS Ethics Committee

A.4.2 HEALTH RESEARCH AUTHORITY ETHICS APPROVAL



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
Health Research
Authority

Dr Sian Reece
NIHR Doctoral Research Fellow
Hull York Medical School
Hull York Medical School
Heslington Road
York
YO10 5DD

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

13 January 2022

Dear Dr Reece

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Impact of a community alliance welfare benefits advice programme co-located in primary care on primary care workload**
IRAS project ID:	**308283**
Protocol number:	**n/a**
Sponsor	**Hull York Medical School**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **308283**. Please quote this on all correspondence.

Yours sincerely,

Kevin Ahmed
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Dr Dimitris Lagos*

A.4.3 SERVICE EVALUATION PARTICIPANT INFORMATION SHEET

Why are you conducting a service evaluation?

We know that suffering from financial difficulties can be harmful to the health and wellbeing of the whole family. You have been referred for this service by your GP in order to receive advice and support to hopefully improve your financial health.

We would like to evaluate our service to make sure we are providing the best possible service to our clients. We would like to do this by looking at what effect our service has on your health and wellbeing. We would also like to see if our service changes your need for GP services in the first three months after you use our service.

Why have I been asked to take part in the evaluation?

We are asking all people referred by their healthcare practitioner for this service if they are happy for their information to be anonymised and used to evaluate our services.

Do I have to agree to be part of the evaluation?

No. It is up to you. Even if you say yes now, you can change your mind at any time without giving any reason.

What will be involved if I agree for my data to be used for this evaluation?

At the start of your first appointment, your welfare advisor will collect some information about you in order to provide their service. They will also give you a questionnaire for you to complete for us to understand what your current health and wellbeing is like. This should take no longer than ten minutes. Three months after your first appointment with your welfare advisor, we will send you the same questionnaire in the post to your home address. We would ask you to return your completed questionnaire to us with the pre-paid return envelope included, so we can see if our service had any impact on your health and wellbeing.

We will also link your information back to your GP to look at whether receiving support from your welfare advisor changed your need for GP services in the first three months after your first appointment with your welfare advisor. We will look at whether you needed a consultation from your GP and if you needed any medication prescribing for your wellbeing. We will not be able to see the details of your medical records or consultations.

What will happen if I do not wish for my information to be used to evaluate this service?

You are free to withdraw your information from our service evaluation at any time. If you withdraw consent for your information to be used in the service evaluation, it will be confidentially destroyed. The service you receive from your welfare advisor will not be affected by this.

Will my taking part in the service evaluation be kept confidential?

All your personal information (name, address and telephone number) will be kept confidential and stored safely at The VCS Alliance. This information will only be used for the purposes of providing you with the welfare service for which you were referred.

We have asked the researchers at the Bradford Institute for Health Research to help us to conduct our service evaluation. In order for them to help us with this, we will share your information to help us to see if our service has helped you improve your health and wellbeing.

How the research team will look after your information?

The researchers at Bradford Institute of Health Research will help us to conduct our service evaluation. This means that they are also responsible for looking after your information and using it properly. They will keep identifiable information about you for ten years after the study has finished. To safeguard your rights, they will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

We will share the findings with the healthcare providers in Bradford. If you wish to obtain a copy of the final service evaluation, you can request one from your welfare advisor or by emailing info@thevcsalliance.org.uk. It is also possible that the results and extracts from the interviews may be presented at conferences and published in research journals. You will not be personally identified in any report or publication.

Who should I contact if I have any further questions?

Bradford VCS Alliance Ltd

Perkin House

Longlands Street

Bradford

BD1 2LU

info@thevcsalliance.org.uk

01274 306624

07598 052857

A.4.4 SERVICE EVALUATION PARTICIPANT CONSENT FORM

Version 1.0 25.07.2021

1.	I confirm that I have read and understood Service Evaluation Client Information Sheet (version 1 dated 25.07.21) about the service evaluation. I have had the opportunity to ask questions, ask questions and have had these answered satisfactorily.	
2.	I understand that my permission for my information to be used for this service evaluation is voluntary and that I am free to withdraw this at any time without giving a reason, without my care or legal rights being affected.	
3.	I understand that I can withdraw my permission for my information to be used for this service evaluation by contacting the VCS Alliance staff using the contact details at the bottom of this form. I understand that if I become unable to consent in the future, you will not collect any further information.	
4.	I understand that my information will used to evaluate the service provided to me. Data protection regulations will be observed. Confidentiality will be maintained unless there are concerns that I, or someone else, is at risk of harm.	
5.	I understand that a copy of this consent form will be stored at the VCS Alliance.	
6.	I understand that any information I give may be included in published documents but my identity will be protected.	
7.	I agree for my information to be shared with the Bradford Institute for Health Research to assist with the service evaluation.	
8.	I agree for researchers at the Bradford Institute for Health Research to link my information with my general practice to understand if my need for health services have changed in the three months following my first appointment with my welfare advisor.	

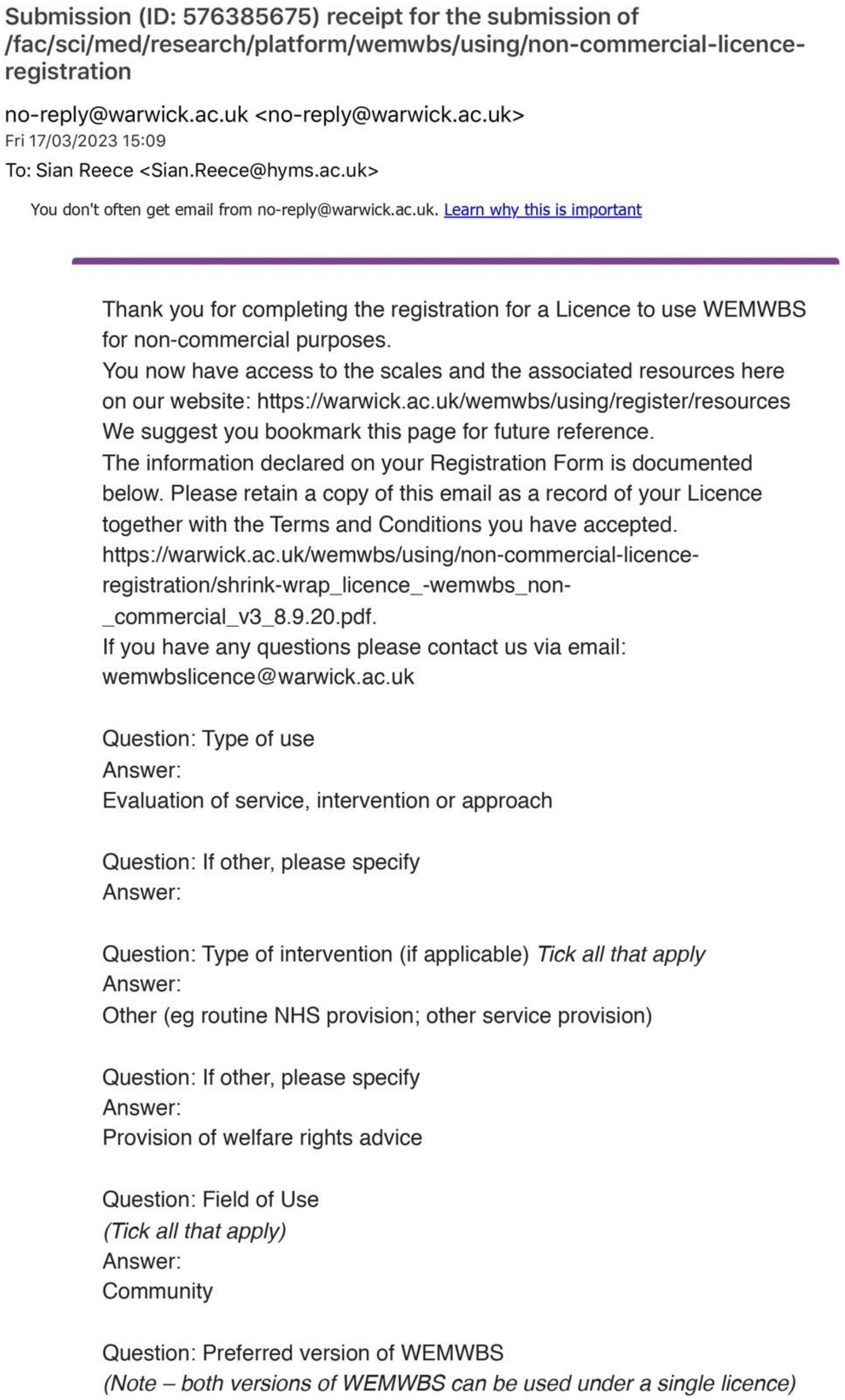
NAME (CAPITALS):	DATE:	SIGNATURE:

Contact details

If you would like any further information or wish to withdraw your permission, please contact us at:

Bradford VCS Alliance, Perkin House, Longlands Street, Bradford. BD1 2LU
Phone: 01274 306624
Email: 07598052857

A.4.5 SWEMWBS LICENCE



Submission (ID: 576385675) receipt for the submission of /fac/sci/med/research/platform/wemwbs/using/non-commercial-licence-registration

no-reply@warwick.ac.uk <no-reply@warwick.ac.uk>
Fri 17/03/2023 15:09
To: Sian Reece <Sian.Reece@hyms.ac.uk>

You don't often get email from no-reply@warwick.ac.uk. Learn why this is important

Thank you for completing the registration for a Licence to use WEMWBS for non-commercial purposes.
You now have access to the scales and the associated resources here on our website: https://warwick.ac.uk/wemwbs/using/register/resources
We suggest you bookmark this page for future reference.
The information declared on your Registration Form is documented below. Please retain a copy of this email as a record of your Licence together with the Terms and Conditions you have accepted.
https://warwick.ac.uk/wemwbs/using/non-commercial-licence-registration/shrink-wrap_licence_-wemwbs_non-_commercial_v3_8.9.20.pdf.
If you have any questions please contact us via email:
wemwbslicence@warwick.ac.uk

Question: Type of use
Answer:
Evaluation of service, intervention or approach

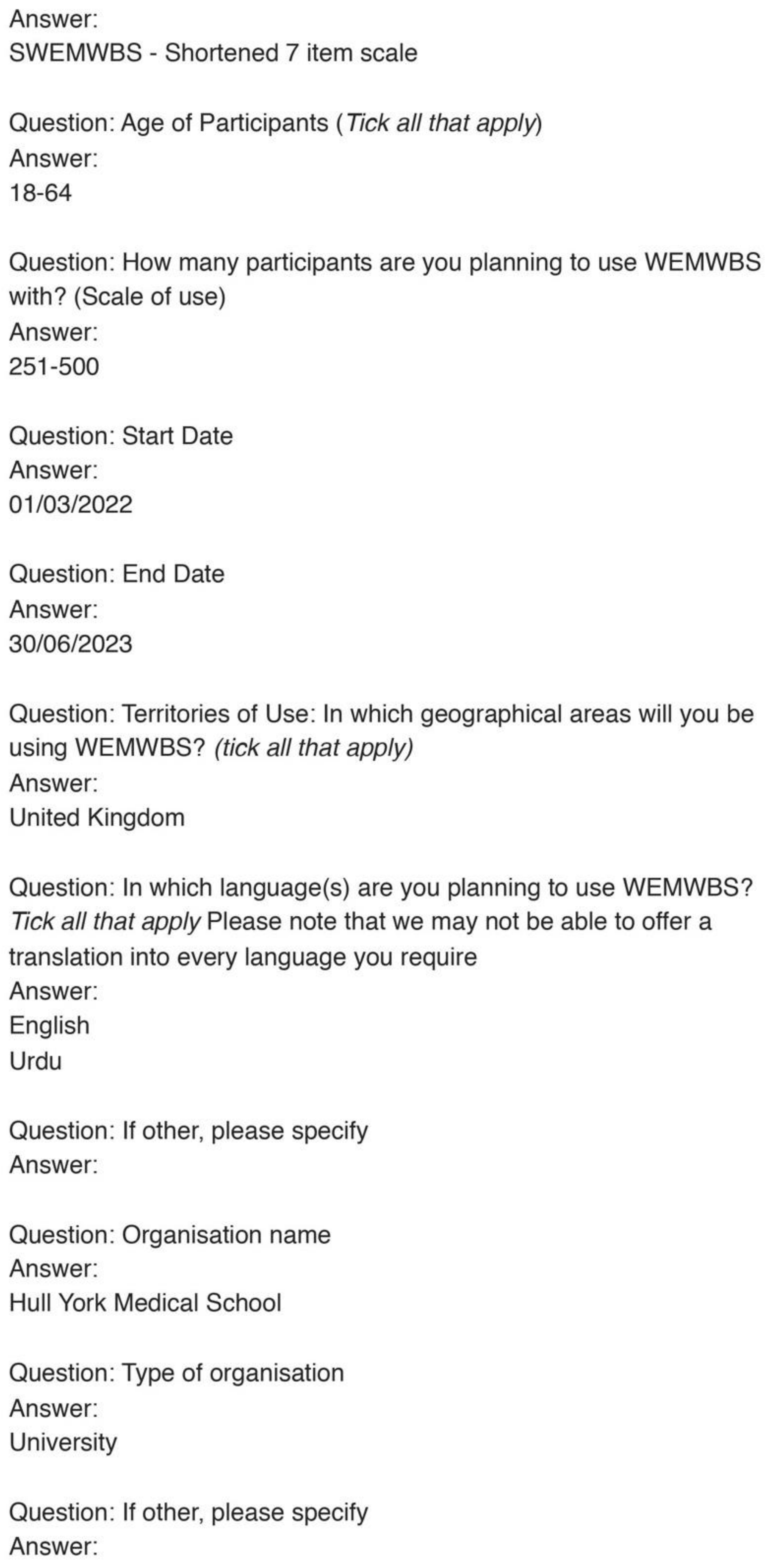
Question: If other, please specify
Answer:

Question: Type of intervention (if applicable) *Tick all that apply*
Answer:
Other (eg routine NHS provision; other service provision)

Question: If other, please specify
Answer:
Provision of welfare rights advice

Question: Field of Use
(Tick all that apply)
Answer:
Community

Question: Preferred version of WEMWBS
(Note – both versions of WEMWBS can be used under a single licence)



Answer:
SWEMWBS - Shortened 7 item scale

Question: Age of Participants (*Tick all that apply*)
Answer:
18-64

Question: How many participants are you planning to use WEMWBS with? (Scale of use)
Answer:
251-500

Question: Start Date
Answer:
01/03/2022

Question: End Date
Answer:
30/06/2023

Question: Territories of Use: In which geographical areas will you be using WEMWBS? *(tick all that apply)*
Answer:
United Kingdom

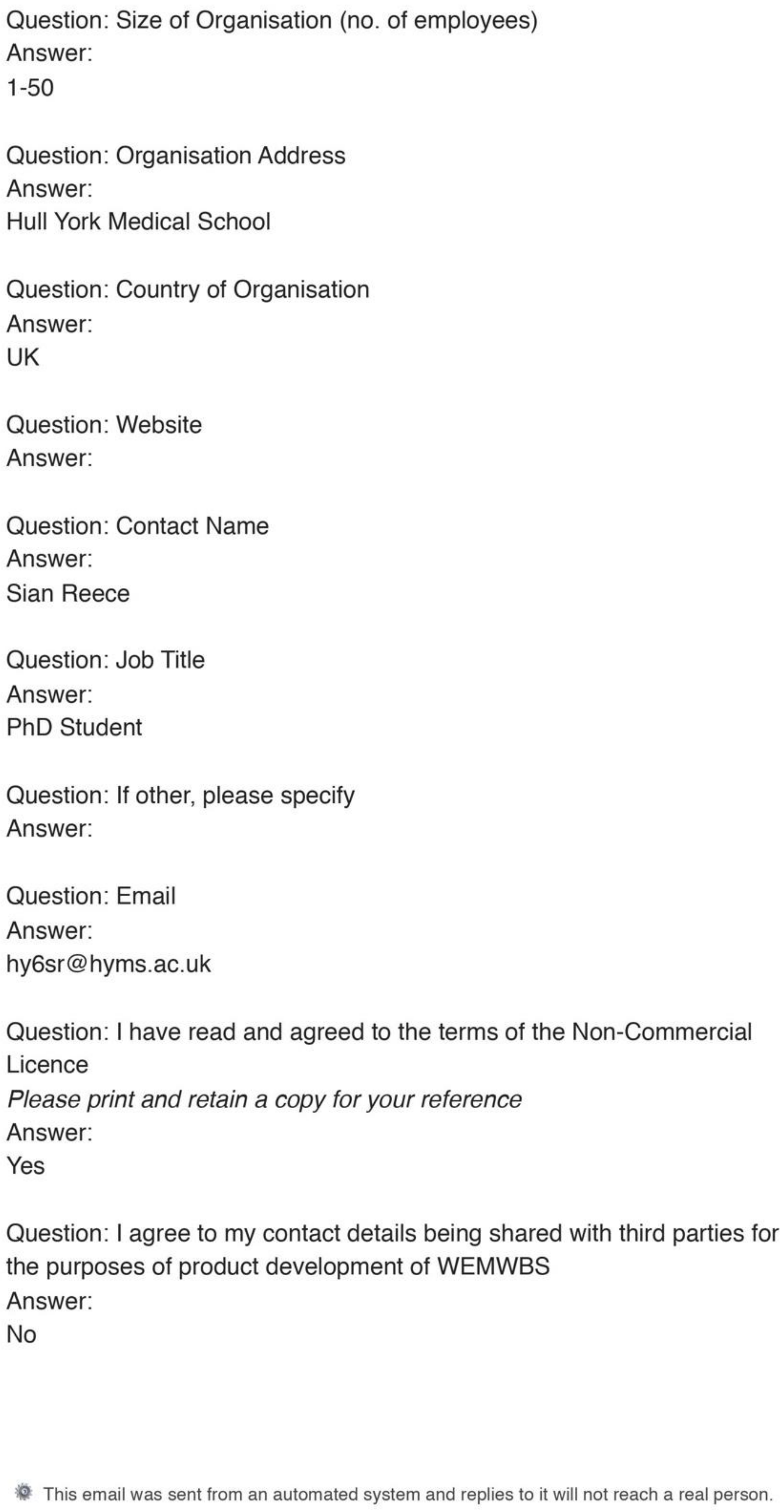
Question: In which language(s) are you planning to use WEMWBS? *Tick all that apply* Please note that we may not be able to offer a translation into every language you require
Answer:
English
Urdu

Question: If other, please specify
Answer:

Question: Organisation name
Answer:
Hull York Medical School

Question: Type of organisation
Answer:
University

Question: If other, please specify
Answer:



Question: Size of Organisation (no. of employees)
Answer:
1-50

Question: Organisation Address
Answer:
Hull York Medical School

Question: Country of Organisation
Answer:
UK

Question: Website
Answer:

Question: Contact Name
Answer:
Sian Reece

Question: Job Title
Answer:
PhD Student

Question: If other, please specify
Answer:

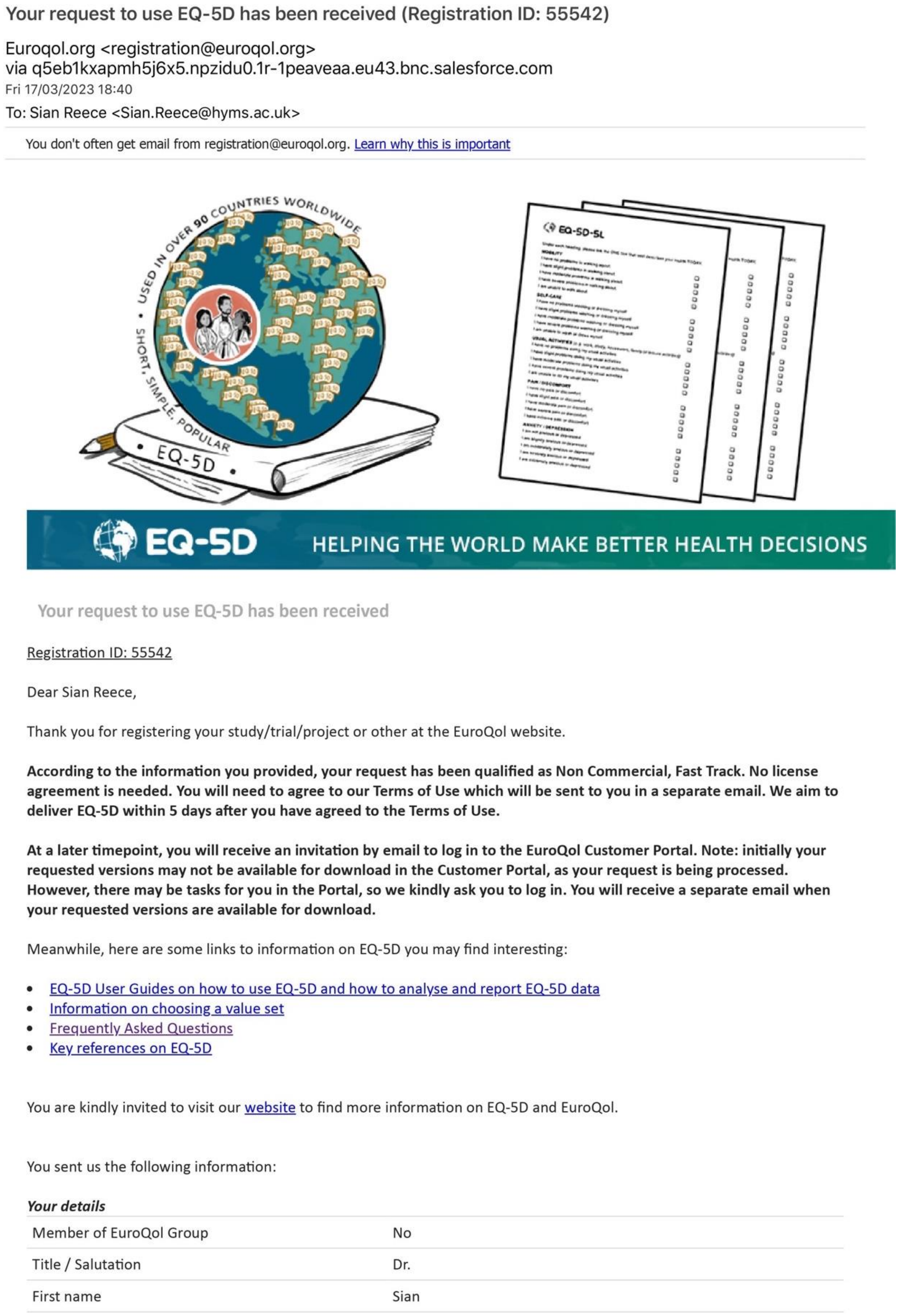
Question: Email
Answer:
hy6sr@hyms.ac.uk

Question: I have read and agreed to the terms of the Non-Commercial Licence
Please print and retain a copy for your reference
Answer:
Yes

Question: I agree to my contact details being shared with third parties for the purposes of product development of WEMWBS
Answer:
No

This email was sent from an automated system and replies to it will not reach a real person.

A.4.6 EUROQOL EQ-5D-5L LICENCE



Your request to use EQ-5D has been received (Registration ID: 55542)

Euroqol.org <registration@euroqol.org>
via q5eb1kxapmh5j6x5.npzidu0.1r-1peaveaa.eu43.bnc.salesforce.com
Fri 17/03/2023 18:40
To: Sian Reece <Sian.Reece@hyms.ac.uk>

You don't often get email from registration@euroqol.org. Learn why this is important

Your request to use EQ-5D has been received

Registration ID: 55542

Dear Sian Reece,

Thank you for registering your study/trial/project or other at the EuroQol website.

According to the information you provided, your request has been qualified as Non Commercial, Fast Track. No license agreement is needed. You will need to agree to our Terms of Use which will be sent to you in a separate email. We aim to deliver EQ-5D within 5 days after you have agreed to the Terms of Use.

At a later timepoint, you will receive an invitation by email to log in to the EuroQol Customer Portal. Note: initially your requested versions may not be available for download in the Customer Portal, as your request is being processed. However, there may be tasks for you in the Portal, so we kindly ask you to log in. You will receive a separate email when your requested versions are available for download.

Meanwhile, here are some links to information on EQ-5D you may find interesting:

- EQ-5D User Guides on how to use EQ-5D and how to analyse and report EQ-5D data
- Information on choosing a value set
- Frequently Asked Questions
- Key references on EQ-5D

You are kindly invited to visit our website to find more information on EQ-5D and EuroQol.

You sent us the following information:

Your details

Member of EuroQol Group	No
Title / Salutation	Dr.
First name	Sian

Last Name / Family Name	Reece
Work environment	University: student
Other work environment	
Organization	Hull York Medical School
Postal Address	Hull York Medical School, Heslington Road
Postal / Zip code	YO10 5DD
City	York
Country	GB
Email	sian.reece@hyms.ac.uk
Phone	07850687377

Intended use of EQ-5D

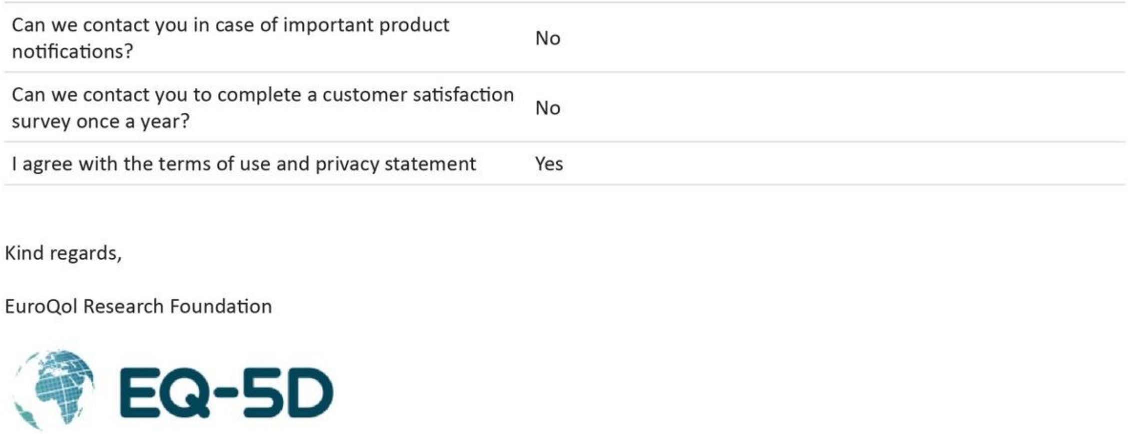
Title / Description / Study Code	IMPACT OF A COMMUNITY ALLIANCE WELFARE BENEFITS ADVICE PROGRAMME CO-LOCATED IN PRIMARY CARE: A MIXED METHODS UNCONTROLLED BEFORE AND AFTER STUDY
Objective	This mixed methods longitudinal study protocol will evaluate the health, social and financial impacts of this programme and its effect on primary care workload.
Source of funding / Sponsor	None
Please list CROs if applicable	
Please list Vendors if applicable	
EQ-5D use	Research (intend to publish the results)
Other EQ-5D use	
Study design / Primary use	Observational study (including case-control, cohort and cross-sectional studies)
Other design / Primary use	
Clinical area	Primary care
Other clinical area	
Number of patients / respondents for this registration	500
Do you plan to use EQ-5D in an app?	No
How use EQ-5D data in an app?	
Start date (year only)	01-Mar-2022
End date (year only)	30-Jun-2023

Requested EQ-5D versions

Requested available versions	1. English (UK) | EQ-5D-5L Self-Complete - Paper
Requested unavailable versions	
Desired date of availability	-None-

Permissions

Are you planning to modify EQ-5D?	No
Planned EQ-5D modification	
Are you prepared to have this information published in any EuroQol reports/surveys regarding usage of EQ-5D? (Note that only anonymised information will be published)	Yes



Can we contact you in case of important product notifications?	No
Can we contact you to complete a customer satisfaction survey once a year?	No
I agree with the terms of use and privacy statement	Yes

Kind regards,

EuroQol Research Foundation

A.4.7 EXAMPLE BASELINE PARTICIPANT SURVEY

RIC Reducing Inequalities in Communities

BRADFORD INSTITUTE FOR HEALTH RESEARCH
MAKING RESEARCH REAL

citizens advice Bradford & Airedale

Client ID ______________________ **Date** ______________________

1. Are you a single parent?

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

2. How well would you say you yourself are managing financially these days?

- ☐ Living comfortably
- ☐ Doing alright
- ☐ Just about getting by
- ☐ Finding it quite difficult
- ☐ Finding it very difficult
- ☐ Prefer not to say

3. Is the main earner in your household currently:

- ☐ Employed
- ☐ On furlough
- ☐ Self-employed: working
- ☐ Self-employed: not working
- ☐ Unemployed
- ☐ Prefer not to say

3. In the next 12 months, do you expect the income of the main earner to still have their job?

- ☐ Yes
- ☐ No
- ☐ Don’t know
- ☐ Prefer not to say

4. Do you worry about getting evicted or having your home repossessed?

- ☐ Yes
- ☐ No
- ☐ Don’t know
- ☐ Prefer not to say

5. Do you worry that food will not last?

- ☐ Yes
- ☐ No
- ☐ Don’t know
- ☐ Prefer not to say

Health Assessment

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

We would like to know how good or bad your health is TODAY.

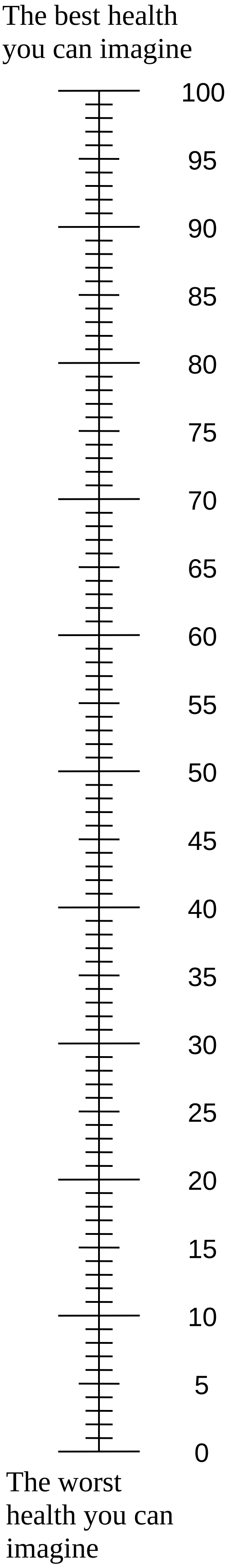
This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

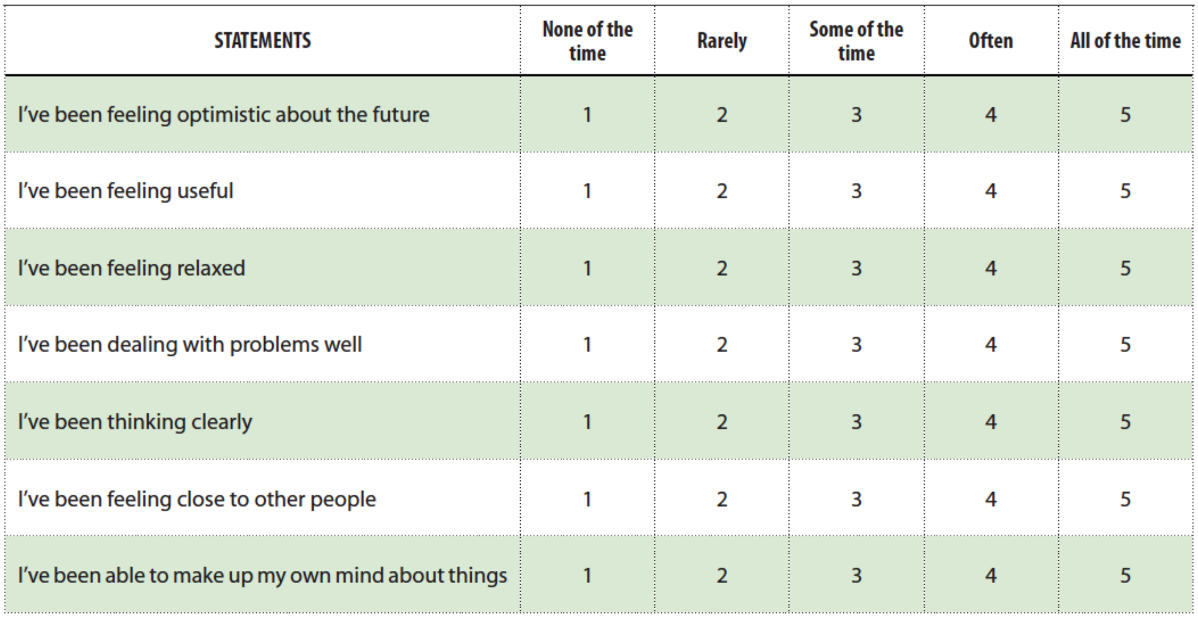
Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Over the <u>last 2 weeks</u>, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3



STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5

Thank you again for taking the time to participate in the evaluation of these services. In order for us to complete the evaluation we will send these questions to you again in 3 months' time to explore whether our services have helped to improve these areas of your health. We thank you again in advance for your time and help with our evaluation.

THANK YOU

A.4.8 EXAMPLE 3 MONTH FOLLOW-UP PARTICIPANT SURVEY

Reducing Inequalities in Communities

BRADFORD INSTITUTE FOR HEALTH RESEARCH
MAKING RESEARCH REAL

citizens advice Bradford & Airedale

Service Evaluation Client Information Sheet - Three Month Follow-Up

We would like to evaluate our service to make sure we are providing the best possible service to our clients. We would like to do this by looking at what effect our service has on your health and wellbeing. We are asking all people referred by their healthcare practitioner for this service if they are happy for their information to be anonymised and used to evaluate our services.

Before your first appointment, you gave us your consent to take part in this evaluation. At this time, we asked you some questions about your health and wellbeing at the time of your appointment. We would now like to ask you the same questions to see if there has been any change to your health and wellbeing over the past three months as a result of your access to these services.

Question 1

How well would you say you yourself are managing financially these days?

Would you say you are:

- ☐ Living comfortably
- ☐ Doing alright
- ☐ Just about getting by
- ☐ Finding it quite difficult
- ☐ Finding it very difficult
- ☐ Prefer not to say

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

We would like to know how good or bad your health is TODAY.

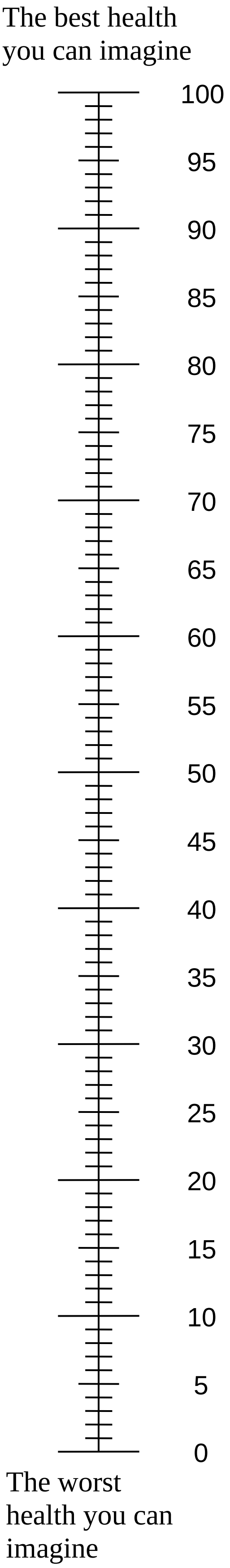
This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

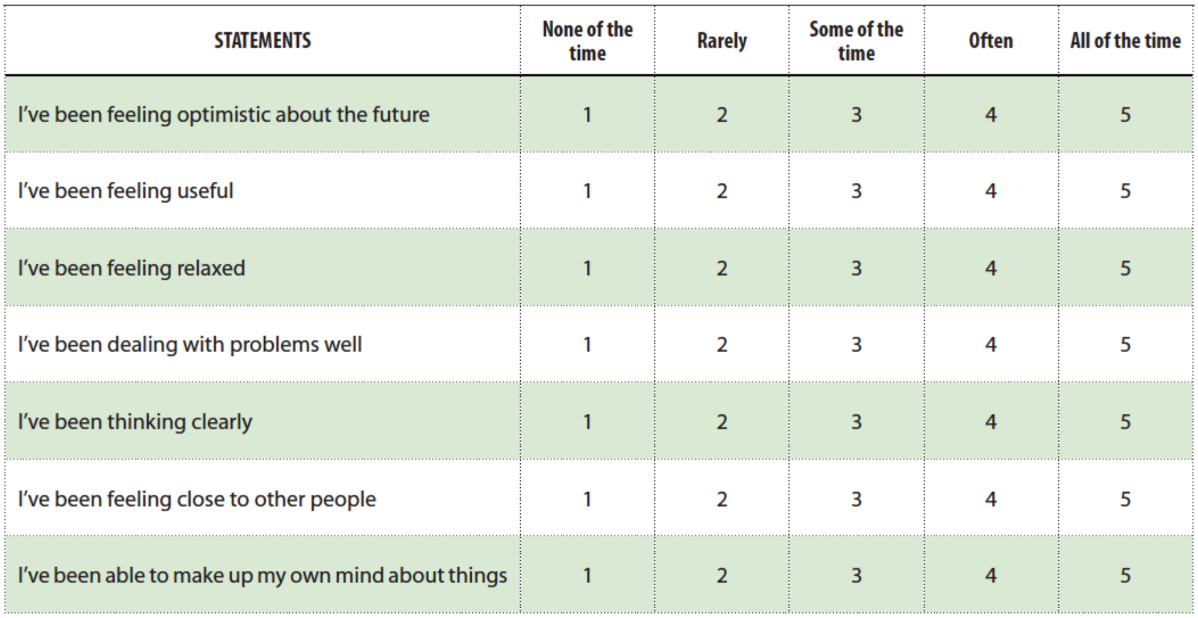
Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3



STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5

Thank you again for taking the time for helping us to evaluate our services.

A.4.9 SERVICE EVALUATION GENERAL PRACTICE STAFF INFORMATION SHEET

Impact of a community alliance welfare advice programme co-located in primary care: a mixed methods uncontrolled before and after study

What is the purpose of this study?

We know that suffering from financial difficulties can negatively impact upon the health and wellbeing of the whole family. There is concern that some families who may be entitled to benefits may not be claiming them.

The Voluntary and Community Sector (VCS) Alliance is a voluntary community organisation that has been developed to co-ordinate the voluntary and community sector in Bradford to deliver different health and social care projects across the area. The VCS Alliance co-ordinate a welfare advice programme co-located within the primary care network across the community. Each service is connected to a general practice in Bradford and is accessed exclusively via GP referral.

An evaluation is being conducted to evaluate the health, social and financial impacts of this programme and its effect on primary care workload. These findings will hopefully allow changes to be made to improve the service for the community.

This study is being completed by researchers in Bradford Institute of Health Research at Bradford Teaching Hospitals NHS Foundation Trust, the University of York and the Hull York Medical School.

If there is anything that is not clear you can contact the researchers (contact details below).

Why have I been chosen?

You have been chosen as you are a GP, practice manager or receptionist based at a host general practice we would like to explore your experience of the service.

Do I have to take part?

No. It is up to you whether you want to take part or not.

What will happen to me if I take part?

A researcher will contact you to arrange a convenient time to complete an interview with you. The interview will take place online and will last about 1 hour and will be audio recorded.

Will my taking part in the study be kept confidential?

Your personal information (i.e. names, signed consent forms) will be kept confidential and securely stored at Bradford Institute of Health Research. This information will only be used to contact you about the research study and to oversee the quality of the study. For more information about healthcare research, how we are approved to undertake research and the rules we have to follow to protect data about you and your family please visit:

https://www.hra.nhs.uk/information-about-patients/

You and your service will be given pseudonyms (false names), and only researchers involved in the study will be able to identify you from your pseudonym. The recording may be sent to a company to be transcribed. The company has a duty of confidentiality and will delete all information once the work has been completed. The actual recordings of the interviews will be destroyed once the study is completed. At the end of the study, your information will be securely archived for 10 years.

What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any time. If you withdraw, the information already completed by you will be included in the final study analysis. If you withdraw consent for your contributions to be used, they will be confidentially destroyed.

What will happen to the results of the research study?

We will share the findings with healthcare services and commissioners in Bradford. We hope to publish the results of this study in an academic journal. It is also possible that the results and extracts from the interviews may be presented at conferences. You will not be identified in any report/publication. If you wish to obtain a copy of any publications, you can request one from the researcher(s) or visit our website using the following address: www.borninbradford.nhs.uk

Who is organising and funding this study?

The sponsor for the study is Hull York Medical School. It is being led by Bradford Institute of Health Research at Bradford Teaching Hospitals NHS Foundation Trust and the University of York. Additional funds have been secured to support the development and evaluation of this service through a National Institute for Health Research doctoral research fellowship.

How the Study Sponsor will look after your information

Bradford Institute of Health Research (BIHR) is the sponsor for this study. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. BIHR will keep identifiable information about you for ten years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use and protect your information at

https://www.bradfordhospitals.nhs.uk/our-trust/our-policies-and-procedures/

Individuals from BIHR and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in BIHR who will have access to information that identifies you will be people who need to audit the data collection process.

Contact details

If you have any questions or would like more information, please contact us at:

Bradford Institute for Health Research, Temple Bank House, Bradford Royal Infirmary,
Duckworth Lane, Bradford BD9 6RJ.

Phone: 01274 383941   Email: bibbs@bthft.nhs.uk

Thank you very much for taking the time to read this sheet and for thinking about taking part in the study.

A.4.10 SERVICE EVALUATION CONSENT FORM

Version 1.0 29.10.2021

		Please tick the boxes
1.	I confirm that I have read and understood the Information Sheet dated 29/10/2021 (Version 1.0) for the above study. I have had the opportunity to ask questions.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason	
3.	I understand that even if I withdraw from the study, the data already collected from me will contribute to the study unless I specifically withdraw consent for this.	
4.	I understand that my data will be collected for this study and may be used to help develop new research. Data protection regulations will be observed. Confidentiality will be maintained unless there are concerns that I, or someone else, is at risk of harm.	
5.	I understand that the interviews will be audio recorded, transcribed and stored safely at Bradford Institute of Health Research, Bradford Teaching Hospitals NHS Foundation Trust and University of York.	
6.	I understand that any information I give may be included in published documents but where direct quotes are used my identity will be protected by the use of pseudonyms.	
7.	I understand that a copy of this Consent Form will be stored at Bradford Institute of Health Research	
8.	I agree to take part in the interview	

Contact details

If you would like any further information or wish to withdraw your permission, please contact us at:

Bradford VCS Alliance, Perkin House, Longlands Street, Bradford. BD1 2LU

Phone: 01274 306624

Email: 07598052857

A.4.11 TOPIC GUIDE; GENERAL PRACTITIONERS

1. Can you tell me about your experiences of social issues (such as problems with benefits, debts, housing, employment or other similar things) amongst your patients?

Probe: how does this manifest in consultations?
Probe: in your view, do patients experience health problems linked to underlying social issues?

2. What tools, if any, do you feel you have available to address issues like these?

3. In your own words could you describe how you see your role in relation to patient social issues?

Probe: is this shared by your colleagues, do you think?

4. Can you describe your experiences with the welfare advice service at this practice?

5. Could you tell me about any interaction you have with the adviser, if any?

Probe: Are there any ways you feel this could be improved at all?

6. Do you think patients might go to see an adviser instead of the GP? *Why? Why not?*

7. Do you think it has the potential to reduce the number of non-clinical appointments? *Why? Why not?*

8. Are there any other ways that having an advice service might influence the practice in your view?

9. Do you get any feedback from patients or colleagues about the service?

Probe: Are there any ways you feel this could be improved at all?

10. Is there anything you would do to change or improve the way the service is run at your practice?

11. Any other comments?

A.4.12 TOPIC GUIDE; PRACTICE MANAGERS AND ADMINISTRATIVE STAFF

1. Can you tell me about your experiences of social issues, such as problems with benefits, debts, housing, employment or other similar things, among your patients?

Probe: how does this manifest in need for consultations?

2. What tools, if any, do you feel your practice has available to address issues like these?

3. In your own words could you describe how you see the role of the GP in relation to patient social issues?

Probe: is this shared by your colleagues, do you think?

4. Can you describe your experiences with the Citizens Advice service at this practice?

Probe: Do you signpost patients to see the advice service here? Why/why not?

5. Could you tell me about any interaction you have with the adviser, if any?

Probe: Are there any ways you feel this could be improved at all?

6. Do you think patients might go to see the adviser instead of the GP? *Why? Why not?*

7. Do you think it has the potential to reduce the number of non-clinical appointments? *Why? Why not?*

8. Are there any other ways that having an advice service might influence the practice in your view?

9. Do you get any feedback from patients or colleagues about the service?

Probe: Are there any ways you feel this could be improved at all?

10. Is there anything you would do to change or improve the way the service is run at your practice?

11. Any other comments?

A.4.13 DATA SHARING AGREEMENT

DATA SHARING AGREEMENT: VCS Alliance and Bradford Teaching Hospitals NHS Foundation Trust

This agreement is to be used in conjunction with the Inter Agency Data Sharing Protocol and complies with all the guidance therein.

1. Parties to this agreement

Organisations Name	Bradford Teaching Hospitals NHS Foundation Trust (Born in Bradford)
Address	Bradford Institute for Health Research Temple Bank House Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ
Responsible Manager	Josie Dickerson, Innovation Hub Programme Manager
Contact Details	Bradford Inequalities Research Unit Temple Bank House Bradford Royal Infirmary BD9 6RJ Josie.dickerson@bthft.nhs.uk
Source/Recipient?	Recipient
Authorised Signatory/Date (Caldicott Guardian, SIRO, Chief Executive, Director etc).	Prof. John Wright, Director of Research

Organisations Name	VCS Alliance
Address	Bradford VCS Alliance Ltd Perkin House 82 Grattan Road Bradford BD1 2LU
Responsible Manager	Joanne Nykol, Project Manager, VCS Alliance
Contact Details	joanne@thevcsalliance.org.uk
Source/Recipient?	Source
Authorised Signatory/Date (Caldicott Guardian, SIRO, Chief Executive, Director etc.).	Kerrie-lee Barr, Chief Operating Officer VCS Alliance

Date of Agreement	17/03/2023

DSA: BDCFT & BTHFT V1.0 PaCT 13th September 2022

2. Specific purpose(s) for which the data sharing is required (all intended purposes should be described, it may be appropriate to describe each one on a separate pro forma)

To support the monitoring and evaluation of VCS Alliance Welfare Benefits Advice programme commissioned by the Reducing Inequalities in City (RIC) programme. The use of sociodemographic data held by the VCS Alliance, linked to the health survey data, will enable evaluation in relation to impact of the service on the health and wellbeing of the clients of the service.

3. Type and status of data shared

Is the data 'person identifiable'?	Yes
Has explicit consent been given and recorded?	Yes
Has implied consent been recorded?	No
Is the subject aware that sharing will take place?	Yes
Is the data anonymised?	The client ID (as used by the VCS Alliance) will be used to link client sociodemographic data (held by the VCS Alliance) with the health survey data collected at baseline and at three month follow-up. Sociodemographic data will extracted and pseudo-anonymised, by a BTHFT colleague at the VCS Alliance premise, before being transferred via an encrypted BTHFT memory stick to BTHFT for data analysis.

4. Legal basis for sharing where no consent is given

As per UK GDPR and DPA 2018, Article 6(1)(a) the data subject will have given consent to the processing of his or her personal data for one or more specific purposes.

Where processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law, shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

5. Data Items shared

This list must be comprehensive and include ALL data items that are to be shared. All data items to be shared must be justifiable as necessary for the purpose. The service user/staff member should be aware that the information will be shared and have consented to it. For the purpose of delivering care implied consent is sufficient. You should tailor this section to suit your organisations specific needs.

Service User Data	Yes/No	Comment
Name, address, Date of Birth, Gender, GP	Yes	Required to match participants with survey data. See Appendix 1
Identifying numbers (NHS No. etc.)	Yes	VCS Alliance client number
Next of Kin, Emergency Contact, Carer Details	No	
Clinical Details (Clinical details should only be shared where there is a justifiable purpose)	Yes	See Appendix 1
Basic Clinical Details (Condition and relevant care requirements)	Yes	See Appendix 1
Full Clinical Details (May include medical history, test results, clinical letters, reports etc.)	Yes	See Appendix 1
Other (Should only be shared where there is a justifiable purpose)	Yes	See Appendix 1
Risk Factors	No	
Other (Please Explain)		
Staff Information	**Yes/No**	**Comment**
Name, Job Title, Work Base, Work Team, Line Manager	No	
Identifiers Such As Payroll No. NI Number	No	
Home Address, Date of Birth and Next of Kin	No	
Full Employment Record	No	

6. Protective Marking

Is Protective marking/Classification relevant to this information?	**No**
If yes please use the system relevant to your Organisation	
1. Top Secret	
2. Secret	
3. Confidential	

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/715778/May-2018_Government-Security-Classifications-2.pdf

7. Data Transfer Method

All parties to this agreement are responsible for ensuring that appropriate security and confidentiality procedures are in place to protect the transfer, storage and use of the shared, person identifiable data.

Regular flow (specify frequency)	**Quarterly in line with the financial year until further notice.**
Ad hoc	

More than 21 items per flow	Yes
Less than 21 items per flow	

Give full details of how the transfer will be made and what security measures will be in place e.g. encryption, business secure mail or recorded signed for etc.

Face to face	Mohammed Hammad will retrieve the data on site from the VCS Alliance database using an encrypted BTHFT USB stick. Which will be taken straight back to BTHFT and data downloaded onto the BTHFT secure network, and data deleted immediately from USB.
Telephone	n/a
Safe haven fax (or faxed following procedure)	n/a
Electronically (state method)	n/a
Secure E Mail	n/a
Secure Mail	n/a
Secure Courier	n/a
Encrypted Removable Media	As above
Other	n/a

Has a risk assessment been carried out on the chosen methods of transfer?	Yes

What are the identified risks?	**1. Secure Transfer** • Data Recipients fail to protect data adequately ○ Data will be stored securely on BTHFT servers and access will be permitted only in line with current BTHFT security protocols ○ Data will not be shared with other organisations without explicit permission

	2. **Published results are used to re-identify patients.** - All reports adhere to the Born in Bradford BTHFT 'Guidelines for reporting data and protecting anonymity and confidentiality' (v3 October 2018); it will not be possible to re-identify patients.

8. Audit and Review

Organisations Name	BTHFT
Address	Temple Bank House Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ
Responsible Manager	Josie Dickerson, Programme Director
Contact number	01274 383941
Review Date	

INCIDENTS
Any incidents occurring as a result of this agreement should be reported to the signatories of all affected organisations. They will then pass on the information in accordance with incident reporting procedures within their own organisation if appropriate. Organisations will agree to share information in order to help investigate any such incidents

9.

Subject Access Requests Will Be Directed To	Josie Dickerson, Bradford Institute for Health Research Temple Bank House Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ
Special Arrangements For Subject Access Requests	BTHFT Information Governance policies will be adhered to, and any requests will be addressed in collaboration with the BTHFT Information Governance manager.

10.

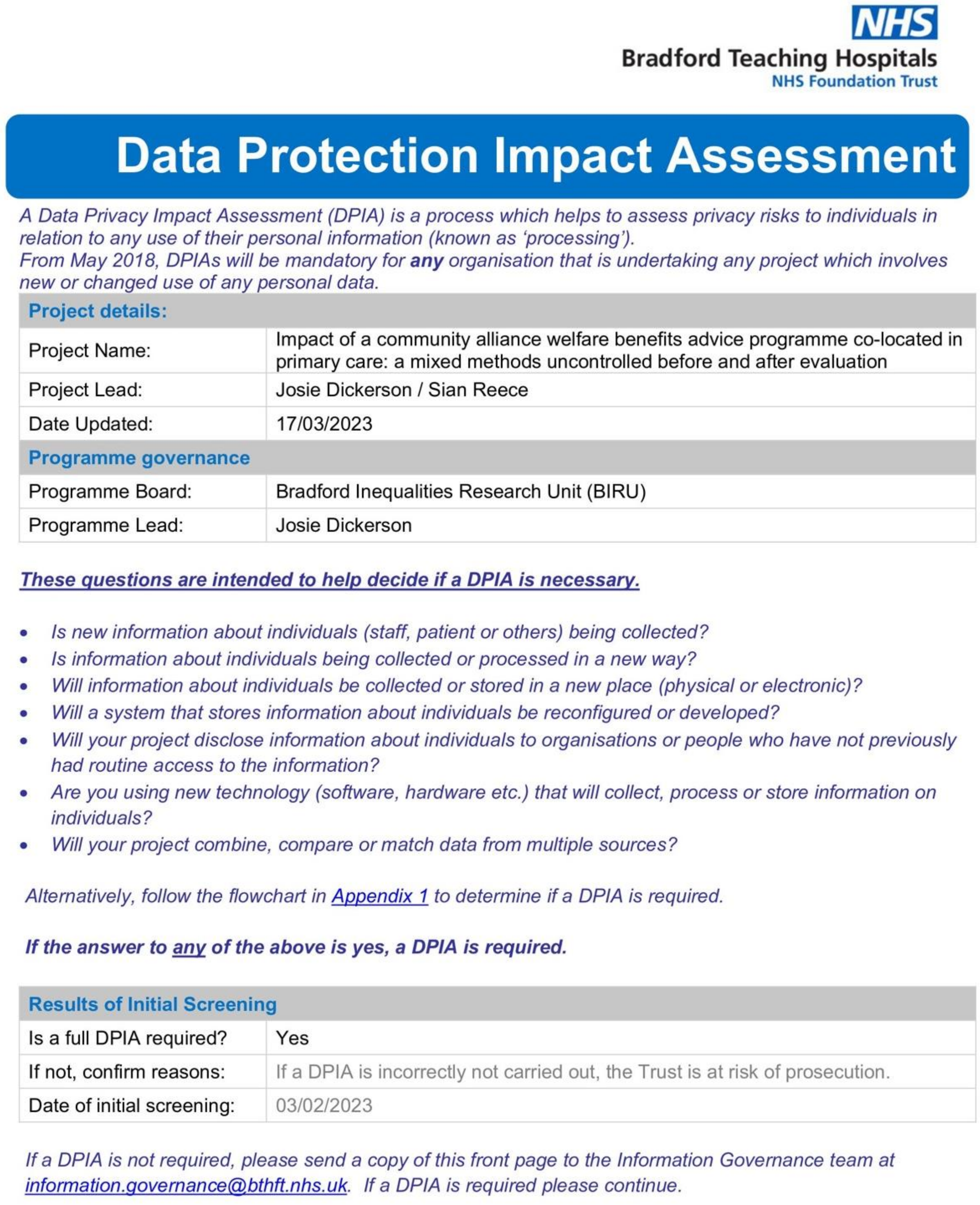
Retention Period For Data	Data will be retained until the RIC programme evaluation has been fully completed (likely 15 years).

Disposal Method For Data	Using BTHFT policies on deletion of electronic data records.

APPENDIX 1

Service User Data	**Yes/No**	**Comment**
Client Details - System Client ID	Yes	Required to match participants with survey data.
Case Details - System Case ID	Yes	Required to match participants with survey data.
Client Details – Initials	Yes	Required to match participants with survey data.
Client Address – Postcode	Yes	Required to match participants with survey data.
Client Details – Gender	Yes	
Client Profile (Current) - Marital Status	Yes	
Client Details - Age (Years)	Yes	
Client Details – Registered GP	Yes	
Client Health Issues - Health Issue	Yes	
Client Profile (Current) - Religion	Yes	
Client Details - Ethnic Origin	Yes	
Welfare Advice – Casework	Yes	
Annual Financial Gains - Sum Calculated Financial Gain	Yes	
Client Details - Preferred Language, e.g. Urdu, Polish, English	Yes	
Number of Appointments with this client for this case?	Yes	
Baseline Assessment Completed Yes/No (use drop down list)	Yes	
Signposted to other support (external to your organisation?	Yes	
Where did you signpost to? (Name the service/s external to your organisation)	Yes	
How satisfied are you with the service you have received? Clients choose one from: Very Low; Low; Average; High; Very High (use drop down list)	Yes	
As a result of accessing the WBA service, does the client report reduced levels stress and anxiety? Yes/No (use drop down list)	Yes	

A.4.14 DATA PROTECTION IMPACT ASSESSMENT



Bradford Teaching Hospitals
NHS Foundation Trust

Data Protection Impact Assessment

A Data Privacy Impact Assessment (DPIA) is a process which helps to assess privacy risks to individuals in relation to any use of their personal information (known as 'processing').
*From May 2018, DPIAs will be mandatory for **any** organisation that is undertaking any project which involves new or changed use of any personal data.*

Project details:	
Project Name:	Impact of a community alliance welfare benefits advice programme co-located in primary care: a mixed methods uncontrolled before and after evaluation
Project Lead:	Josie Dickerson / Sian Reece
Date Updated:	17/03/2023
Programme governance	
Programme Board:	Bradford Inequalities Research Unit (BIRU)
Programme Lead:	Josie Dickerson

These questions are intended to help decide if a DPIA is necessary.

- *Is new information about individuals (staff, patient or others) being collected?*
- *Is information about individuals being collected or processed in a new way?*
- *Will information about individuals be collected or stored in a new place (physical or electronic)?*
- *Will a system that stores information about individuals be reconfigured or developed?*
- *Will your project disclose information about individuals to organisations or people who have not previously had routine access to the information?*
- *Are you using new technology (software, hardware etc.) that will collect, process or store information on individuals?*
- *Will your project combine, compare or match data from multiple sources?*

Alternatively, follow the flowchart in Appendix 1 to determine if a DPIA is required.

If the answer to any of the above is yes, a DPIA is required.

Results of Initial Screening	
Is a full DPIA required?	Yes
If not, confirm reasons:	If a DPIA is incorrectly not carried out, the Trust is at risk of prosecution.
Date of initial screening:	03/02/2023

If a DPIA is not required, please send a copy of this front page to the Information Governance team at information.governance@bthft.nhs.uk. If a DPIA is required please continue.

This template should be used to record the full DPIA process and results. You can start to fill in details from the beginning of the project, after the screening questions have identified the need for a DPIA.

Step 1 - Identify the need for a DPIA

What is the aim of the project/collection?

- The Bradford CCG Reducing Inequalities in Communities (RIC) team have requested an evaluation of the VCS Alliance Welfare Benefits Advice (WBA) Programme, commissioned by the RIC programme.
- This project will be conducted by the Bradford Inequalities Research Unit and will evaluate the health, social and financial impacts of the VCS Alliance WBA programme.

What type of processing will it involve?

- Participant health survey data will be collected by the VCS Alliance providers of welfare benefits advice. Health surveys will be pseudoanonymised at the point of collection using the VCS Alliance client ID. No personal identifiable data will be recorded on the health surveys. This is a new data collection process.
- Sociodemographic data ordinarily collected and held centrally by the VCS Alliance, will be linked to health survey data. Data will be linked at the VCS Alliance office using the VCS Alliance Client ID, checked, and then all personal identifiable data will be removed.
- Pseudoanonymised health survey data and linked sociodemographic data will be transferred to BTHFT using a BTHFT encrypted USB stick. This USB stick will be taken straight back to BTHFT and data downloaded onto the BTHFT secure network, and data deleted immediately from USB.
- BIRU will store and analyse the psuedoanonymised health survey data and linked sociodemographic data.

Summarise why you identified the need for a DPIA.

- The process will involve transferring pseudoanonymised data held about individuals participating in the VCS Alliance WBA programme.
- As this is a brand new flow of pseudoanonymised data, and a new collection of health survey data of VCS Alliance clients, a DPIA is required to assess the suitability of the process.

Step 2 - Describe the information flows

Data collected – Administration data:
Forename: ☑ Surname: ☑
Date of Birth: ☑ Age: ☐
Gender: ☑ NHS No: ☐
Address: ☐ Postcode: ☑
GP details: ☐
Next of kin: ☐
Another unique identifier (*please specify*) : VCS Alliance Client ID

Data collected – Special Category[1]**:**
Ethnic origin ☑ Religion ☑
Medical history ☑
Diagnosis ☐ Treatment ☐
Financial ☑ Sexual Orientation ☐
Workforce ☐ Trade Union Member ☐

Other data collected *(please state)*

Marital status
Whether single parent

As part of standard operations, the VCS Alliance collect baseline sociodemographic data.

For the purposes of this evaluation, the VCS Alliance WBS providers are asking separate and explicit consent from participants to be able to collect health survey data and to share health survey data and linked sociodemographic data with BIRU, for evaluation purposes. The data transferred to BIRU will no longer be identifiable but will include health survey data and linked sociodemographic information from each consented individual.

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[1] Whilst financial and workforce data have not been legally defined as Special Catogory (sensitive) within the GDPR/Data Protection Act 2018 individuals have a reasonable expectation that information relating to these should be held in confidence and privacy issues must therefore be considered when processing.

Step 3 - Consultation requirements

The impact of data sharing has been widely discussed within the collaborative at both project team and programme team meetings.

Who should be consulted, internally and externally?	Josie Dickerson, the programme director for BIRU has been involved in all discussions and will be submitting this DPIA and the Data Sharing Agreement (when available) to Bradford Teaching Hospitals Foundation Trust (BTHFT) Information Governance for sign-off. The data sharing process has been discussed and agreed with the VCS Alliance.
How will you carry out the consultation?	Regular meetings have been held between BIRU and the VCS Alliance to ensure that the right measures are in place (Data Sharing Agreements, proper consent gathering process, this DPIA) and there is a clear, dedicated consent form provided to all individuals who are approached for participation in the evaluation.

Step 4 - Identify privacy and related risks

Highlight KEY associated compliance and corporate risks
Larger-scale PIAs might record this information on a more formal risk register.

Privacy Issue	**Risk to Individuals**	**Compliance Risk**	**Associated Organisation / Corporate Risk**
Data Transfer to introduces the risk of data falling into the hands of unauthorised individuals	Identifiable data falling into the wrong hands puts individuals at risk of Identity Theft or other fraudulent activity	Loss of data	Potential ICO enforcement, reputational damage
Data included from individuals who have not given informed consent and/or who withdraw this consent	Data shared without their permission	Data Breach	Potential ICO enforcement, reputational damage

Step 5 - Identify privacy solutions

Describe the actions you could take to reduce the risks, and any future steps which would be necessary (e.g. the production of new guidance or future security testing for systems).

Risk	**Solution(s)**	**Result** *(is the risk eliminated, reduced or accepted?)*	**Evaluation** *(is the final impact on individuals after implementing each solution a justified, compliant and proportionate response to the aims of the project?*
Data security is compromised during	Agree on an encryption protocol (as per DSA)	The risk is eliminated if proper	This will result in the data being handled exactly as explained in the

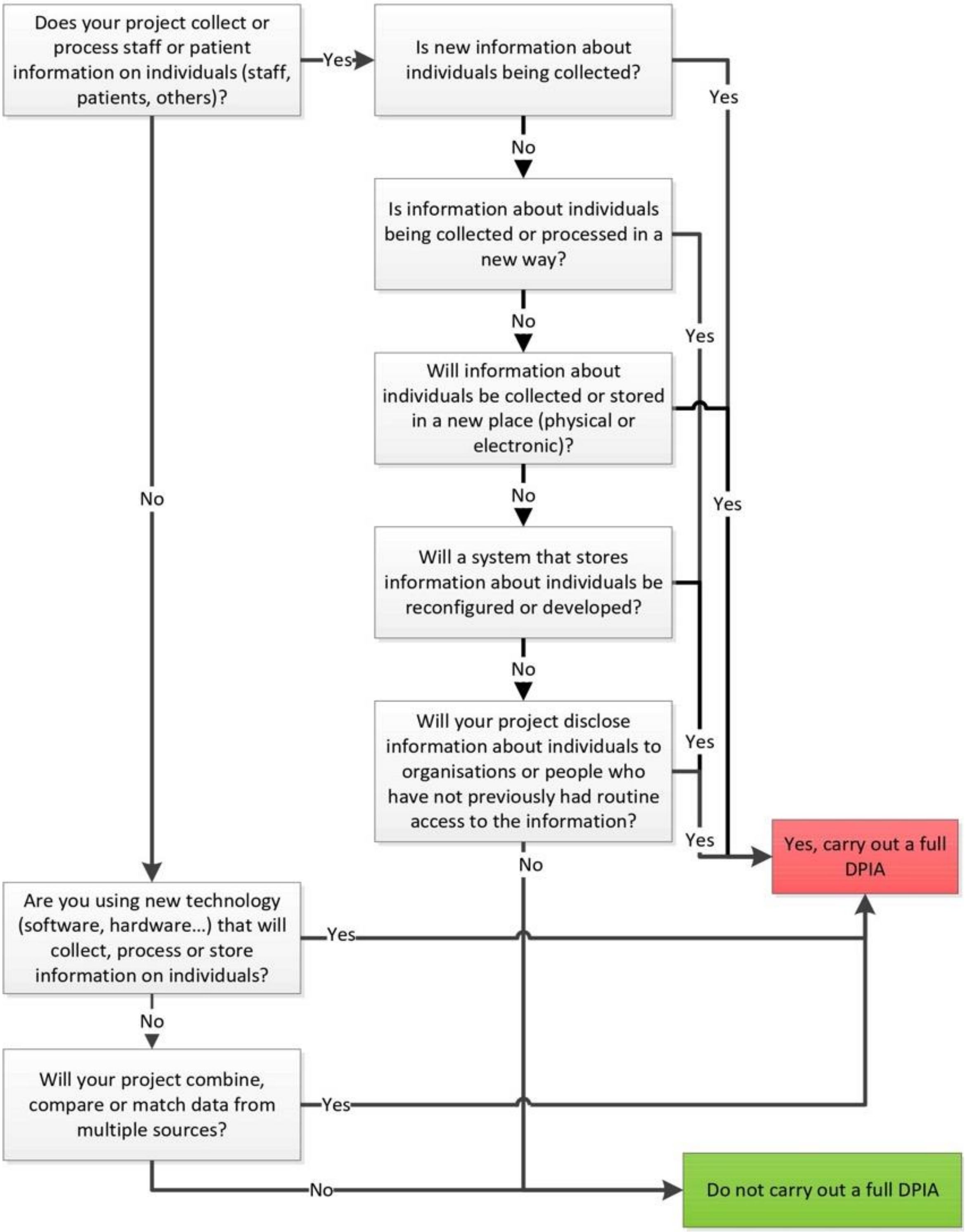
transfer to BIRU	and only send data in strict accordance with this protocol to prevent identifiable information from being visible to unauthorised parties	procedures are followed, as even if the data is intercepted, it will be pseudoanonymised and cannot be meaningfully accessed while encrypted	consent form provided to each individual. Only the agreed data will be transferred, pseudoanonymised and only for individuals who have given their express consent. Compliant
Data is sent from individuals without consent	Data including consent is extracted using reporting code to avoid the any human error in the process. The intention is to complete this as a single data share so there are no risks from updates of data etc.	The risk is eliminated if proper procedures are followed. Data should not be collected if consent it not collected. If consent is later withdrawn, the use of reporting code should facilitate the identification and removal of individual data.	This will result in the data being handled exactly as explained in the consent form provided to each individual and only for individuals who have given their express consent.

Step 6 - Sign off and record the DPIA outcomes	
Solutions to be implemented:	
Approved by:	
Approved Date:	
Step 7 - Integrate the DPIA outcomes back into the project plan	
How will DPIA outcomes be integrated with the project plan?	The agreed actions will form part of the Data Sharing Agreement that will be signed off by all parties involved with the data transfer. A protocol is in place for this study which will be referred to as required.
Contact point for future privacy concerns:	Josie Dickerson (BSBIH Programme Director) josie.dickerson@bthft.nhs.uk

Please ensure that a copy of this completed form is forwarded to the Information Governance team: Information.governance@bthft.nhs.uk

Please note that where a DPIA identifies a high risk and you cannot take any measures to reduce the risk, you cannot go ahead until this is referred to the Information Commissioner's Office. You must refer immediately to the Information Governance team.

Appendix 1



Does your project collect or process staff or patient information on individuals (staff, patients, others)?
Yes
Is new information about individuals being collected?
Yes
No
Is information about individuals being collected or processed in a new way?
No
Yes
Will information about individuals be collected or stored in a new place (physical or electronic)?
No
No
Yes
Will a system that stores information about individuals be reconfigured or developed?
No
Will your project disclose information about individuals to organisations or people who have not previously had routine access to the information?
Yes
Yes
Yes, carry out a full DPIA
No
Are you using new technology (software, hardware...) that will collect, process or store information on individuals?
Yes
No
Will your project combine, compare or match data from multiple sources?
Yes
No
Do not carry out a full DPIA

APPENDIX 5 FURTHER INFORMATION FOR CHAPTER 7

A.5.1 PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Information sheet to link your income and benefits data

We would like to get your permission to link to some information about your income and the benefits your family receive.

In our questionnaire we ask all mums about how their family is managing financially. We would like to ask more detailed questions about family income, but some women find it hard to answer these questions. Instead, we would like to get your permission to get this information directly from the organisations that hold this information, so that we can look at the impact of finances on the health and wellbeing of families. We are also aware that some families might not be claiming the benefits that they are entitled to and this information will help us identify where extra support is available.

What am I being asked to give permission for?

The Department for Work and Pensions (DWP) keeps records of everyone’s benefit claims and time spent on employment programmes. HM Revenue and Customs (HMRC) keeps records of your income and contributions to the National Insurance system. We would like to link this information to the information you give us as part of the BiBBS study.

Do I have to agree to this part of the study?

No. You can still be a part of the BiBBS study even if you don’t want us to collect this information from DWP and HMRC. It is entirely up to you. You can also change your mind at any time.

What will happen if I agree to this?

If you agree to share your information, we will give the DWP and HMRC your name, address, sex and date of birth. It would be helpful provide your National Insurance number with this information, but you do not have to do so.

They will use these details to identify the correct records it holds about you. This information will then be sent to BiBBS who will add this information to your study responses. Your personal information will be removed before any research is done.

The DWP and HMRC will not use the information we give them to do any checks on you. The DWP and HMRC will not store the name, address, sex, date of birth and national insurance information BiBBS gave to them. The data will not be used to work out whether any individual is claiming benefits they should not be and will not affect any current or future claims for benefits.

Who can see my information?

We need your permission for any information to be given to us. Like everything else you have told us, the information will be completely confidential and will be used for research purposes only. It will be used by researchers under restricted access arrangements which make sure that the information is used responsibly and safely. Names and addresses are never included in the results.

We would like to keep the data at Born in Bradford as long as we have live projects that use the data or there is the possibility of future projects that will use the data. We will ensure that your records are secure for as long as we continue this study.

What if I change my mind?

You can withdraw permission at any time for us to have your DWP and HMRC information. If you want to withdraw please contact our project office by phone (01274 383941) or email (bibbs@bthft.nhs.uk).

Consent to link your income and benefits data

Name of Parent
(print)………………………………………………………………………………

1a	I have understood the Information Sheet and Consent for Linking of Economic Records (Version 1.0 23.07.2021). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Yes ☐
1b	I understand that all the information about me will be treated in strict confidence in accordance with the relevant UK data protection regulations and used responsibly and safely for research purposes only. It will not be possible for anyone outside of BiBBS to link my information to me or to my child.	Yes ☐
1c	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that I can withdraw from the study by contacting BiBBS staff using the contact details at the bottom of this form. If we become aware that you have become unable to consent in the future, you will not collect any further information.	Yes ☐
1d	I authorise the Department for Work and Pensions (DWP) and Her Majesty’s Revenue and Customs (HMRC) to disclose to BiBBS information about my income and benefits entitlements. This consent will remain valid until revoked by me in writing.	Yes ☐

Signed by Parent ………………………………………………………… Date: …………………

Researcher confirmation
I confirm that I have explained the nature of the proposed research to the person(s) named on this form and have left a copy of the Information Sheet to link your income and benefits data dated 23.07.2021. and this consent form with them for future reference.

Name of researcher
(print)……………………………………………………………………………

Signed by researcher …………………………………………………… Date: ……………………

Interpreter confirmation
I confirm that I have interpreted the Information Sheet for Linking of Economic Records dated 23.07.2021 and this consent form with them and that the participant understands.

Name of interpreter (print)
………………………………………………………………………………

Signed by interpreter ……………………………………………………Date: …………………

BiBBS contact details

If you would like any further information or want to withdraw your permission, please contact us at:

Born in Bradford's Better Start (BiBBS), Bradford Institute for Health Research,
Temple Bank House, Bradford Royal Infirmary, Duckworth Lane, Bradford BD9 6RJ.
Phone: 01274 383941   Email: bibbs@bthft.nhs.uk

A.5.2 BORN IN BRADFORD EXPRESSION OF INTEREST FORM

Expression of Interest

Collaborator's request to access data and/or biological samples from the Born in Bradford study

1. Lead applicant			
Name	Email	Organisation	Job title
Dr Sian Reece	Sian.reece@hyms.ac.uk	University of York	NIHR Doctoral Research Fellow

2. Co-applicant(s)			
Name	Email	Organisation	Job title

3. Project details	
Title (less than 30 words)	Exploring trends and attitudes towards consent for benefits and income data linkage in BiBBS participants.
Research question	How do trends and attitudes towards consent for benefits and income data linkage vary between BiBBS participants?
Lay summary	Since September 2021, the BiBBS recruitment team have been trialling an approach to facilitate data sharing between BiBBS and the Department for Work and Pensions (DWP) to help us better understand the impact of BiBBS programmes on the financial health of the community. Poverty and deprivation experienced by mothers and their families is linked to poor physical and mental health and can have long lasting effects.[12] Financial difficulties for parents can cause mental health problems and chronic physical illness which affect parenting.[17,18] By enhancing family livelihoods and financial health, this could directly improve the health and wellbeing of families, and reduce wider health inequalities in the long-term.[242] Following normal recruitment into the BiBBS research study, mothers are asked whether they would also be willing to consent to link their data with DWP to better under the impact of BiBBS programmes on financial health. Mothers are provided with a separate information sheet and consent form in order to explain why we are asking to link their data and to explicitly gain consent for this. If the mother does not wish to provide consent to data linkage, her reason for not wishing to consent is recorded as a free text response. It is recognised that data sharing and linkage, particularly around financial data, is a sensitive issue. It well recognised that consent for benefits and income data linkage for research purposes is much lower than for other forms of data linkage.[202,213] However, it is not well understood what impacts upon decisions to consent and the attitudes towards consent, particularly in ethnic minority groups.

	It is hoped that this piece of work will help us to better understand who is more and less willing to consent to benefits and income data linkage and whether this varies by key demographics, existing levels of financial security and mental health in the BiBBS cohort. In the future, it may also help to compare consent rates and trends between alternative models for obtaining consent for sensitive data, should these be trialled.
Anticipated start date	01/02/2023
Anticipated end date	01/08/2023
Aims, objectives and rationale	**Aim** To explore trends and attitudes towards consent for benefits and income data linkage in BiBBS participants. **Research Objectives** 1. To explore rates of consent for benefits and income data linkage within the BiBBS cohort 2. To explore how provision of consent for benefits and income data linkage varies by key demographics, existing levels of financial insecurity and mental health across the BiBBS cohort 3. To explore attitudes towards consent for benefits and income data linkage
How will the data requested be used to achieve the project objectives	The BiBBS recruitment team have created an Excel database to record BiBBS participants recruited since the introduction of the additional consent procedures for benefits and income data linkage, coded by their PY number. This database records whether participants consented to data linkage and their reason for choosing not to provide consent, where appropriate, as a free text response. It is hoped that this data can be linked to their corresponding BiBBS survey, via the participant PY number, in order to explore any correlations between consent and key variables. Table 1 indicates the key variables requested from the BiBBS survey data for this purpose. **BiBBS survey variables** Age (adm_medqage) Language used to administer questionnaire (adm_qlang) Who was present at interview (adm_qpresent) Mother ethnicity all categories (eth_ethnic) Religion (eth_religion) Index of Multiple Deprivation 2019 Decile (where 1 is most deprived) (res_cIMD19decile) First language grouped (lng_1firstlang_group) Highest qualification (equivalised) (edu_mhighested) Are you currently employed? (emp_1employed) Is your partner currently employed? (emp_1pemployed) How well would you say you (and your partner) are managing financially these days (fin_1finman) Compared to a year ago, how would you say you (and your partner) are doing finan (fin_2fincomp) How often food bought not last and no money to buy more(fin_2foodlast)

	I couldn’t afford to eat balanced meals.(fin_2foodbalance) Did you ever cut the size of your meals/ eat less/ skip meals because there wasn(fin_2foodcutsize) PHQ Total score (phq_total) PHQ Category (phq_category) GAD Total Score (gad_total) GAD Category (gad_category) Table 1 BiBBS survey variables requested for analysis In the first instance, the data will be explored and descriptive data will be provided for overall consent rates and consent rates according to each key variable. Where possible, a logistic regression model will be used to explore variation in consent provided according to key variables to identify any emerging trends. Qualitative indicators for withholding consent for benefits and data linkage will be coded and analysed to explore attitudes towards consent for data linkage.
How will the project benefit health and/or social care, included expected measurable benefits *(must be completed if requesting linked NHS data)*	It is hoped that this piece of work will help us to better understand who is more and less willing to consent to benefits and income data linkage and whether this varies by key demographics, existing levels of financial security and mental health in the BiBBS cohort. In the future, it may also help to compare consent rates and trends between alternative models for obtaining consent for sensitive data, should these be trialled. By improving our understanding in this area, we can hopefully then better understand how financially secure our families are, how our projects impact the financial security of these families and how this interplays with health and wellbeing.
Key references	

4. Funding

Does the project have a funder?	The project does not receive funding. However, Sian Reece is in receipt of an NIHR Doctoral Research Fellowship for the purposes of completing a PhD in the co-location of welfare advice services in a maternity setting, of which this project is a part.
Funders name	National Institute for Health Research

5. Outputs

How will the proposal findings be disseminated, to what audience and in what format?	We hope to have my thesis and a possible paper for publication to an academic journal completed before the end of Summer 2023.

6. Data required

Please indicate which datasets you require, *ensuring you have included justification in section 3*. Detailed information of variables required from each dataset will be requested once approval has been granted. For a list of available data please consult: https://borninbradford.github.io/datadict/

☐ BiB 1000
☐ BiB ALL-IN
☐ BiB Metabolomics
☐ BiB Genotyping microarrays

☐ BiB Baseline
☐ BiB Child growth
☐ BiB Cohort information
☐ BiB Congenital anomalies
☐ BiB Education records
☐ BiB Geographic information
☐ BiB Growing up*
☐ BiB MeDALL
☐ BiB Pregnancy
☐ BiB Primary school years*
☐ BiB Starting schools*
☐ BiB Exome sequencing
☐ BiB DNA methylation
☐ Routine healthcare: GP records
☐ Routine healthcare: Hospital admissions
☐ Routine healthcare: Accident and Emergency
☐ COVID-19 surveys*
x BIBBS Baseline

* *Temporary data sharing embargo might apply to newly collected data*

Thank you for completing this form.

Please send via email to borninbradford@bthft.nhs.uk and we will contact you as soon as we can.

A.5.3 DATA SHARING AGREEMENT

BRADFORD INSTITUTE
FOR HEALTH RESEARCH
MAKING RESEARCH REAL

BRADFORD INSTITUTE FOR HEALTH RESEARCH:

DATA SHARING AGREEMENT- SP646

This Data Sharing Agreement 'Agreement' is subject to the terms and conditions set out in the Bradford Institute for Health Research Data Sharing Contract [https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Contract.docx]

The Data Sharing Contract 'Contract' must be signed in advance of entering into the Agreement. In the event of any conflict between the terms in the two documents, the terms of the Contract will prevail.

Each party to this Agreement must have signed up to these terms and conditions before any Data can be shared.

1. Title and Reference Code

BIHR Project	Exploring trends and attitudes towards consent for benefits and income data linkage in BiBBS participants.
Reference	SP646

2. Parties to the Agreement

Receiving Organisation (s)	University of York Heslington York YO10 5DD
Providing Organisation	Bradford Institute for Health Research Bradford Teaching Hospitals NHS Foundation Trust Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ

3. Additional Terms of the Agreement

Start Date	01/12/2022
End Date	30/11/2024
Cost	£0

4. Data Details

Purpose for Sharing	Please see Expression of Interest Enc 4.2 SP646_Reece York.dc
Personnel to have access to the Data	Sian Reece
Details of the Data to be shared	See expression of interest above.
Details of how the Data will be shared	Data will be transferred in Stata files using encrypted email to the recipients named above.
Details of access / storage and destruction	See Terms and Conditions in the Data Sharing Contract BIHR Data Sharing Contract - York (SIGN
Frequency	One-off

5. Re-Identification Controls

Details of Controls to be put in place to minimise the risk of re-identification of patients or service users	Records are de-identified by removing personal identifiers and replacing with pseudonymous study ID codes. Dates of birth and death are degraded to month and year only. Residential information is removed and replaced with postcode sector and/or LSOA. Clinical letters, images and free text are removed from health records.

Signature Page

Parties to the Data Sharing Agreement (add as required)

Signed for and on behalf of Receiving Organisation	University of York Head of Research and Knowledge Exchange Contracts
Name	Michael Gwinnett
Role / Job Title	Head of Research and Knowledge Exchange Contracts
Signature	DocuSigned by: Michael Gwinnett 97163CB73D754A2
Date	19.12.2022

Lead Applicant Signed for and on behalf of Receiving Organisation	
Name	**Sian Reece**
Role / Job Title	NIHR doctoral research fellow
Signature	DocuSigned by: 0E2431B89EA1471
Date	19.12.2022

Signed for and on behalf of Providing Organisation	Bradford Teaching Hospitals NHS Foundation Trust Bradford Royal Infirmary Duckworth Lane Bradford BD9 6RJ
Name	Professor John Wright
Role / Job Title	Director of Research
Signature	
Date	19.12.22

A.5.4 CRAG MEETING PREPARATORY MATERIAL

BIBBS DATA LINKAGE WITH THE DEPARTMENT FOR WORK AND PENSIONS

OUR PROGRESS SO FAR

Since September 2021, our researchers have been trialling an approach to facilitate data sharing between BiBBS and the Department for Work and Pensions (DWP) to help us better understand the impact of our programmes on the financial health of our community. Poverty and deprivation experienced by mothers and their families is linked to poor physical and mental health and can have long lasting effects. Financial difficulties for parents can cause mental health problems and chronic physical illness which affect parenting. By enhancing family livelihoods and financial health, this could directly improve the health and wellbeing of families, and reduce wider health inequalities in the long-term.

WHAT WE HAVE BEEN DOING

Following normal recruitment into the BiBBS research study, women are then asked whether they would also be willing to consent to link their data with DWP to better under the impact of our programmes on financial health. Women are provided with a separate information sheet and consent form in order to explain why we are asking to link their data and to explicitly gain consent for this. So far approximately 50% of women have consented to data linkage in this way.

WHAT WE WOULD LIKE TO DO

We recognise and understand the sensitivity of data sharing and linkage, particularly around financial data, and would like to take the opportunity to discuss your thoughts on alternative approaches to obtaining consent for this. We would like to make the process both transparent and less cumbersome for participants and recruitment staff.

At present, when women agree to be part of the BiBBS research study they are already asked whether they agree to data linkage with a number of other agencies e.g. health, education and local authority. We are trying to understand the best approach to ask women if they would also consent for researchers to link their data with DWP.

WHAT DO OTHER RESEARCH PROGRAMMES DO?

There are a number of other research projects that use data linkage to better understand their communities and the impact of their research on these communities. These research projects all use different approaches to obtain consent for data linkage. Historically, our existing approach has been the most commonly adopted approach, however more recently other approaches have been adopted. These have informed our possible options below.

POSSIBLE OPTIONS

We feel that the following are possible options moving forward and we would like to hear your thoughts on this:

1. Continue with the existing approach, by obtaining consent for linking data with DWP at the end of the existing BiBBS recruitment process
2. Incorporate the consent process for linking data with DWP into the usual BiBBS recruitment process:
    a. Add consent to data linkage between DWP and BiBBS as a separate clause in the usual BiBBS consent form (see Option 2a document attached). This would streamline the two consent processes into one, whilst keeping the consent clause for DWP data linkage separate to the other data linkage clauses. Hopefully this will reduce the paperwork and time burden for the women and recruiters alike but keeping the additional DWP clause explicit.

    b. Add DWP as an additional agency that we share data with within the existing BiBBS data sharing clause (see Option 2b document attached). This would further streamline the consent process, integrating consent together for all data linkage into one clause. Hopefully this would reduce the recruitment and burden of paperwork for the women and recruiters alike. Aligning it with the other data linkage processes might make the idea of data linkage with DWP less daunting and thereby improve uptake of data linkage.
3. Re-design the existing BiBBS consent form, creating an opt-out policy for data linkage with all agencies, assuming all participants agree to data linkage with all agencies

unless explicitly stated otherwise. BiBBS participants would have the option of choosing to opt-out of data linkage with each specific agency e.g. health, education, welfare via a separate form should they wish.

Thank you in advance for your advice and looking forward to meeting with you soon.

17th May 2022

A. 5.4.1 OPTION 2A

BORN IN BRADFORD'S BETTER START

Born in Bradford's Better Start (BiBBS)
Consent Form for Pregnant Women

Id:

Name of Parent (print)…………………………………………………………………..

Confirmation to take part in BiBBS

1a	I have read the Information Sheet for Pregnant Women (version 4 dated 21.02.18) about the BiBBS study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Yes ☐
1b	I understand that my participation in BiBBS is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that I can withdraw from the study by contacting BiBBS staff using the contact details at the bottom of this form. I understand that if I become unable to consent in the future, you will not collect any further information.	Yes ☐
1c	I understand the BiBBS team and their research partners in the United Kingdom and both inside and out of Europe may use my information and samples for approved projects, and that I will not be given the results. It will not be possible for anyone outside of BiBBS to link my information and samples to me or to my child. All information will be treated in the strictest confidence in accordance with the relevant UK data protection regulations, and used for research purposes only.	Yes ☐
1d	I understand that relevant information about me and my child will be accessed by the BiBBS project team. (as detailed in the Information Sheet for Pregnant Women version 4 dated 21.02.2018). This includes relevant information collected by GPs, health visitors, midwives, hospitals (hospital episode statistics), other healthcare organisations such as dentists or opticians, children's services (including children's centres and social care), schools and Better Start Bradford Projects. It includes information held by NHS Digital, other central NHS organisations and the Local Authority. I understand that BiBBS will give some identifiable details such as name, date of birth, address and NHS number to these organisations so they can send us data back.	Yes ☐
	I understand that if there are not enough places for everyone to take part in Better Start Bradford projects, families may be selected to take part by chance (randomly). If my family are not selected to take part in a project, information on me and my child	

1e	may be compared with families who have been selected to take part.	Yes ☐	
1f	I agree to take part in the BiBBS study.	Yes ☐	
2	I understand that any samples taken will be anonymised and stored for future use. This will include the analysis of genes. If I wish to withdraw from the study in the future I agree that these samples will be retained and used unless I specifically request that they are destroyed, in which case I understand that the research team will make every effort to do so and ensure that no further analysis will be done on mine or my child's samples.	Yes ☐	
3	I give permission for my blood sample to be taken when I join the study	Yes ☐	No ☐
4	I give permission for a sensor to measure my vitamin levels by using a light to measure the colours from fruit and vegetables in the skin on my hand	Yes ☐	No ☐
5	I give permission for a sample of blood to be taken from the umbilical cord after it has been cut	Yes ☐	No ☐
6	I give permission for a small sample of my hair to be taken after I have given birth	Yes ☐	No ☐
7	I give permission for the BiBBS project team to access relevant information from the Department for Work and Pensions (DWP) and Her Majesty's Revenue and Customs (HMRC) about income and benefits entitlements for me and my child. I understand that BiBBS will give some identifiable details such as name, date of birth, address and NHS number to these organisations so they can send us data back.	Yes ☐	No ☐
8	I agree that BiBBS can contact me in the future to let me know how BiBBS is getting on and invite me to take part in other research related to BiBBS.	Yes ☐	No ☐

Signed by Parent ……………………………………………………… Date : ……………………………..

Researcher confirmation
I confirm that I have explained the nature of the proposed research to the person(s) named on this form and have left a copy of the Information Sheet for pregnant women version 4 dated 21.02.2018 and this consent form with them for future reference.

Name of researcher (print)……………………………………………………………………………..

Signed by researcher ……………………………………………….. Date : ……………………………..

Interpreter confirmation
I confirm that I have interpreted the Information Sheet for Pregnant Women version 4 dated 21.02.18 and this consent form with them and that the participant understands.

Name of interpreter (print) ………………………………………………………………………………..

Signed by interpreter …………………………………………………Date : ………………………….

BiBBS Contact details:

Born in Bradford's Better Start (BiBBS), Bradford Institute for Health Research, Temple Bank House, Bradford Royal Infirmary, Duckworth Lane, Bradford BD9 6RJ.
Phone: 01274 383941 Email: bibbs@bthft.nhs.uk

A. 5.4.2 OPTION 2B

bibbs

BORN IN BRADFORD'S BETTER START

Born in Bradford’s Better Start (BiBBS)
Consent Form for Pregnant Women

Id:

Name of Parent (print)……………………………………………………………………..

Confirmation to take part in BiBBS

1a	I have read the Information Sheet for Pregnant Women (version 4 dated 21.02.18) about the BiBBS study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Yes	☐
1b	I understand that my participation in BiBBS is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that I can withdraw from the study by contacting BiBBS staff using the contact details at the bottom of this form. I understand that if I become unable to consent in the future, you will not collect any further information.	Yes	☐
1c	I understand the BiBBS team and their research partners in the United Kingdom and both inside and out of Europe may use my information and samples for approved projects, and that I will not be given the results. It will not be possible for anyone outside of BiBBS to link my information and samples to me or to my child. All information will be treated in the strictest confidence in accordance with the relevant UK data protection regulations, and used for research purposes only.	Yes	☐
1d	I understand that relevant information about me and my child will be accessed by the BiBBS project team. (as detailed in the Information Sheet for Pregnant Women version 4 dated 21.02.2018). This includes relevant information collected by GPs, health visitors, midwives, hospitals (hospital episode statistics), other healthcare organisations such as dentists or opticians, children’s services (including children’s centres and social care), schools and Better Start Bradford Projects. It includes information held by NHS Digital, other central NHS organisations, the Department for Work and Pensions, and the Local Authority. I understand that BiBBS will give some identifiable details such as name, date of birth, address and NHS number to these organisations so they can send us data back.	Yes	☐
	I understand that if there are not enough places for everyone to take part in Better Start Bradford projects, families may be		

1e 1f	selected to take part by chance (randomly). If my family are not selected to take part in a project, information on me and my child may be compared with families who have been selected to take part. I agree to take part in the BiBBS study.	Yes ☐ Yes ☐
2	I understand that any samples taken will be anonymised and stored for future use. This will include the analysis of genes. If I wish to withdraw from the study in the future I agree that these samples will be retained and used unless I specifically request that they are destroyed, in which case I understand that the research team will make every effort to do so and ensure that no further analysis will be done on mine or my child's samples.	Yes ☐
3	I give permission for my blood sample to be taken when I join the study	Yes ☐ No ☐
4	I give permission for a sensor to measure my vitamin levels by using a light to measure the colours from fruit and vegetables in the skin on my hand	Yes ☐ No ☐
5	I give permission for a sample of blood to be taken from the umbilical cord after it has been cut	Yes ☐ No ☐
6	I give permission for a small sample of my hair to be taken after I have given birth	Yes ☐ No ☐
7	I agree that BiBBS can contact me in the future to let me know how BiBBS is getting on and invite me to take part in other research related to BiBBS.	Yes ☐ No ☐

Signed by Parent ……………………………………………………… Date : ……………………………

Researcher confirmation
I confirm that I have explained the nature of the proposed research to the person(s) named on this form and have left a copy of the Information Sheet for pregnant women version 4 dated 21.02.2018 and this consent form with them for future reference.

Name of researcher (print)……………………………………………………………………………..

Signed by researcher ………………………………………………. Date : ……………………………

Interpreter confirmation
I confirm that I have interpreted the Information Sheet for Pregnant Women version 4 dated 21.02.18 and this consent form with them and that the participant understands.

Name of interpreter (print)
……………………………………………………………………………………..

Signed by interpreter …………………………………………………Date :
…………………………….

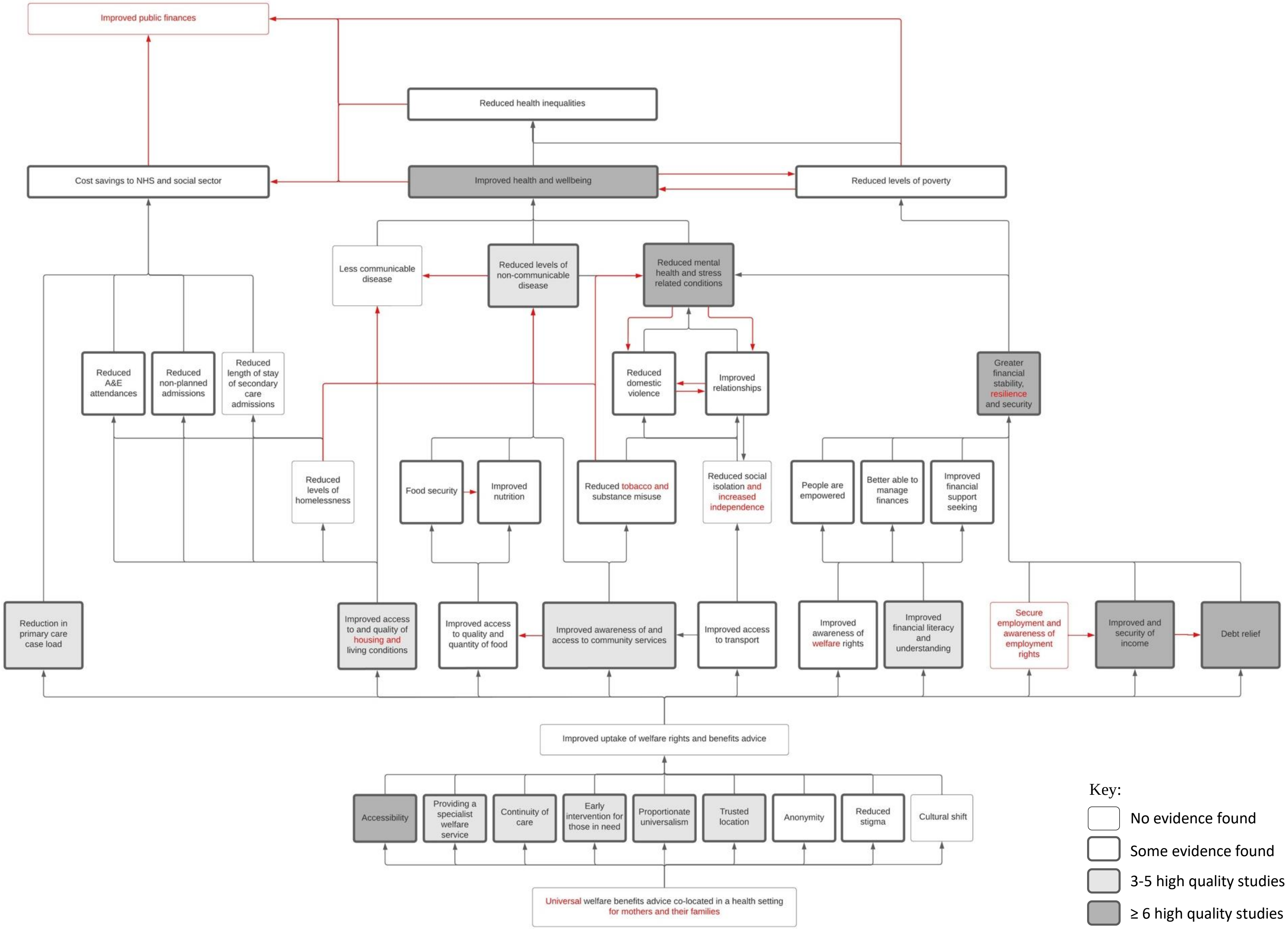
BiBBS Contact details:

Born in Bradford's Better Start (BiBBS), Bradford Institute for Health Research, Temple Bank House, Bradford Royal Infirmary, Duckworth Lane, Bradford BD9 6RJ.
Phone: 01274 383941 Email: bibbs@bthft.nhs.uk

APPENDIX 6 FURTHER INFORMATION FOR CHAPTER 8

A.6.1 AMENDMENTS TO THE A PRIORI THEORY OF CHANGE MODEL

Figure 16 Theory of change model for universal welfare advice services co-located in health settings for mothers and their families with tracked changes to the a priori theory of change model highlighted in red


Improved public finances
Reduced health inequalities
Cost savings to NHS and social sector
Improved health and wellbeing
Reduced levels of poverty
Less communicable disease
Reduced levels of non-communicable disease
Reduced mental health and stress related conditions
Reduced A&E attendances
Reduced non-planned admissions
Reduced length of stay of secondary care admissions
Reduced domestic violence
Improved relationships
Greater financial stability, resilience and security
Reduced levels of homelessness
Food security
Improved nutrition
Reduced tobacco and substance misuse
Reduced social isolation and increased independence
People are empowered
Better able to manage finances
Improved financial support seeking
Reduction in primary care case load
Improved access to and quality of housing and living conditions
Improved access to quality and quantity of food
Improved awareness of and access to community services
Improved access to transport
Improved awareness of welfare rights
Improved financial literacy and understanding
Secure employment and awareness of employment rights
Improved and security of income
Debt relief
Improved uptake of welfare rights and benefits advice
Accessibility
Providing a specialist welfare service
Continuity of care
Early intervention for those in need
Proportionate universalism
Trusted location
Anonymity
Reduced stigma
Cultural shift
Universal welfare benefits advice co-located in a health setting for mothers and their families
Key:
No evidence found
Some evidence found
3-5 high quality studies
≥ 6 high quality studies

A.6.2 A STUDY PROTOCOL FOR AN EFFECTIVENESS EVALUATION OF A WELFARE ADVICE CO-LOCATED IN HEALTH SETTINGS FOR MOTHERS AND THEIR FAMILIES IN BRADFORD

A. 6.2.1 INTRODUCTION

Early childhood deprivation is associated with significant negative physical, mental health and social outcomes that not only limit a child's development in the short-term but have long lasting effects into adulthood.[12] Areas with high levels of early childhood deprivation are linked with: poorer levels of child development, school readiness and educational attainment; high levels of obesity; more high-risk behaviours; more looked after children; poor performing schools and higher school exclusion rates; higher levels of youth crime; and lower entry into further education, training or employment. These wider determinants damage child health, cause clustering of unhealthy behaviours, impair life opportunities and increase longer term non-communicable disease risk.[12]

In adulthood, links between financial difficulties, social deprivation and mental health are also well established.[17] Financial strain can precipitate and perpetuate mental health problems[17,18] and has been found to be a predictor of chronic physical illness.[19-21] Furthermore, individuals suffering with poor mental health associated with financial difficulties, exacerbated in recent years by austerity, are more likely to face challenges in accessing the advice and support needed to address these welfare issues.[18,21]

For families in the UK, living with financial insecurity has become frighteningly more commonplace over recent years. Years of austerity following the global economic recession in 2007 caused financial insecurity for many families. More recently, the COVID-19 pandemic has triggered or further exacerbated socioeconomic insecurity, with the largest effects amongst the most vulnerable in society, including ethnic minorities and those living in socioeconomically deprived areas.[15,26,27] For families with children, the closure of educational settings and the need for home-schooling brought with it additional costs for families and increased pressure on the already stretched budgets of low-income households,[28] as well as stress and tension in the home.[29,30]

In the aftermath and recovery from the pandemic, rising inflation, together with tax increases and rising energy and food costs, has created a cost of living crisis meaning that average household take-home pay is falling further, deteriorating living standards and quality of life for many families in the United Kingdom.[31] A recent report from the International Monetary Fund highlights that the energy crisis is currently affecting UK households harder than any country in western Europe, with the difference between the cost burden on poor and rich households being far more unequal in the UK compared with other countries.[125] These crises particularly affect those on the lowest incomes and who have already been affected by austerity measures, such as women and women from ethnic minority communities, particularly due to their unpaid caring roles, lower savings levels, and poverty.[33,34]

There is evidence that the negative impacts of financial hardship on physical and mental health can be obviated if corrected early on.[20] There is, however, low uptake of means-tested benefits in some communities, and this has been found to be particularly pronounced in some ethnic minority groups.[46] Various schemes have been put in place to improve uptake of benefits by co-locating welfare advice services within health services, with some success.[45,52,53] However, we need more research on how to do this most effectively to reach the populations most in need, and to assess its impact.

Integration of welfare advice services can help to ensure timely and targeted access in a time and place of need. Various schemes have been put in place to improve the accessibility and uptake of welfare advice and the receipt of benefits and other financial support by co-locating welfare advice services within health settings.[45,52,53]

A systematic review, published in 2006, of welfare advice delivered in health settings found that there was evidence that this approach resulted in financial gains but at that time there was limited high quality evidence to determine whether this resulted in improved uptake of welfare advice or measurable health and social benefits.[62] Furthermore, none of the included studies considered variation in uptake or outcomes measures between ethnic groups. Since this time, a further quasi-experimental study has been conducted to examine the impact and cost-consequences of co-located benefits and debt advice on mental health, which demonstrated improved short term mental health and wellbeing for some participants, particularly for Black women.[64] However, further research is required to fully understand the association between co-located welfare advice and improved health and wellbeing. Furthermore, there remains a paucity of empirical evidence and little collective understanding of how best to implement these welfare services in a health setting, how to target those most in need and how best to evaluate its impact.[62]

Pregnancy is a unique life event causing significant, wide ranging and long-lasting changes to the lives of the parents and the rest of the family. Such changes may make some families susceptible to financial insecurity and increase their need for financial support. New mothers and their families may subsequently become entitled to different or new benefits, such as Child Benefit that every parent is entitled to, but may not be aware of these.[65-67] Therefore, there is an opportunity for health services to prevent future health inequalities by protecting against and minimising financial insecurity and its consequences in children and their families.

Maternity care is universal in the offer of provision of care and almost universal in the uptake. Pregnancy therefore offers an important opportunity for health professionals to engage with almost all pregnant women, some who may not otherwise have any contact with health or social services, at several occasions throughout their pregnancy and beyond.[75]

A universal offer of welfare advice, through co-location in a maternity setting, could overcome the stigma and cultural issues associated with financial vulnerability and receiving help by normalising access to welfare advice and re-framing financial security as an issue important to the health of the mother and their family. These services could thereby increase the uptake of welfare advice and benefits to which families are entitled, particularly in under-served populations, and improve financial security for families.

It is, therefore, important to determine the acceptability and effectiveness of a welfare advice service embedded within maternity care and the effects this has upon mental health and wellbeing and health inequalities.

A. 6.2.2 AIM

To determine whether the provision of a welfare advice service co-located in maternity services is feasible to deliver, acceptable to families and demonstrates improvements to financial and health and wellbeing outcomes, whilst representing value for money.

A. 6.2.3 OBJECTIVES

a) To explore the magnitude and direction of effect of the impact of a welfare advice service co-located in a maternity setting on participant health, wellbeing and financial security.

b) To calculate the cost-effectiveness of the intervention

c) To explore whether the welfare advice service co-located in a maternity setting was delivered as intended.

d) To explore the acceptability of delivering the welfare advice within a maternity care setting to mothers, midwives and welfare advisors in a deprived and diverse population.

A. 6.2.4 METHODS

This protocol was developed and structured in accordance with recommendations from the Consolidated Standards of Reporting Trials (CONSORT) extension for the reporting of randomised controlled trials (RCT) conducted using cohorts and routinely collected data (CONSORT-ROUTINE) to improve the transparency and completeness of the conduct and reporting of randomised controlled trials.[243]

A. 6.2.4.1 TRIAL DESIGN

This protocol describes a single blind implementation-effectiveness hybrid randomised trial within a cohort with 1:1 individual, randomised allocation to the intervention (receipt of an immediate welfare advice assessment, advice and active assistance with claims) or control (financial advice leaflet), alongside a planned mixed-methods implementation and economic evaluation.

A. 6.2.4.2 COHORT

Born in Bradford (BiB) research programme is an internationally recognised, applied health research programme comprising health and wellbeing information on more than 30,000 Bradfordians enrolled in a family of three large, multi-ethnic prospective birth cohort studies: BiB Family; Born in Bradford's Better Start (BiBBS); and BiB4All,.[84] The aims of the research programme are fourfold: to describe health and ill-health in the largely bi-ethnic population with high economic deprivation; to identify modifiable causal relationships that contribute to ill-health, and design and evaluate interventions to promote wellbeing; to provide an integrated model of epidemiological and evaluative research based on practice in the National Health Service and related health systems; and to build and reinforce research capacity in Bradford.[85,86]

Born in Bradford's Better Start (BiBBS) is a Big Lottery funded innovative experimental birth cohort, established in 2016, that simultaneously evaluates the impact of multiple early life interventions to improve outcomes for pregnant women and families with children aged 0-3 years in three inner city deprived, multi-ethnic wards in Bradford. It specifically explores: social and emotional development; communication and language development; and nutrition and obesity. Women are recruited from the Bradford Royal Infirmary maternity unit as they attend the clinic for an oral glucose tolerance test, routinely offered to all pregnant women at the time of their anomaly scan at 20 weeks gestation. Recruitment is ongoing and, as of the end of May 2023, 4800 women and their children are in the cohort.[89] BiBBS test interventions utilising trials within cohorts and other quasi-experimental designs, where trials within cohorts are neither feasible nor ethical, to evaluate early life interventions.

All pregnant women living in Better Start Bradford areas (defined by full postcode) who are registered to give birth at Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) are eligible for recruitment. The BTHFT is the only maternity unit covering this area. Women are excluded if they plan to move away from Bradford before the birth.

Demographic and socioeconomic information, physical and mental health, lifestyle factors and biological samples are collected at baseline. Participants in the BiB cohorts consent for routine data linkage to health and education data for research, and to be contacted for future research studies. Data linkage has also been established between the BiBBS cohort and the Department for Work and Pensions and His Majesty's Revenue and Customs. This data linkage permits baseline and follow-up financial data to be collected on income and the nature and value of benefits awarded to participants who consent to this data linkage. Participants in the BiB Family Cohort Study and BiBBS cohort study also complete detailed questionnaires at recruitment and in ongoing waves of data collection, including information regarding wider social determinants of health.[61]

The protocol for this birth cohort study has been approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). Research governance approval has been provided from Bradford Teaching Hospitals NHS Foundation Trust. Details of the full protocol for the cohort study is described elsewhere.[89]

A. 6.2.4.3 TRIAL PARTICIPANTS

Pregnant women aged 16 and over who are booked to deliver at Bradford Royal Infirmary, who live in the Better Start Bradford wards, have consented to participate in the BiBBS cohort and who consent to participation in this study. Participants will be recruited in their first language where possible. Interpreters and written information will be provided in additional commonly spoken languages as required, including Arabic, Bangla, Hebrew, Latvian, Malay, Polish, Romanian, Slovenian and Urdu.

A. 6.2.4.4 INTERVENTIONS

Conduct of the oral glucose tolerance test involves an initial baseline blood test, alongside a pre-measured glucose drink. Women are then asked to wait in the department until a repeat blood test is taken two hours later.

During the waiting time, participants in the treatment group will meet with a qualified welfare advisor who will conduct an initial welfare triage assessment with the participant, with provision of initial welfare advice and arrangements made for follow-up for a full structured assessment of current welfare status and benefits entitlement where required.

During the waiting time, participants in the control group will receive a pamphlet containing written financial advice and how to access further financial support.

A. 6.2.4.5 OUTCOMES

Written informed consent for participation in the trial will be obtained at baseline assessment following recruitment into the BiBBS cohort study. Sociodemographics and other physical and mental health, lifestyle factors and biological samples will be collected at baseline as per the BiBBS cohort recruitment process.[89] The following financial, health and social outcome measures will be collected in a structured face-to-face interview by researchers at baseline, 3 months and 6 months following receipt of the initial welfare advice assessment at baseline, see Table A.5. All participants will receive a £10 Love2Shop voucher at the end of each assessment as a form of recognition of their participation in the study.[174]

Table A.4 Welfare advice services co-located in health settings for mothers and their families proposed effectiveness evaluation outcomes.

Outcome set	Outcome name	Outcome measures	Data source	Outcomes framework mapping
Poverty and inequality	▪ Poverty	▪ Income	▪ Data linkage	▪ COS-EY Set 6: Poverty and inequality[197]
	▪ Financial security and resilience	▪ Self-reported financial security ▪ Worry about paying for rent or mortgage ▪ Worry about eviction ▪ Ability to pay bills	▪ BiBBS participant questionnaire	▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
		▪ Additional benefits received ▪ Additional income gained ▪ Debt relieved	▪ Data linkage	▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
	▪ Food security	▪ Whether food lasted ▪ Ability to eat a balanced meal ▪ Needing to skip a meal ▪ Feeling hungry	▪ BiBBS participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236]
	▪ Secure and fulfilling employment	▪ Secure employment achieved	▪ Participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236]
	▪ Safe and secure housing	▪ Homeowner status ▪ Presence of damp and mould in the home ▪ Number of adults per household ▪ Number of children per household	▪ BiBBS participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236]

Table A.4 Welfare advice services co-located in health settings for mothers and their families proposed effectiveness evaluation outcomes.

Outcome set	Outcome name	Outcome measures	Data source	Outcomes framework mapping
		▪ Number of bedrooms per household		
Physical health and health behaviours	▪ Maternal general health	▪ Self-reported general health	▪ Follow-up participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
Mental health and quality of life	▪ Maternal mental health	▪ PHQ-8[101]	▪ Validated research tool	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
	▪ Maternal wellbeing	▪ SWEMWBS[183]	▪ Validated research tool	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
	▪ Maternal quality of life	▪ EQ-5D-5L[107]	▪ Validated research tool	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236] ▪ NHS Outcomes Framework[235]
Social environment	▪ Family and social relationships ▪ Domestic violence ▪ Loneliness and isolation	▪ Relationship status ▪ Single parent ▪ Loneliness ▪ Relationship quality ▪ Quality of communication in relationship	▪ BiBBS participant questionnaire	▪ COS-EY Set 6: Poverty and inequality[197] ▪ Public Health Outcomes Framework[236]

Table A.4 Welfare advice services co-located in health settings for mothers and their families proposed effectiveness evaluation outcomes.

Outcome set	Outcome name	Outcome measures	Data source	Outcomes framework mapping
	▪ Access to community services ▪ Parenting skills	▪ Arguments within relationships ▪ Conflict within relationship		

To establish participant self-reported financial security, the survey employs the question: ‘How well would you say you are managing financially right now?’.[177] Answer options include: ‘living comfortably’; ‘doing alright’; ‘just about getting by’; ‘finding it quite difficult’; and ‘finding it very difficult’.

Mental health, wellbeing and health-related quality of life are measured using the PHQ-8, SWEMWBS and EuroQol EQ-5D tools respectively.[100,178,179] Mental health is measured using the PHQ-8 questionnaire.[100] The scores from each item will be summed to produce a total score between 0 and 24 points. Summed scores are used as a continuous variable with greater scores indicating a presence of depressive symptoms.

Wellbeing is measured using the seven-item SWEMWBS.[104] The score from each item will be summed to produce a total score between 14 and 35. Summed scores will be transformed and used as a continuous variable with greater scores indicating a more positive wellbeing.

The health-related quality of life of participants is measured using the five-item EQ-5D instrument (EQ-5D-5L).[107] These domains provide a descriptive profile that will be transformed into health utility scores, based on UK societal preference weights for the health state,[108] ranging between 0 representing death and 1 for perfect health. The EQ-5D-5L questionnaire also includes a Visual Analog Scale (VAS), by which respondents can self-report their perceived health status with a continuous grade ranging from 0 representing the worst possible health to 100 representing the best possible health.

A. 6.2.4.6 PROCESS EVALUATION

In order to ensure that a full and holistic process evaluation is conducted of this complex intervention, a process evaluation adopted from the RE-AIM framework is proposed, see

Table A.6.[237-239] This will explore the reach, effectiveness, adoption, implementation and maintenance of the intervention.

Table A.5 Process evaluation adapted from the RE-AIM Framework[238]

Dimensions	Items
Reach	
Exclusion Criteria (percentage and characteristics)	1) How many potential participants were approached? 2) How many participants were deemed ineligible to participate? 3) Of the participants meeting selection criteria, how many participants actually participated?
Percentage on the Valid Denominator	4) Was the percentage of all eligible invited participants who accepted participation reported? If not, can the percentage be calculated?
Characteristics of Participants Compared With Nonparticipants	5) Were the characteristics of those subjects choosing to participate and those unwilling to participate described? If yes, what was the representativeness of those who participated versus those who did not? Comparisons can be made with either nonparticipants or available resource data.
Effectiveness	
Measure of the Effect Size	6) Were effect sizes for significant outcomes provided or can they be calculated?
Measure of Quality of Life or Potential Negative Outcome	7) Were there any qualitative or quantitative measures of quality of life or potential negative outcome?
Measure of Robustness Across Subgroups	8) Were any within-groups analyses conducted that allowed researchers to draw conclusions about how different subpopulations responded to an arm of the design?
Adoption	
Setting Exclusion (percentage and reasons)	9) How many settings in a given population were actually qualified to host the intervention? 10) Among the settings that were approached about hosting the intervention, how many settings were interested in participating? 11) How many settings were not appropriate for the study? 12) How many settings met criteria and chose to participate?
Percentage of Settings Approached (Valid Denominator)	13) What percentage of the total number of available settings actually participated?
Characteristics of Participating Settings Compared With Nonparticipating Settings	14) Were the characteristics of those settings choosing to participate and those unwilling to participate described? If yes, what was the representativeness of those that participated versus those that did not? Comparisons can be made with either non-participating settings or available resource data.
Implementation	

Table A.5 Process evaluation adapted from the RE-AIM Framework[238]

Dimensions	Items
Percent of Perfect Delivery (Implementation Fidelity)	15) Were there measures (preferably statistical but also observational) indicating that Agent A and Agent B delivered the same amount/type of intervention?
	16) Were the methods of intervention delivery described?
	17) Were there any measures of the actual number of intervention pieces that were delivered (e.g., an average or percentage)?
Adaptation	18) Was the intervention changed or modified in any way during the course of the study?
Cost of Intervention	19) Was any information provided on the total time commitment required to implement the intervention?
	20) Was any information provided on the type of staff needed to implement the intervention?
	21) Was any information provided on the cost of the intervention? Was information provided on the actual or estimated cost difference between the intervention and the control condition?
	22) Was any cost-effectiveness or cost-benefit analysis done to determine the economic soundness of the intervention?
Maintenance: Individual Level	
	23) Measure of primary outcome (with or w/o comparison to a public health goal) at ≥ 6mo follow-up after final intervention contact
	24) Measure of broader outcomes or use of multiple criteria at follow- up (e.g., measure of QoL or potential negative outcome) at follow- up
	25) Robustness data – something about subgroup effects over the long- term
	26) Measure of long-term attrition (%) and differential rates by patient characteristics or treatment condition
	27) Use of qualitative methods data to understand long -term effects
Maintenance: Setting Level	
	28) If program is still ongoing at ≥ 6 month post study funding
	29) If and how program was adapted long-term (which elements retained AFTER program completed)
	30) Some measure/discussion of alignment to organization mission or sustainability of business model
	31) Use of qualitative methods data to understand setting level institutionalization

Qualitative data will be taken from the intervention documentation and semi-structured interviews with service providers, practitioners and families to understand the barriers and enablers to the implementation of the intervention.

All welfare advisors providing the new service and midwives working with mothers accessing the service will be included. Mothers will be purposively selected to participate in the qualitative study. Using a sampling framework, participants will be recruited to achieve a maximum variation sample with respect to, for example, age, language, ethnicity and self-reported financial vulnerability and uptake of welfare benefits. Sampling will use BiBBS baseline data.

A minimum of 15 mothers accessing the service, 5 welfare advisors and 5 midwives will be recruited over a 12-month study period. If data saturation has not been reached, the number of participants interviewed will be increased.

Interviews will be conducted in the women's own homes, a community venue convenient to them or online or by telephone if they prefer. Interviews with welfare advisors and midwives will take place at the participant's place of work, other convenient venue or online. In all cases, the study will be explained, and consent will be taken before any questions are asked. A structured topic guide will be developed and piloted. All interviews will be audio recorded, uploaded as soon as possible to a secure Bradford Teaching Hospitals Foundation Trust computer network, and the original recording deleted.

A. 6.2.4.7 SAMPLE SIZE

For the full trial it is estimated that 296 participants per arm would be required to have 90% power to detect a clinically meaningful difference in the primary outcome of quality of life, measured as 0.133 in EQ-5D-5L health index score between groups for 5% two-sided alpha t-test. A sample size of 505 participants per arm would be required to have 90% power to detect a clinically meaningful difference in all quality of life (difference of 0.113 in mean group health index score), wellbeing (difference of 1.27 in SWEMWBS score) and mental health measures (difference of 1 in PHQ-8 score) at 3 months follow-up for 5% two-sided alpha t-test.

A. 6.2.4.8 SEQUENCE GENERATION

Following baseline assessment and recruitment to the BiBBS cohort study, participants will be individually randomly allocated to the intervention or control group by an independent research administrator using a sequential allocation table independently generated from random number tables prior to recruitment.

A. 6.2.4.9 BLINDING

After assignment to intervention, researchers conducting 3- and 6-month follow-up assessment interviews will not be informed of participant allocation. At the start of each visit, the researcher will explain to participants that they do not know what type of financial advice the participant had received and will request that this is not discussed during the visit to protect blinding. If the researcher becomes inadvertently made aware of the participant's trial arm during the assessment visit, then 'unblinding' will be recorded at the time of the data collection visit. Owing to the nature of the intervention, participants will not be blind to allocation.

Separate qualitative researchers will conduct semi-structured interviews with mothers, welfare advisors and midwives who will not be blind to participant allocation status, given the nature of the interview.

A. 6.2.4.10 STATISTICAL METHODS

Analyses will be conducted on an intention-to-treat basis. The analysis will compare outcomes for the intervention at different time points in comparison to the control group.

Baseline sociodemographics will be presented descriptively for participants. Where data are parametric, mean values and standard deviation shall be presented. Where data are non-parametric, median values and the interquartile range will be presented. All statistical analyses will be carried out using Stata 15.[162]

Multiple logistic regression models will be used to explore individual differences in self-reported financial security before and after the provision of welfare advice. Mean PHQ-8, transformed SWEMWBS, transformed EQ-5D-5L utility scores and VAS scores are considered to approximate to a normal distribution with sufficient sample sizes.[100,183,187] Multiple linear regression models will be used to explore individual change in PHQ-8, transformed SWEMWBS, transformed EQ-5D-5L utility scores and VAS scores before and after the provision of welfare advice. To minimise regression to the mean, financial outcome data will be included in regression analyses. Where data are non-parametric Spearman's rank co-efficient will be used.

Data collection and analysis of the semi-structured interviews will be concurrent and continue until it appears that no new substantive themes are identified in the data.[244] NVivo software will be used for coding of transcripts. Once coding is complete, data will be analysed using a thematic analysis within the Theoretical Domains Framework.[182] Pseudonyms will be allocated and confidentiality ensured in all publications and reports. The intervention will be refined in the light of the findings in order to enhance acceptability, uptake, equity and impact.

A. 6.2.4.11 ECONOMIC EVALUATION

Data collected on type and range of welfare advice provided for each participant, alongside financial outcomes awarded for participants, will be presented descriptively. To calculate a return on investment measure, the total financial gains for all participants will be divided by the total cost of the service to commissioners over the data collection period. Total financial gain includes any additional income gained, one off payments and any debt managed for participants.

To calculate the QALY value for this intervention, the utility value associated with a given state of health will be multiplied by the years lived in that state (1 year of life x 1 utility = 1 QALY).[188] he incremental cost effectiveness ration (ICER) will then be calculated by dividing the difference in total costs of the service (incremental cost) by the difference in any QALY gained to provide a ratio of 'extra cost per extra unit of health effect'.[245]

ABBREVIATIONS

BiB	Born in Bradford
BiBBS	Born in Bradford's Better Start
BiBGU	Born in Bradford's Growing Up
BIHR	Bradford Institute for Health Research
BIRU	Bradford Inequalities Research Unit
BSB	Better Start Bradford
CAB	Citizens Advice Bureau
CCG	Clinical Commissioning Group
CEBMa	Center for Evidence-Based Management
CFIR	Consolidated Framework for Implementation Research
CI	Confidence interval
COMET	Core Outcome Measures in Effectiveness Trials
COS	Core Outcome Set
COS-EY	Core Outcome Set for Early Years
CRAG	Community Research Advisory Group
DELTA^2	Difference Elicitation in Trials
DEPESTLE	Demographic, Ethical, Political, Economic, Social, Technological, Legal, Environmental
EU	European Union
GAD-7	Generalised Anxiety Disorder
GP	General Practitioner

HYMS	Hull York Medical School
ICER	Incremental cost effectiveness ratio
IMD	Index of Multiple Deprivation
IQR	Interquartile range
MeSH	Medline Medical subject headings
MMAT	Mixed Methods Appraisal Tool
MPI	Multidisciplinary Poverty Index
MRC	Medical Research Council
NHS	National Health Service
NHSOF	NHS Outcomes Framework
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OECD	Organisation for Economic Co-operation and Development
OR	Odds ratio
PESTLE	Political, Economic, Social, Technological, Legal, Environmental
PHOF	Public Health Outcomes Framework
PHQ-8	Patient Health Questionnaire
PICO	Participants, Intervention, Comparison, Outcome
PICOSS	Participants, Intervention, Comparison, Outcome, Setting, Study
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-P	Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols

QALY	Quality-adjusted life year
RIC	Reducing Inequalities in Communities
ROSCA	Rotating savings and credit associations
SD	Standard deviation
SROI	Social Return on Investment
SWEMWBS	Shortened Warwick-Edinburgh Mental Wellbeing Scale
UK	United Kingdom
UK LLC	UK Longitudinal Linkage Collaboration
UKPRP	UK Prevention Research Programme
UNDP	United Nations Development Programme
VAS	Visual Analogue Scale
VCS	Voluntary and Community Sector
WEMWBS	Warwick-Edinburgh Mental Wellbeing Scale