

FULL/LONG TITLE OF THE STUDY

Evaluation of the mental health impacts of Universal Credit: a mixed methods study

SHORT STUDY TITLE / ACRONYM

Health impacts of Universal Credit

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SIGNATURE PAGE

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

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

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

For and on behalf of the Study Sponsor:

Signature: Date: reh Name: Debra Stuart Position: Head of Research Governance, MVLS Chief Investigator: eterCra Signature: Name: Peter Craig

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Date:14/05/2021

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STUDY SUMMARY

Study Title	Evaluation of the mental health impacts of Universal Credit: a mixed methods study
Internal ref. no. (or short title)	Health impacts of Universal Credit
Study Design	Mixed methods study involving secondary analysis of surveys and routinely collected data; qualitative study of recipients of Universal Credit and those involved in advising claimants and processing claims; a dynamic microsimulation of the health effects of changes in the design and delivery of Universal Credits; and an economic evaluation of the cost consequences of Universal Credit implementation, and the cost-benefit of alternative models of design and delivery.
Study Participants	Recipients of Universal Credit and other low income households; advisers and others involved in supporting Universal Credit claimants and recipients
Planned Size of Sample (if applicable)	The study will use a range of survey and routinely collected datasets of varying sizes, as well as a synthetic population. The qualitative study will seek to interview up to 80 UC claimants and up to 30 people working in organisations supporting claimants.
Follow up duration (if applicable)	The study will analyse and model the impacts of Universal Credit over a range of periods lasting up to 10 years. The qualitative study will follow a subsample for up to two years.
Planned Study Period	01/05/2021-30/08/2025
Research Question/Aim(s)	(1) what are the effects of Universal Credit on population health and health inequalities, how do they vary, geographically or between groups of claimants, and how do the effects change as rollout progresses? (2) what are the mechanisms that cause these effects? (3) what can be done to mitigate harms or enhance positive effects of Universal Credit? (4) what is the overall cost-consequence of Universal Credit and the cost-benefit of specific mitigating/enhancing measures? (5) How might the changes to Universal Credit administration and caseload associated with COVID-19 moderate the relationship between Universal Credit and claimants' health?

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
National Institute of Public Health Research Public Health Research Programme	Project grant
Contact: Ms Hannah Sainsbury, netspostawardsetup@nihr.ac.uk	

ROLE OF STUDY SPONSOR AND FUNDER

The study is sponsored by the University of Glasgow. The University holds insurance providing cover for the design of the research study protocol. Otherwise, the sponsor has no role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

The funder has no role in study design, conduct, data analysis and interpretation, or manuscript writing. Dissemination will be subject to NIHR's requirements for Publication and notification: https://www.nihr.ac.uk/documents/nihr-research-outputs-and-publications-guidance/12250#Notifying_NIHR_of_upcoming_research_outputs

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The Study Steering Committee (SSC) will meet annually. It will be independently chaired by a senior academic and comprise five additional senior researchers who are independent of the study team, and a representative of the public (Appendix 9.2). We will ask the SSC to formally review progress at each meeting based on a set of pre-specified criteria. The criteria will be discussed and agreed at the first meeting of the SSC, but are likely to include progress with UC migration, levels of recruitment and retention into the qualitative study, and success in obtaining estimates of health impacts from WP1 and WP2 to include in the WP4 modelling and WP5 economic evaluation work.

The study will also have a Study Advisory Group (SAG) that meets quarterly. Like the SSC the SAG will have an independent chair. The group will comprise representatives of a range of stakeholder organisations and a representative of the public. We have confirmed involvement from Department for Work and Pensions; Public Health Scotland; Scottish Government; Gateshead Public Health; Citizens Advice; Child Poverty Action Group and a senior legal academic. Professor Petra Meier, leader of the NIHR-funded SIPHER Consortium, has also agreed to join the Group to ensure alignment between this project and SIPHER's planned work on the health impacts of the economic shock associated with the COVID-19 pandemic. The SAG will advise on our knowledge mobilisation strategy, and on the detailed design and conduct of the study, and in particular of any modifications that are required in the light of changes in Universal Credit implementation and the wider social security policy context.

In developing the proposal, we built good working relationships with a number of organisations supporting claimants and other stakeholders through regular communication and formal and informal opportunities for engagement, drawing on existing partnerships in the North East of England, Liverpool and Scotland. During the study we will continue to seek input from people with lived experience of UC and from staff with working knowledge of the implementation of UC to:

- Inform the proposed RQs and the creation of policy scenarios for simulation modelling and economic evaluation
- Shape the logic model and research questions and review the values framework we will develop to inform public involvement and engagement (PIE).
- Provide timely insights about how any changes to UC policy introduced play out in practice.
- Facilitate, guide and support sampling and recruitment and suggest practical solutions to issues encountered by the team.
- Contribute to the development of research materials for WPS3, including Participant Information Sheets, consent forms, other documentation to improve readability.

- Inform the development of the ethics application and ensure the study is conducted according to ethically sound principles.
- Link with wider networks, advise on feasibility, sounding boards to test ideas
- Ensure a diverse range of views are sought, including members of groups adversely affected by health and social inequalities
- Host research activities, help to interpret findings and inform dissemination strategies
- Co-author publications and jointly present at conferences.

Our approach is informed by the SPHR strategy for public involvement and engagement <u>https://sphr.nihr.ac.uk/wp-content/uploads/2019/12/NIHR-SPHR-PIE-Strategy_V1.0.pdf</u>), Involve National Standards for Public Involvement (<u>https://www.invo.org.uk</u>) and evidence of what works in developing and maintaining effective public involvement. Using these resources and our own experience, we will support members of the public to contribute to the research through a range of activities to optimise the relevance, implementation and dissemination of research. These will include regular opportunities for public involvement and engagement (PIE), online and through PIE meetings in each study locality. The format and frequency of face-to-face meetings will be negotiated with participants, who will be reimbursed for their contribution, avoiding any potentially adverse effects on UC entitlement.

PROTOCOL CONTRIBUTORS

This protocol was developed by the study investigators.

UC claimants and staff from third sector organisations responsible for providing advice and support services were directly involved in developing the research proposal and plans for public involvement and engagement. We held a meeting with representatives of Citizen's Advice Gateshead, Liverpool City Council, One Parent Families Scotland, and the Your Voice Counts group to discuss the draft research plan and our proposals for public involvement and engagement. We also drew on our good working relationship with Universal Credit Essentials, an advice and education charity that uses social media platforms to engage with people claiming UC (and currently has 83,000 subscribers to its Facebook page).

We involved partners from Liverpool City Council and Citizens Advice Liverpool in shaping the research questions for Work Package 1 and identifying relevant UC claimant subgroups. Work Package 2 was co-developed with input from Citizens Advice Newcastle and Citizens Advice Liverpool. Colleagues in Citizens Advice had identified a need to understand the health and financial impacts of Universal Credit but lacked the capacity to analyse the data collected through their surveys. Neil Duffy, the research and campaigns officer for Citizens Advice Newcastle, is a collaborator on the grant and will play an active part in the interpretation and implementation of the findings from the workstream.

We involved partners from Newcastle Council welfare rights service, Citizens Advice Gateshead and Your Voice Counts, an advocacy organisation for people with learning disabilities in the design of Work Package 3, which also draws on embedded research undertaken in North East England in 2017 commissioned by Gateshead Public Health in response to elected concerns about the roll out of UC, and its potential impact in local communities. [11] These studies informed the development of a theatre production due to be performed and livestreamed on YouTube with a panel discussion in September 2020. Questions, comments and feedback from members of the public were used to inform the systems map and research design of this study.

KEY WORDS

Universal Credit, mental health and wellbeing, secondary data analysis, longitudinal qualitative research, dynamic microsimulation modelling, economic evaluation

STUDY FLOW CHART

See Appendix 9.3

STUDY PROTOCOL

Evaluation of the mental health impacts of Universal Credit: a mixed methods study

1 BACKGROUND

Universal Credit (UC) is transforming social security for working age people by combining six existing benefits and tax credits (known as legacy benefits) into a single monthly payment. UC is designed to improve work incentives for people on low incomes but has been criticised for causing hardship due to conditions related to eligibility, and the way that claims are managed and payments made. UC is being introduced gradually, with rollout due to be complete in 2024. [4] There are substantial differences in how UC and other recent social security reforms are being implemented in Scotland compared to England and Wales. Research to date has not provided a comprehensive picture of UC's impact on population health or health inequalities. Our proposed study will be the first to do so, by examining the impact of the introduction of UC on mental health and wellbeing, and how these effects are moderated by variation in implementation across Great Britain.

During the COVID19 pandemic, substantial but temporary changes in the way UC is administered have been made in response to the economic shock associated with the COVID-19 lockdown measures. Conditionality and some forms of debt recovery were suspended for three months and the standard cash allowance (the most a household could receive, before taking income and savings into account) was raised by £1000 per annum in April 2020 for one year. [1] A very large number of new claims were made and processed in the early months of the lockdown. Claims rose 9-fold, to 500,000 per week in early April, before returning to previous levels by July 2020. [2] A new cohort of UC recipients has been created whose composition is likely to differ significantly from the pre COVID-19 caseload (for example, they are less likely to have received benefits in the past and more likely to have savings).[3] As well as estimating the impact of UC on population mental health, we shall explore the experiences of these new recipients to gain insights into whether differences in health impacts might be expected.

In preparing our proposal we updated and extended the literature searches from our recently published study of the impact of UC on psychological distress [5] to include papers published in 2019-20. We searched six bibliographic databases (MEDLINE (number of hits=0), PubMed (5), Scopus (5), PsycInfo (0), Social Science Citation Index (8, EconLit (3)) using the terms ("universal credit" AND "mental health" OR "wellbeing" OR "well-being" OR depress* OR anxiety OR "psychiatric disorder*" OR "common mental disorder*" OR "psych* morbidity"). We also searched two preprint servers (Socarxiv (2), Medarxiv (1). We found 17 papers, but no new studies, other than our own, that dealt with the health impacts of UC.

Several reports from public bodies draw attention to possible health harms. Based on evidence from local authorities and charities, the Commons Public Accounts Committee has raised concerns about financial hardship associated with the five week wait for the first payment, compounded by delays in processing new claims. [6] The UN Special Rapporteur on extreme poverty and human rights highlighted difficulties faced by 'poorer and more vulnerable households' in negotiating the online application process, concluding that 'UC was harming many claimants' mental health, finances, and work prospects.' [7] Doctors' organisations have reported increased consultations in General Practices following the transition to UC. [8] Significant concerns have been raised about the impact of UC on rising child poverty in the UK. [9] Qualitative studies have reported 'widespread and deeply negative impacts on wellbeing.' [10] In our own research, [11, 12] claimants reported that the threat of

sanctions, delays in payment and financial insecurity associated with UC harmed their physical and mental health. There has been one quantitative study of health impacts to date, again by our team. [12] A comparison of changes in mental health among unemployed people in areas where UC had been implemented with areas where legacy benefits remained in place found a seven-percentage point increase in psychological distress in the former.

2 RATIONALE

Although evidence to date suggests mainly adverse effects, UC may improve health if it provides a higher or more dependable income for recipients than existing benefits, or if it supports paid work. Research conducted by the Department for Work and Pensions' (DWP) found that more intensive support for job-seeking under UC increased earnings [13] and helped unemployed claimants return to work sooner. [14] This may lead to beneficial effects on health although health outcomes were not measured. To date therefore, the evidence of health impacts is limited and relates to a period when UC has only been implemented for some groups of new claimants. The overall health and equity impacts may change markedly as legacy benefit recipients migrate to UC. We therefore propose a comprehensive mixed methods study that will investigate the impacts of UC as it proceeds to full implementation

3 THEORETICAL FRAMEWORK

We propose a mixed methods study with five closely linked work packages. We shall take a natural experimental approach to identify the effects of UC on mental health and wellbeing using two largescale population surveys (WP1). We shall supplement this by analysing novel sources of survey and linked data on people who seek advice in connection with UC claims (WP2). We shall conduct a qualitative longitudinal study to explore in depth the experiences of UC recipients, and how they change over time, and supplement this with interviews with people working in organisations that support UC claimants (WP3). We shall incorporate effect estimates from WP1 and the evidence from WP2 and 3 into a new microsimulation model to explore the implications of alternative implementation scenarios (WP4), and into a cost-consequence and cost-benefit analysis of UC (WP5). WP2-3 will also help us to refine assumptions and hypotheses underpinning the analyses in WP1, and WP5 will draw on the scenario modelling from WP4. By using this combination of methods and data sources, we aim to provide original evidence about the health impacts of UC and the mechanisms underpinning them, that can inform decisions about the design and implementation of social security policy.

UC began to be used for new claims in October 2013, with rollout for new unemployed claimants complete by December 2018. Existing claims for the legacy benefits and tax credits will now be transferred in a process of 'managed migration', beginning with a geographically limited pilot. How migration will be scaled up subsequently is not yet known, and plans may have to be modified following the pandemic, but the process had been expected to begin in November 2020 and to be complete by 2024. UC combines six existing benefits and tax credits for people who are unemployed or on a low income into a single monthly payment. It is intended to encourage an early return to work by incorporating support for job-seeking and removing disincentives associated with high marginal withdrawal rates under the legacy benefits.

UC may improve recipients' health via increased income and employment, but some features of its design and delivery may be harmful. The application of conditionality and sanctions, the five week wait for the first payment, the two child limit and benefit cap, and the inclusion of support for housing costs within a single monthly household-level payment made to one individual, have all attracted concern. Some households, such as working families living in rented accommodation, will have higher incomes from UC than they would receive from legacy benefits, but others, including people receiving disability benefits, self-employed people with low earnings, and some working lone parents who were formerly receiving tax credits, may lose income. [15] UC is a UK-wide system but in Scotland, under arrangements known as 'Scottish Choices,' claimants can opt for two-weekly payments, to have the housing element paid direct to their landlord, and/or have separate payments to each member of a couple. [16, 17]

The effects on health of the transition to UC are therefore likely be complex and geographically variable, with some households benefitting from improved living standards and greater financial security, but others facing an increase in hardship and insecurity. Effects may be direct, for example by increasing stress, or be mediated by changes in behaviours such as smoking or drinking. Children's health likewise will be affected directly by changes in household living standards, for example in relation to diet or warmth, but also by effects operating through parental stress and consequent changes in parenting and other behaviours.

As noted above, substantial but temporary changes in the way UC is administered have been made in response to the economic shock associated with the COVID-19 lockdown measures. As well as estimating the overall impact on UC on population mental health, we shall compare the experiences of existing and new recipients to gain insights into whether differences in health impacts might be expected.

4 RESEARCH QUESTION/AIM(S)

Our research questions are (1) what are the effects of UC on population health and health inequalities, how do they vary, geographically or between groups of claimants, and how do the effects change as rollout progresses? (Work packages 1-3); (2) what are the mechanisms that cause these effects? (WP2-3); (3) what can be done to mitigate harms or enhance positive effects of UC? (WP4); (4) what is the overall cost-consequence of UC and the cost-benefit of specific mitigating/enhancing measures? (WP5); (5) How might the changes to UC administration and caseload associated with COVID-19 moderate the relationship between UC and claimants' health (WP1,3).

4.1 Objectives

Our objectives are: (WP1): to measure the impacts on mental health and wellbeing among adults and children affected by UC, compared to a legacy-benefits comparator group; to explore how impacts are distributed and effects vary between England/Wales and Scotland, and the implications of the COVID-19 related changes to UC for the health of recipients. WP2: to identify features of the UC claim and payments process associated with health difficulties for claimants, and to explore inequalities within and between regions in the pattern of advice-seeking from Citizens Advice. WP3: to explore the ways in which the experience of claiming and managing UC affects claimants' health, and how experiences differ between England/Wales and Scotland. WP4: to use a new microsimulation model to investigate possible income, employment and health consequences of differing UC implementation scenarios, up

to ten years post-implementation. WP5: to measure the cost-consequence of UC, analyse its distributional consequences and conduct a cost-benefit analysis of moderating/mitigating measures implemented in Scotland or by specific Local Authorities.

4.2 Outcome

Our overall aim is to understand the impacts of the implementation of Universal Credit on mental health and wellbeing among people in low income households; whether and how the changes associated with the COVID19 pandemic have led to a different pattern of impacts; and what measures might be implemented in future to mitigate harms or enhance positive effects of UC?

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

We first provide a summary of the population, setting and outcomes for the study as a whole. We then set out each work package in more detail.

Study population_UC is for households headed by working age people who are not in paid employment, or who are working but on a low income. We will estimate its overall effect on the health and wellbeing of adults and children across Great Britain (GB), that is, England, Scotland, and Wales. We will also investigate the way effects vary across subpopulations defined by protected characteristics such as age, sex and disability, but also by factors that define benefit entitlement such as household type and employment status.

Setting Our study covers Great Britain. We shall also investigate differences in health impacts between Scotland and the rest of GB in WP1, WP4 and WP5, and use the qualitative interviews in WP3 to explore how Scottish Choices mediate these differences. In WP2 and 3 we shall explore regional differences in the pattern of advice seeking, to identify how UC interacts with local housing and labour markets and other contextual factors to influence claimants' experiences.

Outcome measures_Our primary focus is on mental health and wellbeing._Poor mental health is a major cause of illness and disability, costing the UK economy £100 billion a year, [18] with social security policy a crucial determinant. Mental health is an important dimension of overall health and wellbeing, that is sensitive to the effects of changes in employment or income, and an important mediator of physical health. Parental mental health is also an important mediator of the impact of poverty on child health. [19] In the survey analyses (WP1) we shall use standard measures of mental health and wellbeing, such as the Mental Component Summary (MCS) of the 12-item Short-Form Health Survey (SF-12) for adults, the Strengths and Difficulties Questionnaire (SDQ) for children, and the Office for National Statistics (ONS) ONS4 measure of wellbeing (life satisfaction, sense that life is worthwhile, happiness and anxiety). [20] Secondary outcomes include other mental and physical health measures available in the surveys. In WP2 we shall use the Warwick Edinburgh Mental Wellbeing Scale (WEMWBS). WP4 and 5 will use similar outcomes to WP1, and WP5 will also explore the costs and non-health consequences of implementing UC. In WP3 we shall explore other health outcomes identified as important by respondents.

Work package 1: Identifying the impact of UC on mental health of working age adults and their children using population surveys and routinely collected data for small areas

WP1 aims to measure the population impacts on self-assessed mental health and wellbeing among working age adults affected by UC and their dependent children (aged 0-15), compared to a legacy-

benefits comparator group. We will explore how impacts vary among subgroups of the recipient population and between recipients in England/Wales and Scotland, and investigate mechanisms (e.g. changes in income or employment) that mediate the effects on individuals (attachment 4). We will also explore the experiences of people who have claimed UC since the COVID-19 lockdown and their implications for mental health and wellbeing among this new cohort of recipients. We will refine our research questions and analysis strategies in the light of evidence from and discussion with WP2-5 and through public involvement and engagement.

Research Questions

1.1 What is the impact of UC rollout on mental health and wellbeing of working age adults and their dependent children?

1.2 How do these impacts vary geographically and between subgroups of the UC recipient population?

1.3 To what extent do income, employment and housing problems mediate any association between UC rollout and health outcomes?

1.4 What are the effects of UC on area-level mental health outcomes?

1.5 What is the experience of new UC claimants during the pandemic and lockdown; how effectively has UC buffered the effects of job loss; is there a geographical difference?

Study population and setting To investigate the impact of UC across the population of Great Britain we utilise three complementary datasets:

Understanding Society, or the UK Household Longitudinal Study (UKHLS), is a nationally representative, longitudinal survey based on a stratified clustered random sample of 40,000 households from the four UK countries that has collected rich data on job loss, wages and poverty, mental and physical health and a measure of children's mental health (SDQ) annually from 2009. From April 2020 participants have been asked to complete additional COVID-19 modules using web-based questionnaires to obtain detailed data on the changing impact of the pandemic on the welfare of individuals and families. Seven waves are currently planned, from April 2020 to January 2021.[21]

Secondly, we will utilise the Annual Population Survey (APS). The APS uses a stratified clustered random sample of households and is the largest survey of its kind in the UK, with a sample size of 320,000 people per year. The APS includes detailed information on health, wellbeing, employment and wages. Its large sample size is designed to permit analysis of variation between areas such as local authorities. [22]

Thirdly, we will utilise a longitudinal neighbourhood dataset for 42,000 small areas (Lower Super Output areas in England and Wales and Data Zones in Scotland), that we have developed through the NIHR North West Coast Applied Research Collaboration – Place-based Longitudinal Data Resource (https://pldr.org). This will include monthly measures indicating which population groups (e.g., new claimants, existing claimants, people with/ without children, people with disabilities), were affected by the phased rollout of UC in each neighbourhood in each time period derived from DWP data.[23] To identify any area-level mental health effects of UC, we will utilise a composite neighbourhood mental health measure – the Small Area Mental Health Index (SAMHI), available annually for the same small areas.

Study design We will compare recipients of UC and their children with recipients of legacy benefits and their children, using the phased rollout as a natural experiment. We will use information on the timing and other details of the migration process, coupled with information on geographical and sociodemographic characteristics of survey respondents to define exposed and unexposed groups. We will also investigate mediators of these effects including loss of income, employment and problems with housing payments.

Applying the approach from our previous study of the mental health effects of UC on single, unemployed claimants, [5] we will link our longitudinal neighbourhood dataset outlined above to each of the survey datasets (UKHLS, APS) to provide an indicator of whether UC was available in each respondent's area of residence at the date of interview. To address RQ1.1-1.3 we will compare health outcomes for new recipients of UC with outcomes for otherwise comparable legacy benefit recipients. The introduction of large changes to the welfare system such as UC may lead to health effects at the community level, as well as on individual claimants, for example, because loss of income, debt, homelessness and changes in employment have multiplier effects beyond the individuals initially affected. To investigate these combined effects (RQ1.4) we will use the PLDR and SAMHI datasets to investigate whether the introduction of UC in a neighbourhood was associated with a change in neighbourhood level mental health outcomes. To address RQ1.5, we will compare the experiences of new UC claimants in the COVID-19 waves of the UKHLS with those of existing benefit recipients and of people who remain in work (RQ1.5).

Outcome measures Our primary outcomes are the SF-12 for adults and the SDQ for children in the UKHLS analyses and self-rated health and wellbeing for the APS analyses. The primary outcome for RQ1.3 will be the Small Area Mental Health Index (SAMHI), a composite annual measure of population mental health for each Lower Super Output Area (LSOA) in England, that combines data from multiple sources including: anti-depressant prescribing rates, mental health related hospital attendances (A&E attendances and admitted patient care for alcohol misuse, drug misuse, self-harm and common mental disorders), prevalence of diagnosed depression in general practice from the Quality and Outcomes Framework and the suicide rate. We will extend this to include LSOAs in Wales and datazones in Scotland. Secondary outcomes include the General Health Questionnaire-12, GHQ) in the UKHLS, and the ONS4 measure of wellbeing.

Sample size Sample sizes for WP1 are fixed by the surveys and the number of units of analysis in the longitudinal neighbourhood dataset. The analysis of the UKHLS between 2009 and 2022 will involve approximately 280,000 observations on around 52,000 adults and 30,000 observations on 5,000 children. Our previous study [5] demonstrates this provides adequate precision for key outcomes. To identify the impact of UC, we are planning to conduct difference in difference analyses (see below), comparing members of households newly exposed to UC, as rollout proceeds, with households who are unlikely to be exposed. Focusing on child health outcomes, because the numbers available are smaller, from the Understanding Society survey from 2009-18 we will have 300 children in the intervention group and 3300 in the control group, providing 80% power to detect an 8% relative increase in SDQ scores. This is a markedly smaller effect than we found in our previous study of the impact of Universal Credit on adult mental health up until 2018, i.e., a 7 percentage point or 20% relative increase in the prevalence of psychological distress, so provides a conservative estimate of the power of the proposed study. Sample sizes available are much larger for adults as illustrated in our previous published analysis using these data. [5] Given the increasing size of the UC caseload, the larger sample sizes available in the APS, and the fact that both UKHLS and the APS have been

used successfully to evaluate the health impacts of changes in the benefits system [22a] and related policies [22b], we are confident that we will have sufficient power in both the child and adult health analyses.

The sample size in the UKHLS COVID-19 surveys is approximately 10,000, of whom c.4,000 report substantial (>5%) income losses, and around 300 reported new UC claims in the April survey wave. The number of new claims may be expected to increase in subsequent waves, although the number of recipients may fall as some claimants return to work. The APS collects self-assessed health and wellbeing data on approximately 180,000 working age people per year, so provides good power for England-Scotland comparisons and other subgroup analyses. We anticipate being able to use data collected up until the end of 2024. Our analysis of area level mental health effects will utilise annual data from our longitudinal neighbourhood dataset for 42,000 neighbourhoods from 2011 to 2022, i.e. 504,000 neighbourhood-years.

Data analysis To identify the effects of UC in the UKHLS and APS datasets we shall use methods similar to those we have used previously.[5] We will fit difference-in-difference (DiD) models, with terms for group and period to define respondents who are exposed or unexposed to UC, depending on their socio-demographic characteristics, location and date of interview, and a group by period interaction term to identify the effect of UC. We will add individual and area-level covariates to account for time-varying confounders and fit mixed-models to account for clustering of observations within households and areas. Sensitivity analyses will be conducted using alternative definitions of exposed and unexposed populations. [24-7] We will test the validity of the key identifying assumptions, such as common pre-intervention trends, and use additional (e.g. matching) methods if needed. We will also conduct falsification tests using placebo outcomes to test for specificity of effects.

For the SAMHI analyses we will used fixed-effect panel regression methods to investigate whether increases in UC in each LSOA are associated with changes in mental health problems, while controlling for time-varying confounders (e.g. local government expenditure). We will check the robustness of the results by using alternative ways of estimating effects, such as continuous DiD and synthetic control methods [28] to compare outcomes in areas where UC has been introduced to comparator areas not yet exposed.

To investigate the extent to which changes in income, employment status and hours, and financial housing difficulties (e.g. rent arears) mediate the effects of the introduction of UC on health outcomes, we will apply modern methods for causal mediation analysis whilst adjusting for time-varying confounding.[24] Subgroup analysis will investigate differences in health impacts between Scotland and the rest of GB, or between areas with differing labour market characteristics (e.g. job vacancy rate). By stratifying the analysis before, during and after the pandemic we will investigate whether moving onto UC had the same effect during these different time periods, when the policy and wider social context were very different.

Using the COVID-19 waves of the UKHLS, we shall compare mental wellbeing among new UC claimants, other respondents who have experienced income losses and existing UC claimants. These analyses will be primarily descriptive rather than designed to formally identify impacts.

Work package 2: Who seeks help with UC claims and why? Analysis of Citizen's Advice (CA) survey and linked health service data

WP2 will use a series of surveys and linked datasets with information on the characteristics of people seeking help in connection with UC claims. They include an England-wide survey of people seeking help from Citizens Advice (CA), a longitudinal survey of 2500 people who sought advice from CA in the North East of England, and a linked dataset derived from the Liverpool 'advice on prescription' service. WP2 will provide evidence on what types of people need extra support with the UC process, and the circumstances that lead to advice seeking. The results will feed into the microsimulation model in WP4 and economic analysis in WP5. They will also aid the development of future interventions to support claimants who find the process difficult.

Research Questions

2.1 What are the socio-demographic characteristics and health profiles of people needing advice on claiming UC in England? Are there regional differences?

2.2 What is the financial impact of the five-week delay in UC payment by demographic and health characteristics?

2.3 Is there a change to the health, multimorbidity profile, and health care utilisation of people before and after UC is introduced?

2.4 How has the COVID-19 pandemic changed the composition of people seeking advice for UC?

Study Population and Setting Our study population comprises adults who have contacted CA for assistance with claiming UC from 2016 onwards (currently data is available until June 2020). Sociodemographic and health data are collected by a survey administered to all individuals seeking advice in England. For in-person advice seeking the survey comprises a self-completion paper questionnaire that must be completed in order to receive advice. For individuals seeking advice by phone or through a web chat, the survey is administered verbally and the answers are filled in by the CA adviser. For a sub-sample of respondents from North East England a postal survey five weeks after the initial contact with CA was sent to all individuals who had made a UC claim to understand the characteristics of people who experience financial hardship.

We also have access to a unique linked dataset from an "advice on prescription" service introduced in Liverpool in 2014. This is a CA service to which GP practices refer people seeking or needing welfare support. CA Casebook data of people accessing the advice on prescription service in Liverpool has been linked with (1) primary care records, (2) secondary care records, (3) mental health services, and (4) community services data. Longitudinal data is available for people seeking advice for UC since 2014 and includes all contacts with health and social care services as well as socio-demographic and diagnostic data. Data will be available for people engaging with CA Liverpool from 2014, but linked data will span 2010 to 2023.

Study design To understand the socio-demographic and health profiles of people needing advice in connection with UC claims (RQ2.1) and how this has changed during the COVID-19 pandemic (RQ2.4) we will utilise the England wide survey data. To estimate the financial impact of the five-week delay in UC payments by health and demographic characteristics (RQ2.2) we will use of the follow-up to the CA survey from the North East of England. To understand changes to the health, multimorbidity profile, and health care utilisation of people before and after UC is introduced (RQ2.3) we will use the

linked data from Liverpool. Population level data available from NOMIS, the ONS labour market statistics portal (https://www.nomisweb.co.uk/), on the profile of each local authority will be used to compare advice seekers to the general population (RQ2.1, 2.3, 2.4). We will use these comparisons to determine the relative socioeconomic position of advice seekers compared to the average of the area where they live. We can then better understand who is seeking advice to develop future interventions or revise the claim procedure to reduce inequalities. This will also be used to inform WP4 to understand how and if the data available captures vulnerable populations.

Outcome Measures Our primary outcome is mental wellbeing measured by the WEMWBS. Secondary outcomes include limiting long term conditions, comorbidities and health care utilisation (RQ2.1, 2.2, 2.4). Financial insecurity (RQ2.2) will be measured by whether the respondent was unable to pay for utilities, required financial support from friends, family or a charitable institution, was unable to pay for food, or sold or pawned items for additional money. Change to mental health of people seeking advice in connection with claiming UC will be measured by anti-depressant prescriptions, health care utilisation, referrals to IAPT services, comorbidities.

Sample size The survey dataset contains information on approximately 280,000 people using CA services. The longitudinal survey contains information on 2500 people, with a response rate of 85%. The advice on prescription dataset contains information on approximately 5000 people each year since 2014.

Data Analysis For RQ2.1 descriptive analysis of the England-wide survey data will be used to summarise the health and socio-demographic characteristics of people seeking advice in applying for UC We will explore differences at the local authority level in key demographic and health characteristics of individuals seeking advice with claiming UC.

To address RQ2.2 we will use longitudinal data from North East England to identify the sociodemographic and health characteristics at baseline of people who are most and least likely to experience financial insecurity as a result of the five week delay until the first payment. Multivariable (logistic) regression analysis will be employed. Missing data will be explored using the Verbeek-Nijman test for sample attrition [29] and inverse probability weights used to address attrition.

For RQ2.3 we will apply longitudinal multivariable regression analysis to the linked data from Liverpool, similar to the methods utilised in WP1. We will explore the use of zero-inflated regression models if there is a large number of people that do not use health services.

To address RQ2.4, we will use the cross-sectional national data from March 2020 onwards to determine whether the socio-demographic and health profile of people seeking advice with claiming UC has changed by comparison with the pre COVID-19 data.

To explore the changing composition of advice seekers after COVID-19, non-parametric tests such as Wilcoxon-rank sum test will be performed on summary statistics from RQ2.1 and RQ2.4 to identify differences in the health and socio-demographic characteristics of advice seekers.

Work package 3 The experience of claiming UC: longitudinal qualitative research with claimants and staff

WP3 will examine how Universal Credit (UC) implementation affects claimants, their households and staff working with claimants. We will study the impact of COVID-19 on existing claimants and their family members, those who moved onto UC during the UK's lockdown period and those who have

subsequently become claimants due to the economic impact of the pandemic. Qualitative research is necessary in order to understand mechanisms linking the experience of benefit receipt with health, examine the differences between official policy and what is actually taking place. It enables taken-forgranted assumptions about UC to be examined from a range of perspectives. We will explore issues of health, wellbeing, debt, food security, fuel poverty, housing, employment, family life, social relationships, health and social care service use, and other related outcomes. Insights derived from our analysis of this qualitative data will inform WP1, 4 and 5, particularly in relation to mechanisms of effect, subgroup effects, and local variation in implementation.

Research questions

3.1 How is the experience of claiming, managing and migrating onto UC related to mental health and wellbeing, and other health outcomes identified as important by respondents?

3.2 How does the experience of receiving UC relate to changes in mental health, wellbeing, financial security, employment, family life, housing, service use and other related outcomes over time, and how does this vary between England and Scotland?

3.3 How have staff working with UC claimants from health, education, local government, third sector, and the Department for Work and Pensions experienced the roll out of UC, and how can their insights help understand its impact?

3.4 How have COVID-19 and related UC changes affected claimants' experiences of UC? Do the experiences of new claimants and existing claimants differ in ways that might affect health and wellbeing?

Study population and setting We will interview UC claimants and staff working to support them in two urban conurbations, Glasgow City Region (population 1.2 million) in Scotland and Tyne & Wear (population 1.1 million) in North East England. UC rollout has varied across the 13 local authority areas that make up these two conurbations (8 in Glasgow City Region and 5 in Tyne & Wear) e.g. Newcastle and Gateshead were part of the accelerated UC rollout in 2017 [30]. These differences allow us to recruit claimants who applied at different times and with varying periods of receipt. Both conurbations include areas of high socio-economic deprivation, high unemployment, child poverty, sickness, disability and premature mortality, and are ethnically diverse. By conducting fieldwork in both England and Scotland we will be able to explore differences in UC implementation between Scotland and England, such as alternative payment arrangements. [16, 17, 31]

Study design We will use longitudinal qualitative [32] and photo-elicitation [33] research methods to elicit rich and detailed data on claimants' experiences and enable us to understand the impact of policy changes from the perspectives of end users. Interviewing claimants twice will provide insights into change and continuity and enable us to distinguish the effects of living on UC, from the immediate impacts of the events leading to a claim.

Interview topic guides: Topic guides for the interviews with claimants will evolve as the fieldwork proceeds in line with good qualitative research practice. [34, 35] Adjustments will be made to take account of specific circumstances (e.g. employed/unemployed, COVID-19 related claim), as well as issues that emerge as important as the interviews are competed. Topic guides for follow-up interviews will be developed to take account of the changing circumstances of individual participants. Topic guides for interviews with staff will be developed in response to emerging findings from the initial

claimant interviews and adapted to the sector and organisation in which the staff member works. Interviews will be digitally recorded (with permission), deidentified and transcribed.

Photo-elicitation interviews: Asking participants to take photographs during their everyday lives provides insights that interviews sometimes fail to capture. This visual method can mitigate against the prioritisation of verbal knowledge and offer greater inclusion for those less articulate in an interview setting. [34] It enables participants to direct the conversation, potentially leading to insights unobtainable by the more traditional semi-structured researcher-led interviews. Photo-elicitation can therefore provide a powerful means of accessing participants' reflections on everyday experiences, giving unique insights into how changes to welfare play out in everyday lives. [33] It also allows our follow-up interviews to be participant-led, exploring issues unanticipated by interviewers, highlighting the fluid and changeable nature of everyday life. Between Waves 1 and 2, for a subsample of participants who feel comfortable with this method, we will provide digital cameras (or participants can choose to use their own mobile phones) and ask them to photograph aspects of their lives they consider relevant to the welfare system. The researcher will use photographs to elicit information and reflections during the Wave 2 interview.

Outcome measures The initial list of topics for the first wave of claimant interviews will include: circumstances leading to the claim, experiences of the claims process, online access, wait for benefit payments (and access to advance payments), managing the claim (e.g. claimant commitment, online journal), awareness and use of the Scottish Choices, impact on personal finances, employment, debt, housing, other household members, caring responsibilities, effects on health/disability, social relationships, family and social networks. The follow-up interviews will focus on how respondents have managed on UC, including their experience of conditionality and whether they have been subject to a sanction. [36]

Sample size

Claimant Interviews: We will recruit up to 80 UC claimants aged 18–65 (or state pension age), divided equally between Glasgow City Region and Tyne & Wear. The sample size reflects the need to capture a diversity of claimant characteristics, circumstances and experiences. We will aim for a sample of maximum variation, taking account of age, gender, ethnicity, household composition, education level, health, disability, employment and housing status. The sample will include people who have been on UC for some time, new claimants and those transferring to UC from legacy benefits; those who require assistance with their claim and ongoing management of UC and those who do not.

A number of recruitment strategies will be used, including recruiting via gatekeepers (building on the links developed through our previous research [11, 12] with a wide network of public, voluntary and community sector organisations as well as workplaces, trades unions) and also using social media and leaflets placed in community locations such as libraries. Study information leaflets (co-produced with our PIE team) will be provided and discussed with potential participants to ensure informed consent. Interviews will be conducted at a convenient time, place and via a suitable medium. Participants will be offered the option of a face-to-face or a remote interview (e.g. via zoom, whatsapp, skype or telephone).

Permission will be sought from participants to undertake a follow-up interview. The follow-up period will vary from 18-24 months. This is to allow exploration of how life course dynamics affect and are affected by UC, for example a move into or out of paid employment/ volunteering, birth of children,

changes in relationship status, housing circumstances, or other alterations in life circumstances that emerge from fieldwork. The exact number of follow-up interviews will be determined as fieldwork progresses, but it will be no fewer than 20 in each of Scotland and England. We have considerable experience in retention strategies, including contacting participants via phone, text, email, culturally appropriate greetings cards and participant newsletters. Follow-up interviews over periods of up to three years have been successfully undertaken in recent welfare benefit research [10, 37] indicating that retention is achievable.

Staff Interviews: Up to 15 staff from a range of organisations in each locality will be recruited via our extensive professional networks in each conurbation. We will interview staff supporting claimants through the process of claiming UC, as well as front line staff from the NHS, education, local government, housing and the voluntary and community sectors who support people claiming UC. These interviews will provide insights into the uptake, experiences and effectiveness of third sector and other support service providers in local areas, investigate the effects of the rollout of UC on staff working with claimants, identify variations in implementation and examine any impacts across the wider system which may lead to further indirect consequences for health (e.g. employment, demands for health and social care, or on police or criminal justice).

Data analysis Thematic content analysis will be conducted that incorporates methods of longitudinal qualitative data analysis. This will be achieved for each wave by reading and re-reading transcripts to develop a coding frame. Data will be coded line by line within NVIVO qualitative software to assist data management, retrieval and cross working between the two post-doctoral research associates. Photo-elicitation data will be coded and incorporated within the analysis of the interview material. A comparative analysis across time, locality and participant characteristics will be undertaken. As well as enabling identification of any differences of experience by locality, this will allow in-depth analysis of characteristics including (but not limited to) gender, age, employment status and will also allow us to compare the experiences of longer term (pre-COVID) and post-COVID claimants. For example, we know that there are significant differences in the characteristics of longer-term UC claimants in comparison to those claiming as a result of the pandemic, and this will be thoroughly explored in the analysis.

Themes that arise from, summarise and reflect the data – the topics, views, experiences and beliefs voiced by participants – will be identified. Constant comparison within and between datasets will be undertaken to identify the breadth and detail of each theme, to explore deviant cases, and to enhance validity and sensitivity. We will look for explanations that account for all the data collected, including any that do not 'fit' the patterns identified. Interviews with staff will be analysed thematically, affording opportunities for triangulation of the qualitative and quantitative findings. [38] We will liaise regularly with researchers from the other work packages to identify how the data from WP3 can augment our logic model (attachment 4), our quantitative analysis (WP1,2), our modelling (WP4 and 5) and the project's understanding of pathways linking UC to mental health.

WP4: A microsimulation model to estimate the impact of different implementations of Universal Credit on population health and health inequalities

In WP4 we shall create a new stochastic dynamic microsimulation model of the health impacts of UC building on an existing static microsimulation model of income and welfare policy (UKMOD, www.microsimulation.ac.uk/ukmod), as well as information about effects and mediators from other WPs. We shall use the model to simulate the health impacts of different UC implementation scenarios,

and to explore how these differ between subgroups of the working age population, defined by personal characteristics, household type or geography. Estimates of impact will be derived by making comparisons of different forms of UC implementation against three baseline scenarios: 1) a 'no intervention' scenario (i.e. if legacy benefits remained in place); 2) UC as implemented early in the COVID-19 pandemic; and 3) UC as implemented at the time of modelling. We will compare these baseline scenarios against plausible alternative implementation scenarios developed through engagement with DWP and Scottish Government stakeholders and informed by our public involvement activity.

Research questions

4.1 What are the anticipated income, employment and health consequences of differing UC implementation scenarios, up to ten years into the future?

4.2 How do the anticipated income, employment and health consequences of differing UC implementation scenarios, vary by age, sex, disability, household type, geography, socio-economic position, etc., and what are the implications for health inequalities?

4.3 What changes to UC would best increase the health benefits or mitigate against health harms?

Study population and setting In keeping with WP1-3, the geographical setting of our study is GB. We will investigate differences in health impacts across three nations (England, Scotland, Wales) and also by government office region. We will create a dynamic, synthetic population that reflects the GB population, using data from UKHLS, APS, census data, population projections, mortality estimates and the Family Resources Survey. To create our baseline population, we will inflate the UKHLS sample (ideally from wave 12, covering the time period 2020-2022) based on the cross-sectional probability weights provided by the study. We will compare the population characteristics to the other available datasets and modify the weights to enhance the representativeness of our population if necessary. Should data from UKHKLS wave 12 be unavailable, we will use earlier data (e.g. wave 10 has already been collected) for our baseline population. We will append additional variables of potential interest for our analyses (such as the ONS wellbeing measure) by mapping values for detailed population subgroups between UKHLS and other surveys containing those variables. We will derive transition probabilities for each variable included within our microsimulation by analysing longitudinal UKHLS data, supplemented by estimates from the published literature and relevant additional datasets (such as population projections for births and deaths from the ONS). To incorporate heterogeneity in our input population, we will randomly sample values for the population subgroup based on the mean and standard deviation of the observed data.

Study design Our model incorporates six components: a synthetic realistic population of Great Britain; estimates of the impacts of UC on health and economic outcomes (from WP1-3 and WP5); a structural labour supply model to estimate employment status; a tax-benefit model to estimate income (building on UKMOD); a population demographic model for changes in household composition (incorporating births, deaths and household changes) and estimates of income-health and employment status-health relationships. The COVID-19 pandemic has had major impacts on people's income, employment and receipt of social security benefits which we will incorporate within all aspects of our model, drawing on WP1-3.

Once we have developed our synthetic population, we will transition the population forward in one year increments, under different combinations of baseline and implementation scenarios, drawing on

inputs from other WPs and following recommended practice. [39] We anticipate creating three baseline scenarios which will be refined with input from policy and public stakeholders. Our first baseline scenario will be to consider what would have happened if legacy benefits had been continued. Our second will be the continued implementation of UC as it was implemented during the early phase of the COVID-19 pandemic response. The third scenario will be UC in its contemporary form, at the time modelling is conducted.

We will define several intervention scenarios for different forms of UC implementation, again informed by stakeholder engagement and PIE. Our preparatory work has suggested that these are likely to include: a) changing the generosity of income transfers, both overall and targeted at specific population subgroups; b) removing conditionality elements of UC; c) varying the frequency of payments (e.g. monthly vs 2-weekly); d) removing the delay to initial payment; and e) addressing nontake-up of UC benefits. In addition, we will intervene on our synthetic population to conduct policy swaps, such as applying 'Scottish Choices' to the population of England. However, a strength of simulation modelling is the flexibility to implement a variety of different intervention scenarios, so we anticipate the ultimate scenarios to be modelled could differ following changes to social security policy.

Microsimulation modelling is specifically designed to allow inequalities to be investigated. By modelling individual-level data, microsimulation allows any dimension of inequalities to be assessed for which data are available. We plan to assess how impacts vary according to socioeconomic position, gender, age, household type (e.g. lone parents), disability and government office region). We will also explore the feasibility of analysing impacts on ethnic inequalities.

Outcome measures A range of outcomes will be included within our dynamic microsimulation model. The primary outcome of interest will be mental health, assessed using the mental health subscale of the SF-12, and psychological distress ('caseness'), assessed by the GHQ-12. Other important outcomes which our model will report include self-rated health, mortality, employment status and household income.

Sample size We will use largescale survey and census data (key datasets described under WP1) to create our representative synthetic population with a sample size of 10% of the GB population, thereby large enough to study subpopulations of interest.

Data analysis

Income and employment models To calculate the effect of UC on household income, we will use UKMOD, an open-source, static microsimulation model to estimate changes in household income (after housing costs). UKMOD (and its parent model EUROMOD) [40] has been described in detail previously and subject to extensive validation. It calculates changes in household income by deterministically applying taxation and benefits rules to the Families and Resources Survey (FRS), a representative survey that collects detailed information on earnings, social security benefits and socio-demographic characteristics. To allow for changes to employment status and labour market income in response to UC-related income changes, we will create a Discrete Choice Random Utility Maximisation (DC-RUM) model drawing on an approach previously implemented with EUROMOD.[41, 42] This will allow us to incorporate the dynamic interplay between UC and changes to employment status and earned income which could modify the longer-term health impacts of the policy.

Health model We will draw on the estimates of the effect of UC on health outcomes from WP1 and 2, distinguishing direct income effects from indirect effects mediated via employment status. For the

direct effect of income, we will distinguish the effect of poverty (i.e. an income below the poverty threshold) from that of OECD equivalised log household income. We will incorporate parameters for any further direct effects of UC that are not mediated via income or employment status. We will use these parameters to estimate how an individual's health changes as a consequence of different forms of UC implementation.

Validation and robustness checks We will check how well our microsimulation model performs by estimating health outcomes for UKHLS participants in further waves (e.g. wave 13) not used to parameterise the model and compare predicted outcomes to other data sources (e.g. Scottish Health Survey) not used in our model. We will similarly apply our model to historical UC changes. To allow for uncertainty in parameter estimates and sampling, we will use Monte Carlo simulation (10,000 runs) to derive 95% credible intervals. We will also conduct deterministic sensitivity analysis by applying different post-COVID-19 economic recovery scenarios.

WP4b A geographically disaggregated microsimulation model for the mental health impacts of Universal Credit

In this additional workstream, we shall extend the study to provide more geographically informative and inclusive analyses of population mental health. The work described in WP4a will provide estimates of the impacts of Universal Credit on mental health over a ten-year time horizon, but will only yield produce estimates for England, Wales and Scotland. WP4b will develop the first microsimulation model of population mental health at a local authority level, with the aim of informing local decision-making.

Study population and setting

As for WP4, but disaggregated by local authority.

Research questions

4b.1 How do the anticipated income, employment and health consequences of differing UC implementation scenarios, vary between local authorities, and what are the implications for health inequalities?

4b.2 How do the effects of changes to UC designed increase the health benefits or mitigate against health harms vary between local authorities?

Study design

Producing simulation models at the local authority level is not straightforward. Available datasets, including those we are using in WP1, are either too small to allow local authority-level disaggregation, or can only provide imprecise estimates. Furthermore, studying the health impacts of welfare policies requires individual-level data to be structured into households (allowing derivation of benefit units). Internal migration across geographical areas must be explicitly considered when studying more refined geographical areas. In WP4b we will expand our microsimulation modelling by developing a realistic synthetic population that reflects the population characteristics of all local authorities across Great Britain (GB). This will involve analysing the Census (2011 and 2021/2), UK Household Longitudinal Study (also known as 'Understanding Society'), Annual Population Survey and population projections. Using these datasets in combination, we will expand the input data for the simulation using spatial microsimulation techniques and construct a synthetic population comprising individuals nested within households nested within local authorities. Analyses of longitudinal data will allow us to

incorporate geographic mobility, including the potential for poor mental health to reduce mobility and thereby reinforce experiences of persistent deprivation.

We will work with local authority policymakers to develop the model and maximise its relevance. We will prioritise work with policymakers in North West coastal, North East and Greater Manchester local authorities, drawing on our team's existing links in these areas. In addition to the work required to create a geographically disaggregated synthetic population, we will need to incorporate methodological developments throughout the modelling process. This will involve analyses of trends in mental health at local authority level (based on analyses of prescriptions and survey data planned within our existing grant), to align the model with real-world trends. We will also need to model the introduction of UC at different times across different local authorities, reflecting the varying policy implementation over time. Leveraging the recently launched web interface for UKMOD (www.microsimulation.ac.uk/ukmod/ukmod-explore), we will explore the possibility of creating a web interface for our dynamic model to allow local policymakers to appraise the implications of different UC options on mental health inequalities for their local area, and create new maps of vulnerabilities and inequalities across GB and its constituent nations. This tool will allow policymakers to explore the postential employment benefits of improving mental health, as well as localised impacts of UC itself.

WP5: Health Economic Analysis of the costs and consequences of UC and the cost-benefit of mitigating/enhancing measures

Work Package 5 (WP5) will build on previous work packages and perform a cost-consequence analysis of Universal Credit (UC) as a whole, as well as considering distributional impacts by health, income, and other individual and area-level characteristics. We will then perform cost-benefit analyses of the various localised actions that have been implemented to mitigate the negative impacts of implementing UC identified in earlier work. [5]

We will identify and provide estimates of the magnitude of the wide range of potential positive and negative consequences of introducing UC. We will provide, where appropriate, monetarised valuations of these effects and detail which sectors and government departments experience them. We will compare these to the costs of implementing the scheme. Costs and consequences will be compared to the baseline scenario of continued legacy benefits. In order to maximise transferability to the approaches used across government, we will produce an economic assessment following guidelines published in the Treasury Green Book [37].

This WP will comprise **three** linked pieces of empirical analysis, using information obtained in, and building on, previous work packages. We will use the estimated *ex-post* effects (WPs1, 2, and 3) to consider the short-term costs and consequences of moving to UC as well as the predicted *ex-ante* effects (WP4) to consider the longer-term costs and consequences.

Research questions

5.1 What are the overall costs and consequences of Universal Credit?

5.2 Are there distributional effects in the costs and consequences of Universal Credit? For example, are there regional/national differences? How did COVID-19 impact on the costs and consequences?

5.3 What are the best policy actions to take, in terms of cost and benefits, to mitigate any detrimental effects?

Study population and setting Consistent with earlier WPs, our study population is the working age population of GB and subgroups of this population for RQ5.2. This will allow us to investigate if the costs and consequences of UC have heterogeneously affected sub-populations and exacerbated existing inequalities, based on personal, household and area characteristics, including: geographical place of residence (e.g. regional effects); household composition (e.g. multi-generational, lone parents); area deprivation; gender; age; household income; ethnicity; employment status; pre-existing health status (measured by self-reported presence of long-term conditions); and new claimants registering since COVID-19.

For RQ5.1 and RQ5.2, we consider the rollout of UC across GB. For RQ5.3 the interventions are the strategies taken by the Scottish Government or by local authorities to mitigate against possible detrimental effects of UC, such as the Scottish Choices or the 'Ways to Wellness' scheme in Liverpool. Particular attention will be paid to the North East, Liverpool, and Scotland – where we can use the rich data available from WP2 and 3 and the links established by WP2, WP3 and our public involvement and engagement work to identify local strategies. We will liaise with LAs (and the Scottish Government) to obtain information on their strategies and also the rationale behind their policies. It is important to understand why local policy makers implemented certain policies, as we need to understand if this decision could bias any effect sizes we obtain (i.e. be endogenous). This will influence the choice of statistical/econometric analyses we utilise (see below).

Study design UC is a policy whose primary outcomes are related to income and work, rather than health; impacts on health, either positive or negative, are unintended or downstream consequences. An economic assessment must therefore consider the complete system effects of UC. We will use Cost Consequence Analysis (CCA) [44, 45] to address RQ2. CCA has been recommended for complex interventions that have multiple effects and for public health interventions which have an array of health and non-health benefits that are difficult to measure in a common unit. Unlike cost-effectiveness and cost-benefit analyses, CCA does not require the researcher to impose a perspective on the analysis, and instead allows decision makers to examine the impact of different perspectives. Consistent with WP4, we will consider a ten-year time horizon.

To address RQ2, we will employ similar programme evaluation methodology to WP1 to estimate the effects of UC on all of the outcomes in our estimation dataset (see below). This will ensure all our measures of costs and consequences are calculated from the same dataset covering the same time horizons.

To address RQ5.3, we will employ a cost-benefit analysis (CBA) whereby all outcomes are translated into monetary values. The perspective here will be that of the decision makers in the Scottish Government or local authorities who are implementing the policies.

RQ5.1 and RQ5.2 follow on from WPs1-4. The short-term health effects will be guided by WP1, the subgroups to consider will be guided by WPs1-3, and the longer-term health effects guided by WP4. The consequences we will consider will be guided by discussions with decision makers, but also respondents in WP3 as well as PIE. The choice of localised mitigating strategies to examine in RQ5.3 will be influenced by WP2 and WP3 and will use their well-established links.

For RQ5.1 and RQ5.2, the treatment and comparator groups will be identified by the timing of the rollout of UC and will be the same as identified in WP1. For RQ5.3, the treatment group(s) will be local areas who have implemented localised mitigation strategies (e.g., Local Welfare Assistance Schemes

or Scottish Choices). The comparator areas will be drawn from the rest of GB. We will consider two types of comparator areas: (1) those who have progressed to UC but have no formal mitigation strategies; and (2) those who have not progressed to UC.

We will further consider time-lags between the implementation of UC and any effects this may have. We will not assume instantaneous effects and will examine whether there is divergence over time that would be consistent with an emerging, lagged effect. In line with recommendations, discount rates will be applied (see below) with a ten-year time horizon (WP4).

Outcome measures

Measures of cost For RQ5.1 & RQ5.2, we will liaise with our project partners in DWP and SG to get detailed information on the costs of implementing UC (including fixed-, variable-, and operating costs) as well as costs associated with running the existing six separate benefits. For RQ5.3, we will liaise with LAs and the Scottish government to obtain information on the costs of implementing the localised mitigating strategies. We will adopt the perspective of the local decision maker for RQ5.3 and the societal perspective in RQs 5.1 and 5.2.

Measures of consequences We will consider consequences in a holistic way, guided by the Treasury Green Book [43] and consultations with stakeholders. They will include, but not be limited to, health and wellbeing; income (at both individual and household level); employment opportunities; economic productivity (i.e., Gross Value Added; GVA); and use of health and care services. Following discussions with our PIE Group, we will also look at the amount of voluntary work provided (in hours per week) to help support claimants.

Income, employment opportunities, and economic productivity can be translated into monetary values using Treasury Green Book methods. Heath and care utilisation can also be assigned a monetary value by applying NHS Reference Costs and the PSSRU unit costs. Health and wellbeing outcomes can be monetarised if appropriate. These can include calculating healthy life expectancies and disability free life years. [46, 47]

The initial time horizon for the accrual of costs and consequences will be ten years (consistent with WP4). However, we will consider alternative time-horizons informed by discussions with stakeholder, PIE, and WPs1-4. Discount rates of 3.5% will be used, as per guidelines. [43, 48]

Data on economic outcomes (e.g. income, employment opportunities, and economic productivity) will be obtained from NOMIS. Data on health care utilisation will be obtained from NHS Digital, Public Health England, and the Information Services Division of Public Health Scotland. Health and wellbeing data will be guided by WP1 and will include UKHLS and the APS. We will utilise the data described in detail in WP2. We will further work with WP4 to consider longer-term CCA analysis by utilising the estimates from their modelling exercises.

Sample size For RQ5.1 and RQ5.2, see WP1. For RQ5.3, both APS and UKHLS are large enough such that respondents within local areas are representative of that area.

Data analysis CCA, distributional CCA, and CBA will be conducted following well-established guidelines. [43, 46] Missing data will be imputed. Subgroup analysis (distributional CCA) will be conducted on samples large enough to identify any effects. In line with recommendations, uncertainty will be incorporated using a combination of scenario-based deterministic sensitivity analyses, threshold analyses and/or probabilistic sensitivity analyses. [42]

Parameter estimates for the short-term health effects of UC will be obtained from WP1. For parameter estimates for the consequences, we will utilise policy-evaluation methodologies, such as DiD. However, this is not always the most appropriate methodology to use, particularly if there is evidence that the exposed and comparator groups were not suitably similar – or had similar trajectories in outcomes – prior to the implementation of UC. These can be formally tested (similarity of area characteristics and parallel trends), and if there is evidence of differences, we will consider alternatives, such as lagged dependent variables and synthetic control methods. Co-WP lead Sutton has extensive experience of different policy evaluation methods with controlled pre-post designs [49, 50] All parameter estimates will include 95% confidence (or, where appropriate, credible) Intervals, and where appropriate be calculated by applying bootstrapping techniques

Assessment of efficacy/effectiveness For CCA we will avoid making a summary assessment of effectiveness and instead enable decision makers to form an overall judgement based on the relative weights they apply to the different consequences. For the localised CBA analyses, we will judge effectiveness using a range of estimates of the societal values of health and other non-monetary outcomes.

6 ETHICAL AND REGULATORY CONSIDERATIONS

6.1 Assessment and management of risk

The only part of our study that involves primary data gathering is the qualitative study. As summarised above, participant information sheets will be co-produced with our PIE team and discussed with potential participants to ensure informed consent. Interviews will be conducted at a convenient time, place and via a suitable medium. Participants will be offered the option of a face-to-face or remote interview (via zoom, whatsapp, skype or telephone). Face-to-face interviews will take place at a time and preferred location including participants' homes, community venues (e.g. library, community centre, workplace, childcare centre) with reimbursement for travel incurred. During fieldwork, researchers will fully adhere to the MRC/CSO Social and Public Health Sciences Unit's lone-worker safety policy, as set out in the Unit's Standard Operating Procedure (SOP-RMPS-013) and guidance GUI-RMPS-013 (copies available on request). Prior to interview, call-in and post-interview call-out procedures between the researcher and staff member or security service will enable the researcher's whereabouts to be known at all times.

We will be sensitive to any issues that arise during interviews and refer participants to appropriate help lines or support agencies if necessary. Researchers will be given mental health first aid training, to ensure they have the tools to recognise mental health issues that might require professional support. Participants (with their consent) will be kept informed of study progress and emerging findings via mail outs or email. Throughout the period of data collection we will work within COVID-19 restrictions, ensuring complete adherence to government guidelines and with safety the priority.

We will develop a risk register according to MRC/CSO Social and Public Health Sciences Unit Standard Operating Procedures (SOP-RMPS-011 and GUI-RMPS-011 – copies available on request) before primary data gathering or secondary data acquisition begins. These will be added to the protocol within one month of study commencement and before data gathering begins. The risk register will be continually updated and reviewed at each study team, study advisory group and study steering committee meeting.

6.2 Research Ethics Committee (REC) and other Regulatory review & reports

The University of Glasgow will be the study sponsor. We will seek ethical approval for the qualitative study from the MVLS Research Ethics Committee at the University of Glasgow. We will ask our public representatives and plain English-trained information specialists in the Population Health Research Facility at the SPHSU to review all letters and information sheets used to recruit qualitative research participants to ensure they are clear and accessible.

6.3 Peer review

An outline and a full proposal for the study were reviewed by the NIHR Public Health Research Programme Funding Committee. Independent peer review was also sought to inform the Committee's decision.

This protocol has been reviewed by the research governance lead for the College of Medicine, Veterinary and Life Sciences at the University of Glasgow.

6.4 Patient & Public Involvement

In preparing the research proposal we consulted extensively with organisations representing and providing support for UC claimants. During the study we will build on these relationships to ensure that there is strong public engagement. We describe in detail how members of the public have been involved in developing the proposal and how they will be involved in the conduct of the study on pp. viviii above. Here we explain the principles underlying our approach.

We avoid use of the term 'patient', noting a tendency to "assume commonality between patients and the public, rather than recognising their distinctions" [53] We adapt the INVOLVE definition of 'public' to include current or former UC claimants, and users and staff of advice and support services that help UC claimants, including those provided by health and social care, local government and third sector organisations. Our preferred term for engaging with these groups is Public Involvement and Engagement (PIE).

We will manage and co-ordinate public engagement activities through a named PIE lead (Dr Mandy Cheetham (MC)). She will be supported by a PIE manager based in the NIHR North East and North Cumbria applied research collaboration, who will offer independent advice, monitor progress and offer constructive feedback. MC will co-ordinate PIE activities and facilitate appropriate support for PIE members of the research team, who will be offered library access, training and development, mentoring, opportunities for co-authorship of publications and attendance at conferences, seminars and wider dissemination events.

We will follow the NIHR guidance on payments for public contributors [54]. On the basis of discussions with DWP we propose the following approach. We will encourage participants who are UC claimants to seek early advice about how their potential involvement and engagement in this research study, and any payments received, might affect their UC claim. We will ask UC claimants to do this prior to agreeing to participate and to follow advice from specialist welfare rights advisers and Job Centre work coaches who will be able to tailor advice to claimants' specific circumstances. Where UC claimants are also representatives of our PIE partners, we will make payments to the partner organisation, thus avoiding any impact on entitlement to benefits. We will advise UC claimants that they will be offered payment for the contribution they make to PIE activities but are not obliged to accept payment and can choose instead to donate the payment to a registered charity of their choice if

they prefer. Our approach will be negotiated with public involvement leads and explained clearly in written information provided. We will involve our PIE partners in producing this information.

We will reimburse all reasonable expenses associated with involvement in PIE activities such as the costs of participating remotely or travelling to a meeting incurred (e.g., standard class rail travel, internet, telephone, IT access, childcare, interpreting, indemnity insurance and DBS checks). Transparent arrangements for processing expenses claims will be established. Participants will be asked to complete a claim form for expenses and return it with original receipts/travel tickets as proof of payment. When face to face meetings become possible (in line with future government guidance on COVID 19), we will arrange travel in advance to help reduce costs and encourage involvement of people on low income.

We will capture, evaluate and report the impact of public involvement and engagement activities, using the Public Involvement Impact Assessment Framework. [55] Each WP will maintain an impact log [56] to capture their public involvement and engagement activities and outcomes in a consistent way. Logs will use standard headings such as date, attendees, discussion, impact, with the final format decided through discussion with public members of the research team. We will use the GRIPP2 short form [57] to report PIE activities. This includes a description of the aims, methods used, results, including both positive and negative outcomes, discussion of how PIE influenced the study and critical reflections on what went well and what can be learnt from our experiences.

6.5 Protocol compliance

Compliance with the protocol will be monitored by the Study Steering Committee (SSC). Any revisions required to the protocol will be submitted to the SSC for approval, before being incorporated in a new version of the protocol that will be submitted to the funder.

6.6 Data protection and patient confidentiality

We will develop a data management plan according to MRC/CSO Social and Public Health Sciences Unit Standard Operating Procedures before primary data gathering or secondary data acquisition begins. This will be curated online at <u>www.dmponline</u>.dcc.ac.uk and a copy will be added to the protocol within one month of study commencement and before data gathering begins. Key considerations for data management are summarised below.

Work packages 1,2, 4 and 5 will use deidentified data. Data for WP2 is available via the Citizen's Advice data portal (https://public.tableau.com/profile/citizensadvice#!/). We will obtain Secure Access approvals for UKHLS and APS datasets for 2019 onwards under our existing special licence arrangements, updating the licences and User Accreditation as required. The datasets from the Liverpool 'advice on prescription service' are all pseudonymised and linked by NHS Digital's Data Services for Commissioners Regional Office (DSCRO) and only then shared with Liverpool 'advice on prescription service' are all pseudonymised from the Liverpool 'advice on prescription service' and university of Liverpool researchers. The datasets from the Liverpool 'advice on prescription service' are all pseudonymised and linked by NHS Digital's Data Services for Commissioners Regional Office (DSCRO) and only then shared with Liverpool 'advice on prescription service' are all pseudonymised and linked by NHS Digital's Data Services for Commissioners Regional Office (DSCRO) and only then shared with Liverpool CCG and with authorised University of Liverpool researchers.

For work package 3, interviews will be digitally recorded with permission. Interviews will be transcribed by a transcription company approved by Glasgow university and fully versed in confidentiality processes. Transcriptions will be checked by the research interviewer. Names and other identifying information will be removed in transcripts used by the research team for analysis.

Recordings (original data) will be securely stored in password protected files accessible only to the small number of individuals working on WP3. Pseudonyms will be used for participants in all subsequent materials including publications. The names and contact details of study participants who have agreed to be contacted for follow-up will be stored securely and kept on a separate drive from research data. Research data (transcripts and deidentified participants information) will be securely stored and accessible only to the immediate work package 3 research team. Access to participants' personal data will be controlled using the Data Privacy Access Log (DPAL). Data sharing will be overseen and approved by the SPHSU Data Access Committee, in line with the Unit's Standard Operating Procedures on data management. Qualitative data will be transferred between collaborating institutions via SPHSU's secure cloud system. All data will be encrypted and password protected prior to transfer. Encryption will be conducted using 7-zip and AES-256bit encryption. Data will be securely stored for 10 years after the completion of the research project. The PI will be the data custodian.

Work package 4 will create a dynamic microsimulation model with the underlying source code made freely available (e.g. on github) for reuse by other researchers and policymakers. Source datasets (such as the UK Household Longitudinal Study) are already available for researchers through the UK Data Archive and any new datasets which we create (such as a dataset of a synthetic population) will be similarly made freely available online. The availability of the model, underpinning data and access arrangements will be advertised through publications, reports and other outputs from the project which will be accessible via the project website and existing sites, including UKMOD.

6.7 Indemnity

The study is sponsored by the University of Glasgow. The University holds insurance providing cover for the design and conduct of the research.

6.8 Access to the final study dataset

Work package leads will have full access to the datasets used in their respective work packages. Data will only be shared between work packages in a deidentified form, where licence arrangements allow, and where sharing is required to further the aims of the study (for example where data from work package 1 is needed as an input to the models used in work packages 4 and 5).

7 DISSEMINATION POLICY

7.1 Dissemination policy

A final report of the study will be published in the NIHR's Journal Library, in line with NIHR's requirements https://www.nihr.ac.uk/documents/nihr-research-outputs-andfor publication and notification: publications-guidance/12250#Notifying_NIHR_of_upcoming_research_outputs. We anticipate high interest in the outcomes of our research across a number of sectors. Potential research beneficiaries include service users - and the wider public, welfare advice services, DWP, public health and primary care practitioners, voluntary sector staff, service commissioners and academics. We will use our extensive networks (e.g., through the NIHR School of Public Health Research, the NIHR Public Health Policy Research Unit, the NIHR Applied Research Collaborations and the UKPRP SIPHER consortium) as well as the networks of our SAG members to facilitate dissemination to research participants, practitioners and policy-makers. Our ambition is to ensure that the opportunities to improve UC and the wider welfare system to improve health and reduce inequalities are adopted across all relevant policy and practice arenas.

Our impact strategy will be refined with our SAG and PIE groups, but early engagement with diverse users and relevant evidence on how to enhance knowledge mobilisation within complex policymaking environments, [51] have informed our initial plans. Specific impact-focused activities will include: (1) Coproduction of non-academic outputs for national and local government actors, provider organisations and advocacy groups e.g. text and video narrative summaries; 'policy briefings'; infographics; research digests; (2) Photo/text exhibition for a national public engagement tour of libraries, community centres, museums, galleries; (3) Targeted, interactive work-in-progress and policy briefing sessions for varied policy and practice audiences; (4) Stakeholder workshops and learning events for key interest groups; (4) Joint research meetings involving contributions from academics, policy and practice and public; (5) A purpose-built website to: disseminate results via policy briefs, blogs and infographics; act as a 'one-stop-shop' for our partners as well as for a wider set of stakeholders and the public; (6) The website will also host 'open source' versions of the WP4 policy models to enable government policy analysts to use them to inform future decision-making and for other researchers to apply our methodology into other areas; (7) Public engagement sessions via science festivals and various university initiatives e.g. Pint of Science, Café Scientifique; (8) Social media and traditional media press releases of key results.

We will present at relevant national and international academic events (such as the annual meetings of the Society for Social Medicine, and the European Public Health Association) and policy/practice conferences (such as the Public Health England Annual Conference, and the Local Government Association Annual Conference). We will publish peer-reviewed open access journal articles including a protocol paper and two findings papers per WP. Target journals include British Medical Journal, Lancet Public Health, Journal of Epidemiology and Community Health, Social Science and Medicine, Sociology of Health and Illness, Journal of Social Policy, and European Journal of Public Health. All statistical code will be made freely available, when the related analyses are published. The WP4 microsimulation model will be made publicly available for researchers and policymakers to reuse at the end of the study.

7.2 Authorship eligibility guidelines

All of the investigators and research associates working on the study will be co-authors of the final report. Authorship of individual papers will depend on specific contributions, as defined by the ICMJE, or by other criteria, such as CReditT (<u>https://www.elsevier.com/authors/policies-and-guidelines/credit-author-statement</u>) where required by the journal to which the paper is submitted.

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9. APPENDICES

9.1 Study Steering Committee

Professor	Mark	Petticrew	Professor of Public Health Evaluation	Room PHES, Room 243, LSHTM, 15-17 Tavistock Place, London WC1H 9SH United Kingdom	mark.petticrew@lshtm.ac.uk
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Professor	Peter	Craig	Professor of Public Health Evaluation	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, Berkeley Square, 99 Berkeley Street, Glasgow G3 7HR	peter.craig@glasgow.ac.uk

Professor	Clare	Bambra	Professor of Public Health	Population Health Sciences Institute, Faculty of Medical Sciences, Newcastle University, Sir James Spence Building, Royal Victoria Infirmary, Newcastle upon Tyne NE1 4LP	clare.bambra@newcastle.ac.uk
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9.2 Study flow chart

NIHR 131709 Attachment 3 Study flow diagram: start date, 01/05/2021; end date, 30/08/2025																																			
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9.3 Data management plan

To be added

9.4 Risk register

To be added

9.5 Fieldwork documents

Consent forms and participant information sheets for Work Package 3 will be appended before fieldwork begins.