HWFinEL

Healthier Wealthier Families in East London (HWFinEL): evaluating and extending health and wellbeing benefits of universal co-located money advice for parents of newborns

Version	2.0
Date	27/05/2025
Sponsor	University College London (UCL)
Comprehensive Clinical Trials Unit Trial Adoption Group #	N/A CCTU/2023/464
Sponsor R&D ID #	160921
Trial registration #	ClinicalTrials.Gov [NCT06871137]
REC #	TBC
IRAS #	333125

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General information

This document was constructed using the Comprehensive Clinical Trials Unit (CCTU) at UCL Protocol template Version 7. It describes the HWFinEL trial, sponsored by UCL and co-ordinated by CCTU.

It provides information about procedures for entering participants into the trial, and provides sufficient detail to enable: an understanding of the background, rationale, objectives, trial population, intervention, methods, statistical analyses, cost-effectiveness analyses, ethical considerations, dissemination plans and administration of the trial; replication of key aspects of trial methods and conduct; and appraisal of the trial's scientific and ethical rigour from the time of ethics approval through to dissemination of the results. The protocol should not be used as an aide-memoire or guide for the treatment of other patients. Every care has been taken in drafting this protocol, but corrections or amendments may be necessary. These will be circulated to registered investigators in the trial. Sites entering participants for the first time should confirm they have the correct version through a member of the trial team at CCTU.

CCTU supports the commitment that its trials adhere to the SPIRIT guidelines. As such, the protocol template is based on an adaptation of the Medical Research Council CTU protocol template and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement for protocols of clinical trials[1]. The SPIRIT Statement Explanation and Elaboration document[2] can be referred to, or a member of CCTU Protocol Review Committee can be contacted for further detail about specific items.

Sponsor

University College London (UCL) is the trial sponsor and has delegated responsibility for the overall management of the HWFinEL trial to CCTU. Queries relating to UCL sponsorship of this trial should be addressed to the CCTU Director, CCTU at UCL, Institute of Clinical Trials & Methodology, 90 High Holborn 2nd Floor, London, WC1V 6LJ or via the Trial Team.

Funding

National Institute for Health and Care Research (NIHR), Public Health Research (PHR) Programme, grant number NIHR158551.

Trial Registration

This trial has been registered with the ClinicalTrials.gov Register, where it is identified as NCT06871137.

Trial Administration

Please direct all queries to the HWFinEL Trial Manager at UCL CCTU in the first instance; clinical queries will be passed to the Chief Investigator by the Trial Manager.

Coordinating Site:
Comprehensive Clinical Trials Unit at UCL (UCL CCTU)
Institute of Clinical Trials & Methodology
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Structured trial summary

Acronym or short title	HWFinEL
Scientific Title	Healthier Wealthier Families in East London: evaluating and extending health and wellbeing benefits of universal co-located money advice for parents of newborns
CCTU Trial Adoption Group #	CCTU/2023/431
Sponsor R&D ID #	160921
REC #	TBC
IRAS #	333125
Primary Registry and Trial Identifying Number	ClinicalTrials.gov Identifier: NCT06871137
Date of Registration in Primary Registry	10/03/2025
Source of Monetary or Material Support	National Institute for Health and Care Research (NIHR), Public Health Research (PHR) Programme, grant number NIHR158551
Sponsor	University College London with sponsor responsibilities delegated to CCTU.
Contact for Public Queries	ctu.enquiries@ucl.ac.uk
Contact for Scientific Queries	Professor Claire Cameron Professor of Social Pedagogy at UCL Thomas Coram Research Unit, Room 202, 55-59 Gordon Square, London WC1H 0AA Email: c.cameron@ucl.ac.uk
Countries of Recruitment	England
Health Condition(s) or Problem(s) Studied	Financial wellbeing and mental health in parents of newborns living in areas of high deprivation
Intervention(s)	Participants will be individually randomly allocated with a 1:1 ratio to receive either one of the following arms: **Arm A:** Welfare Benefits Advice (WBA) co-located with routine health appointments. **Arm B**: Standard WBA services available within the London Borough of Tower Hamlets (LBTH).
Key Inclusion and Exclusion Criteria	**Inclusion criteria**: • Parents aged 16 years or over.* • Parents with a live baby/babies less than three months old who are registered with the health visitor service in LBTH, at the point of consent, who respond Yes to a screening question asking if they wish to receive advice about money.** • Able to provide informed consent. • Able and willing to complete questionnaires. **Only one parent will be recruited. If one parent is under the age of 16, they will not be eligible.*

	***If multiple children, at least one child must be <3 months old.* **Exclusion criteria**: • Parents with: ○ any known safeguarding concern. ○ maternal or paternal diagnosis of learning difficulty that affects the capacity to consent. ○ a baby/babies who have significant medical complications (e.g., inpatient on a neonatal unit).
Study Type	Interventional (randomised controlled, open label) trial with an internal pilot • Blinding ○ Analyses will be conducted by suitably qualified and experienced statisticians according to a detailed prespecified statistical analysis plan ○ Participants will not be blinded ○ WBAs, Health Visitors involved in service delivery will not be blinded ○ Researchers conducting the process evaluation will not be blinded • Randomisation ○ Individual participant randomisation using minimisation factors
Study setting	Primary care: New parents at Children's and Families Centres (CFCs) attending Health Visiting (HV) appointments for the baby's 6-8 week health check.
Date of First Enrolment	March 2025
Target Sample Size	1153
Trial Duration	3 years
Primary Outcome(s)	Difference in depression (PHQ-8) scores at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values and adjusted for stratification variables (if any). The outcome will be examined to ensure that it meets the assumptions for regression analyses and transformed, if necessary, to an appropriate scale so that the resultant distribution approaches normality.
Key Secondary Outcomes	**Financial gain** Difference in financial income at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values and adjusted for stratification variables (if any). The outcome will be examined to ensure that it meets the assumptions for regression analyses and transformed, if necessary, to an appropriate scale so that the resultant distribution approaches normality. **Anxiety** Difference in GAD-7 scores at 6 months' follow-up in

	the intervention arm compared with the control arm accounting for baseline values. **Quality of life** Difference in SWEMWBS scores at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values. **Quality of life (economic evaluation measure)** Difference in EQ-5D-5L scores at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values.
Other Work Packages (WP)	Process Evaluation to explore service uptake and qualitative experiences of the service (embedded within WP1). Economic Evaluation of inequality impacts (WP2). Service Design for Marginalised Mothers (WP3) Knowledge Exchange and Policy Impact (WP4)

Roles and responsibilities

These membership lists are correct at the time of writing; please see terms of reference documentation in the TMF for current lists.

Protocol contributors

Name	Affiliation	Role
Claire Cameron	UCL Social Research Institute	Chief Investigator
Richard Cookson	University of York	Co-applicant & Oversight Health Economist
Catherine Harris	UCL	Senior Research Fellow
Elizabeth Cecil	UCL	Research Fellow
Michelle Heys	UCL	Co-applicant & Professor Global Child Health
Shainur Premji	University of York	Co-applicant & Health Economist
Aase Villadsen	UCL	Co-applicant & Senior Research Fellow
Nazma Begum-Ali	UCL CCTU	Clinical Project Manager
Nicola Harris	UCL CCTU	Clinical Project Manager
Rafael Gafoor	UCL CCTU	Co-applicant & Senior Statistician
Georgia McRedmond	UCL CCTU	Trial Statistician
Jo Hornby	UCL CCTU	Trial Manager
Rahi Jahan	UCL CCTU	Trial Manager
Anvi Wadke	UCL CCTU	Clinical Project Manager

Role of trial sponsor and funders

Name	Affiliation	Role
UCL Comprehensive Clinical Trial Unit (CCTU)	UCL	UCL as the trial sponsor has delegated all sponsor duties to UCL CCTU. CCTU will be involved in trial design; collection, management, analysis, and interpretation of data; writing of the report
National Institute for Health and Care Research (NIHR) Public Health Research (PHR) Programme	NIHR	Funder

Trial Team

Name	Affiliation	Role and responsibilities
Claire Cameron	UCL Social Research Institute	Chief Investigator, primarily responsible for the concept, design and the conduct of the trial.
Michelle Heys	UCL	Co-Applicant
Elizabeth Cecil	UCL	Research Fellow - Trial and Process Evaluation Coordinator
Catherine Harris	UCL	Senior Research Fellow - Trial and Process Evaluation Coordinator

Rafael Gafoor	UCL CCTU	Oversight Statistician
Jo Hornby	UCL CCTU	Trial Manager
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Trial Management Group

Name	Affiliation	Role and responsibilities
Claire Cameron	UCL Social Research Institute	Chief Investigator Overall responsibility for the conduct of the trial, ensuring deliverables and expectations of the oversight group are met
Catherine Harris	UCL	Senior Research Fellow Provide expertise to trial design and trial deliverables
Elizabeth Cecil	UCL	Research Fellow Provide expertise to trial design and trial deliverables
Michelle Heys	UCL	Professor of Global Child Health Provide expertise to trial design and trial deliverables
Pratima Singh	Queen Mary University London	Patient Participation, Involvement and Engagement Lead
Richard Cookson	University of York	Oversight Health Economist Provide expertise to trial design and trial deliverables
Shainur Premji	University of York	Health Economist Provide expertise to trial design and trial deliverables
Jo Hornby	UCL CCTU	Trial Manager & Trial Management Group Facilitator Manage the day-to-day running of the trial according to the protocol and regulations
Anvi Wadke	UCL CCTU	Clinical Project Manager Provide oversight of governance, contracting budget management and oversight of trial delivery
Rafael Gafoor	UCL CCTU	Oversight Statistician Oversight statistician providing statistical oversight
Simon Twite	London Borough of Tower Hamlets	Public Health Lead Provide expertise to trial design and trial deliverables
Aase Villadsen	UCL	Senior Research Fellow Provide expertise to trial design and trial deliverables

Trial Steering Committee

Name	Affiliation	Role
Nick Axford	University of Plymouth	Independent Chair
Nina Johansson	Uppsala University	Independent Member
Jackie Chin	OHID, Department of Health and Social Care	Independent Member
Daisy Gaunt	University of Bristol	Independent Statistician
Sian Reece	University of Exeter	Independent Member
Sarah Bates	University of Sheffield	Independent Health Economist
Katherine Auty	UCL	Independent Member

Community Steering Committee

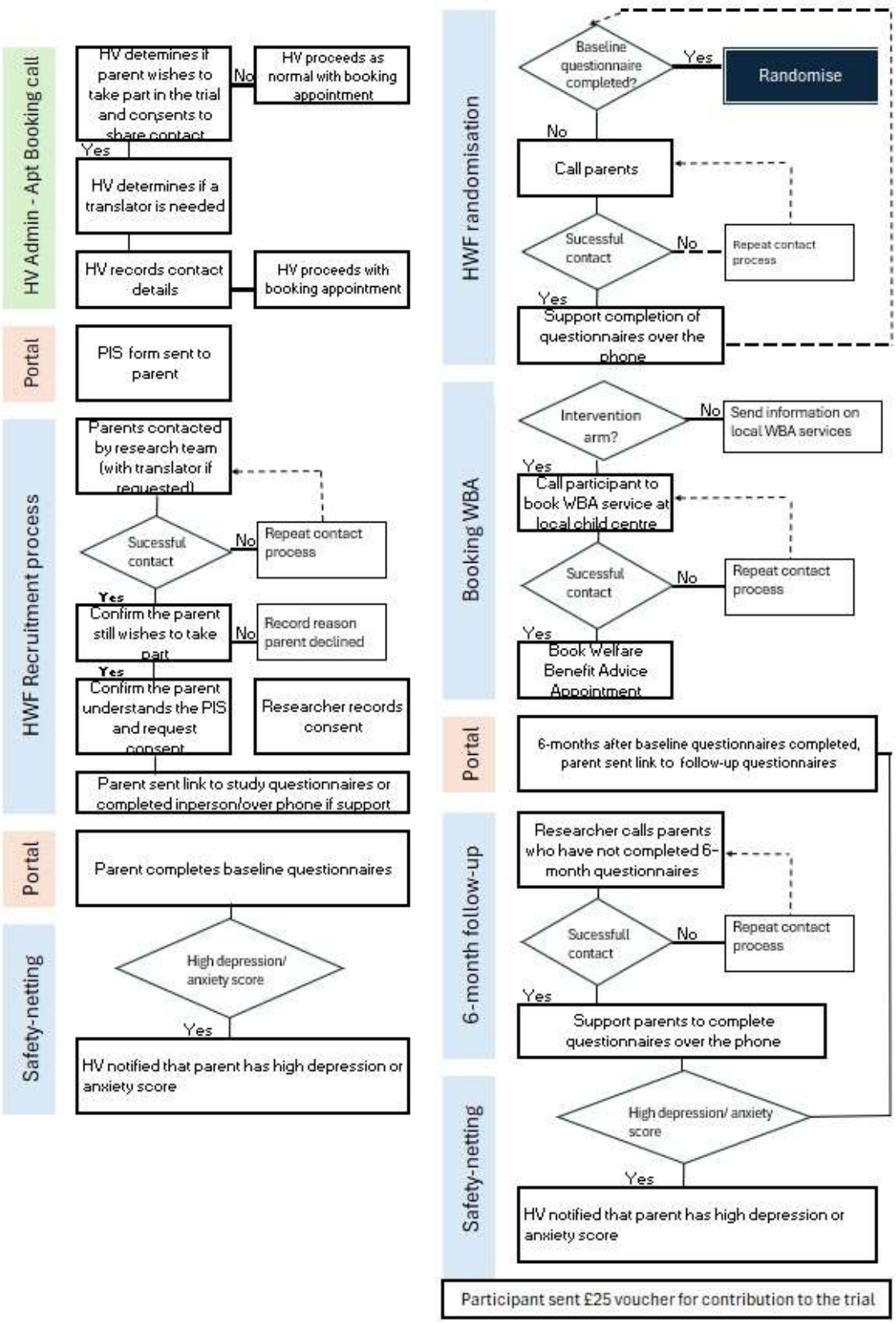
Name	Affiliation	Role
Denise Bentley	First Love Foundation	CSC Member
Sam Crosby	Tower Hamlets Council for Voluntary Service	CSC Member
Maura Farrelly	Social Welfare Consultant	CSC Member
Jane Williams	The Magpie Project	CSC Member
Sheli Kadir	Children's Services Tower Hamlets	CSC Member
Mohammed Abdul-Jolil	Children's Services Tower Hamlets	CSC Member
Georgia Ramirez	Public Health Tower Hamlets	CSC Member
Judith Davis	Children's Services Tower Hamlets	CSC Member
Hamida Serdiwala	Tower Hamlets GP Care Group	CSC Member
Sarah Sauvat	Island Advice Centre	CSC Member
Paramjeet Lehl	Mary Ward Legal Centre	CSC Member

Patient & Public Involvement Group

Name	Affiliation	Role
Jomya Tahsin	Resident of Tower Hamlets	PPI Member
Shayma Zaman	Resident of Tower Hamlets	PPI Member
Sultana Begum	Resident of Tower Hamlets	PPI Member
Farzana Khanom	Resident of Tower Hamlets	PPI Member
Anna Wolna	Resident of Tower Hamlets	PPI Member
Seynabou Emma Sow	Resident of Tower Hamlets	PPI Member

Trial Diagram

Figure 1: Anticipated flow of participants through trial.



Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CCTU	Comprehensive Clinical Trials Unit at UCL
CFC	Children's and Families Centres
CI	Chief Investigator
CRF	Case Report Form
DHSC	Department of Health and Social Care
EBCD	Experience Based Co-Design
EC	Ethics Committee
EDC	Electronic Data Capture
EU	European Union
GAD-7	General Anxiety Disorder - 7
GCP	Good Clinical Practice
GCSE	General Certificate of Secondary Education
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GP	General Practitioner
HDRC	Health Determinants Research Collaboration
HE	Health Economist
HEAP	Health Economics Analysis Plan
HJP	Health Justice Partnership
HRA	Health Research Authority
HV	Health Visitor/Health Visiting
ICH	International Conference on Harmonisation
ICF	Informed Consent Form
IRAS	Integrated Research Application System
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
LBTH	London Borough of Tower Hamlets
LBN	London Borough of Newham
MCS	Millenium Cohort Study
NHS	National Health Service
NIHR	National Institute for Health and Care Research
OHID	Office for Health Improvements and Disparities
PHQ-8	Patient Health Questionnaire-8
PIN	Participant Identification Number
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
QA	Quality Assurance
QALY	Quality Adjusted Life Years
QC	Quality Control
QMMP	Quality Management and Monitoring Plan
R&D	Research and Development
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SWEMWBS	Short Warwick–Edinburgh Mental Well-Being Scale
TMF	Trial Master File
TMG	Trial Management Group
ToR	Terms of Reference
TSC	Trial Steering Committee
UCL	University College London
UKPRP	UK Prevention Research Partnership
WBA	Welfare and Benefits Advisor
WP	Work Package

Glossary

Term	Definition
EQ-5D-5L	EuroQol-5 Dimension 5-level; a 5-item instrument measuring health-related quality of life.
GAD-7	General Anxiety Disorder-7; a 7-item instrument measuring anxiety with a 4-item scale.
LifeSim	A computer programme for childhood policy analysis that models developmental, economic, social and health outcomes from birth to death.
PHQ-8	Patient Health Questionnaire Depression Scale; an 8-item instrument measuring depression with a 4-item scale.
Subjective Financial situation[15]	A single item measure on a 5-level scale, 'living comfortably' to 'finding it very difficult'.
SWEMWBS	Short Warwick-Edinburgh Mental Wellbeing Scale; a 7-item self-report measure of mental wellbeing with five response options ('none of the time' to 'all of the time'), to give a total score ranging from 7-35, which is validated for use in multiple languages and contexts.
WELLBY	Wellbeing-adjusted Life Year; a one-point life satisfaction measured on a 0-to-10 Likert scale for one individual for one year.

1 Background

1.1 Rationale

Addressing the financial challenges faced by low and middle-income parents, especially during the crucial early years of child development, is vital for improving health outcomes for both parents and child (Pickett and Wilkinson 2015)[3].

Almost two thirds of low and middle income parents with young children in East London's Tower Hamlets (LBTH), were worried about job security in 2021 and over half were financially insecure[4]. In neighbouring Newham (LBN), more than 50% of children live in poverty[5] and 1 in 11 families live in temporary accommodation.

Evidence on improving access to financial advice services is promising (Reece et al 2021)[6]. By making these resources more accessible, parents can be empowered to navigate complex systems, and claim benefits they may be unaware of such as Universal Credit. This not only has the potential to enhance their financial stability but also to alleviate some of the mental health burdens associated with financial stress.

A previous review of the landscape of advice services located in health settings suggests there is strong support from health services because clinicians frequently encounter unaddressed social welfare needs which they are ill-equipped to address.

Integrating welfare benefit advice with HV appointments for the 6-8 week check-up is a promising approach. This critical period in a child's life is often marked by significant adjustments for new parents, and addressing financial concerns alongside health check-ups can have several advantages:

1. **Timely Support:** Parents are already engaged with health services, making it an ideal time to address any financial worries or unmet welfare needs.
2. **Holistic Care:** By integrating financial advice with health assessments, you can provide a more comprehensive support system that addresses both physical and financial health, recognizing the interconnectedness of these factors.
3. **Increased Access:** Co-location can help reduce barriers to accessing financial advice, especially for parents who may feel overwhelmed or unsure about seeking help separately.
4. **Immediate Referrals:** Health visitors can identify families in need of assistance during appointments and facilitate immediate referrals to financial advisors, streamlining the process.
5. NHS health visitors is a trusted service, take up of financial advice will benefit from nomination by trusted professionals.

We hypothesise an integrated, co-located approach will serve as a vital step toward a more integrated approach to health and social welfare, ultimately benefiting families in need.

This protocol outlines the evaluation the impact of co-locating welfare benefit advice with HV appointments and triangulates findings from:

1. A **randomised controlled trial** assessing the impact of money advice services on parental mental health.
2. A **process evaluation** to assess how the intervention is implemented and how it impacts on users
3. An **economic evaluation** to assess the cost-benefit of the intervention (refer to section 9 for further information).

The protocol focuses on the trial with separate section covering the process and economic evaluations.

1.1.1 Explanation for choice of comparators/Intervention

We are comparing one group of participants who will receive welfare benefits advice from a welfare benefits advisor (WBA) that is co-located with routine 6-8 week newborn health appointments in a Children and Families Centre. The second group will receive standard care and be given information on where they can access welfare benefits advice.

1.2 Objectives

1. To assess the effect of co-located WBA on parental mental health and wellbeing
2. To assess the effect of co-located WBA on household income and perceived financial situation
3. To assess participants' and service providers' experience of co-located WBA

1.3 Trial Design

HWFinEL is a randomised controlled trial with appropriately blinded statisticians and health economists during the conduct of the study. All analyses will be conducted by suitably qualified and experienced statisticians according to a detailed prespecified statistical analysis plan (SAP).

Participants will be randomised, after completion of their baseline questionnaire, in a 1:1 ratio to the intervention group (WBA appointment) or the control group and will be unblinded to their group allocation. Additionally, WBAs and HVs involved in service delivery, and researchers conducting the process evaluation, will be unblinded to the group allocation.

Participants who are randomised to the intervention group will be contacted by telephone (by a UCL Researcher) and invited to attend a WBA appointment within 3 months of randomisation. Wherever possible, this will be timed to coincide with their baby's/babies' 6-8 week check.

Participants who are randomised to the control group will be emailed or posted a card to their address detailing LBTH's existing 'service as usual' WBA services which reproduces what is available on their website (signposting to LBTH and voluntary sector welfare benefits advice service, national websites and helplines).

All participants will be required to complete a baseline questionnaire and a 6-month follow-up questionnaire upon study completion. Participants will be reminded twice (by email, post or telephone – telephone being the first point of contact) to complete their questionnaires: for

two months after receiving the questionnaires, if these have not been completed. Therefore, the total duration of the trial for each participant will be up to 9 months.

Additionally, a subsample of 45 participants from both groups will be purposively selected at random to complete an in-depth interview after the 6-month follow-up (refer to section 10 for more information about the interviews which forms the process evaluation).

1.4 Benefit Risk Assessment

The intervention plans to evaluate if there are additional benefits from receiving welfare benefit advice. There are no anticipated risks involved in participating in the intervention.

It is expected that the only risks of participation in the HWFinEL trial may be the possible unease or discomfort resulting from answering sensitive questions from the questionnaires/interviews pertaining to the participant's life. Contact information will be available for appropriate consultation should any of the material become distressing. The researchers will be alerted to scores of 10 or higher recorded on the mental health questionnaires (PHQ-8 and GAD-7) and this information will be shared with a health professional if it warrants further evaluation or support.

2 Selection of Sites/Investigators

2.1 Site Selection

The trial sponsor has overall responsibility for site and investigator selection and has delegated this role to CCTU.

2.1.1 Study Setting

Eight (8) Children's and Families Centres (CFCs), in LBTH, will take part in this study, providing Health Visitors Appointment services for 6-8 week postnatal check-up. Each CFC will host a WBA one day a week.

2.1.2 Site Eligibility Criteria

Once a site (CFC) has been assessed as being suitable to participate in the trial, the trial team will provide them with a copy of this protocol.

To participate in the HWFinEL trial, trial sites must fulfil a set of criteria that have been agreed by the Sponsor and HWFinEL Trial Management Group (TMG) and that are defined below.

Eligibility criteria:

1. Suitably trained staff who are available to recruit participants and enter data
2. Eight of the twelve potential sites have been assessed as having suitable space and resources to host the WBA service

2.1.2.1 Qualifications and Agreements

The CFC staff must be willing to comply with the trial protocol (confirming their specific roles and responsibilities relating to the trial, and that their site is willing and able to comply with the requirements of the trial). This includes confirmation of appropriate qualifications (provide

an up to date CV), and agreement to comply with the principles of Good Clinical Practice (GCP). The CFC staff must agree to permit monitoring and audit as necessary at the site, and to maintain documented evidence of staff who have been delegated significant trial related duties.

2.1.2.2 Resourcing at site

- The investigator should demonstrate potential for recruiting the required number of suitable participants within the agreed recruitment period.
- The CFC staff should have sufficient time to conduct and complete the trial properly within the agreed trial period.
- The CFC should have available an adequate number of qualified staff and suitable facilities for the anticipated duration of the trial in order to conduct the trial properly and safely.
- The CFC should ensure that all persons assisting with the trial are adequately informed about the protocol and their trial-related duties and functions.
- The site should have sufficient data management resources to allow prompt data return to the CCTU (refer to the Data Management Plan for timelines).

2.2 Site approval and activation

Site training will be performed prior to the activation of each site and will include all processes for the trial including but not limited to protocol training, data management procedures, and frequency and expectations for monitoring visits. A log of Site Initiation Visit attendees will be kept in the Trial Master File (TMF) as a record of participants present. The Visit may occur in person or via Videoconference as outlined in the Quality Management and Monitoring Plan (QMMP).

The trial manager or delegate will notify the CFCs in writing of the plans for site activation. Sites will not be permitted to recruit any participants until a letter for activation has been issued. On receipt of the signed Organisation information document (OID), completed delegation of responsibilities log and staff contact details, the Trial Manager or delegate will complete the green light process and issue written confirmation of site activation to the site.

The site must conduct the trial in compliance with the protocol as agreed by the Sponsor and, which was given favourable opinion by the Ethics Committee (EC). The CFC must document and explain any deviation from the approved protocol and communicate this to the trial team at CCTU.

A list of activated sites may be obtained from the Trial Manager.

3 Selection of Participants

There will be **NO EXCEPTIONS** (waivers) to eligibility requirements at the time of trial entry. Questions about eligibility criteria should be addressed PRIOR to attempting to randomise a participant.

The eligibility criteria for this trial have been carefully considered and are the standards used to ensure that only appropriate participants are entered. Participants not meeting the criteria should not be entered into the trial for their safety and to ensure that the trial results can be appropriately used to make future decisions for similar groups of parents. It is therefore vital that exceptions are not made to these eligibility criteria.

Participants will be considered eligible for enrolment in this trial if they fulfil all the inclusion criteria and none of the exclusion criteria as defined below.

3.1 Participant Inclusion Criteria

- Parents aged 16 years or over.*
- Parents with a live baby/babies less than three months old who are registered with the health visitor service in LBTH, at the point of consent, who respond Yes to a screening question asking if they wish to receive advice about money.**
- Able to provide informed consent.
- Able and willing to complete questionnaires.

**Only one parent will be recruited. If one parent is under the age of 16, they will not be eligible.*

***If multiple children, at least one child must be <3 months old.*

3.2 Participant Exclusion Criteria

- Parents with:
  - any known safeguarding concern.
  - maternal or paternal diagnosis of learning difficulty that affects the capacity to consent.
  - a baby/babies who have significant medical complications (e.g., inpatient on a neonatal unit).

3.3 Recruitment

See figure 1: anticipated flow of participants

3.3.1 Rationale for recruitment

There are approximately 4000 live births in Tower Hamlets each year and 5300 over the recruitment period of 16 months. Over half (56%) of children live in low-income households and there is widespread financial uncertainty among middle income households so an estimated 60% (3180) of families will constitute a recruitment pool of eligible families. Following the Bradford study[7], we anticipate 1590 parents will consent. Assuming a similar follow up to final outcome of 90%, we could have 1431 eligible, recruited and retained study participants, well within our target sample size of 1153. The sample size (1153) as a percentage of the total births in the borough (5300) is 22%.

3.3.2 Process of recruitment

When parents enrol with the health visiting service, usually around the time of an expected delivery, they will be given initial information and asked if they wish to participate in the study. The HV service will record demographic details (ethnicity, gender and age) of the parent they are talking with, which will remain anonymised unless the parent wishes to take part in the trial. This information is needed to determine whether the families who take part in the trial represent the overall population. The HV service will give a brief background and outline of the aims of the evaluation. They will then invite parents to take part in the trial. Parents who state an interest in taking part will be asked if they consent for their contact details to be shared with the research team. Information on interested parents will be recorded on the administrative database on REDCap (restricted authorised access only) and parents will then receive copies of the Participant Information Sheet (PIS) via email or post (whichever is their preferred method). A simplified and easy-read version of the PIS will be provided, including a full version of the PIS to ensure that participants have access to all the trial information. Links to audible translation of languages in Hindi, Bengali and Sylheti will be provided within the PIS and on the project webpage. Translators will also be provided to those that require this.

Two weeks after receiving the PIS, the research team will check the research portal to determine interested eligible parents. The researcher will call parents to establish:

1) If the parent still wishes to take part in the study
2) If there are any issues with participants giving informed consent for example if a translator is required to support the parent.

The researcher will take consent over the telephone and written consent taken electronically via a database link in REDCap which is sent to the participant. If required a translator will be booked and translator will join call, with the consent process repeated. Occasionally face to face consent will be undertaken at the CFC if participant requires assistance. Written consent will still be completed via an electronic database link on REDCap.

3.3.3 Methods to increase response

The following strategies will be implemented to increase response rate and mitigate loss to follow-up in this trial:

1. **Clear Informed Consent Process**
   We ensure that participants and their families fully understand the study's commitment and benefits through a transparent informed consent process. Families are only randomised after completing baseline questionnaires, which allows us to assess their initial commitment to participation.

2. **Follow-up Reminders and Support**
   Reminders will be sent to participants to complete follow-up questionnaires and follow-up phone calls will be made to ensure participants remain engaged and are reminded of their importance to the trial.

3. **Parent-Centric Support**
   Multiple data collection methods, including use of telephone or in person interviews, champion or researcher support to complete questionnaire if needed, and use of a translator when required, will be provided for participants encountering challenges completing online questionnaires, or facing technical issues. This will be offered at a time and place convenient for the participant to ensure ease of participation.

4. **Clear Points of Contact**
   We will provide participants with clear contact information, either via email or phone, for any questions or concerns they may have throughout the study. This helps maintain open communication and fosters a supportive relationship.

5. **Incentives for Engagement**
   A £25 shopping voucher will be provided as an incentive for the completion of six-month follow-up questionnaires and £25 for partaking in the in-depth interview. This offers participants additional motivation to stay engaged in the study.

6. **Monitoring Withdrawal and Dropout Reasons**
   We will carefully track and record reasons for non-participation, whether participants decline or withdraw. By monitoring these reasons, we will be able to adapt study processes and make improvements, such as proactively reaching out to participants who may be at risk of dropout to address any concerns they may have early on.

3.3.4 Recruitment progression criteria

Although feasibility has been demonstrated in general, and within context of this borough, in our feasibility and acceptability project, changes such as in local authority circumstances may occur and influence likely progression of the study. To address this, we will run an internal pilot. We will assess recruitment by the number of parents randomised into the trial, at the end of the first 6 months, from recruitment of the first participant, using the progression criteria out lined as a traffic light system, shown below (Table 1). Retention will be measured by completion of the 6-month follow-questionnaire, within 7 months of recruitment, allowing participants a month to complete them. Monitoring will be conducted through our governance structures.

Table 1: Progression criteria using 'traffic light system'.

Parameter	Parameter	Traffic Light	Action
Recruitment	Recruitment of fewer than 150 parents in first six months (from first participant recruited)	Red	Trial TMG to urgently meet with TSC and inform funder. Meet with the funder to discuss the possibility of closure.
	Recruitment of at least 150 parents in the first six months (from first participant recruited)	Amber	1. Urgent TMG and TSC meeting with funder. 2. Discuss additional measures with PPI standing group. 3. Review reasons for non-referral. 4. Increase publicity including talks to local community leaders to encourage increased participation
	Recruitment of at least 230 parents in first six months (from first participant recruited). This equates to approximately one fifth of the total recruitment target.	Green	Trial to proceed
Retention	Completion of PHQ-8 follow-up questionnaire by less than half of those recruited (<50%)	Red	Trial TMG to urgently meet with TSC and inform funder. Meet with the funder to discuss the possibility of closure.
	Completion of PHQ-8 follow-up questionnaire by half (≥50%) and less than three quarters (<75%) of those recruited	Amber	1. Urgent TMG and TSC meeting with funder. 2. Review reasons for non-retention with PPI standing group. 3. Re-visit discussions with local community leaders to try to understand participation hesitation, including advertising the thank you vouchers more widely.
	Completion of PHQ-8 follow-up questionnaire by three quarters (≥75%) of those recruited	Green	Trial to proceed

3.3.5 Recruitment period

Recruitment will begin after the assigned ethics committee has given approval to carry out the trial. A target of 1153 participants will be recruited for this trial, over a 16-month period.

This trial will be advertised at the CFCs (using a Research Ethics Committee / Health Research Authority (REC/HRA approved trial poster)) and the PPI group will support the design of recruitment materials developed alongside the Sponsor. PPI representatives will also utilise their connections within LBTH to aid recruitment.

Reporting of the trial set-up and recruitment period will be conducted on a regular basis to the HWFinEL TMG, independent trial oversight committee and the study funder. Remedial actions will be put in place if any concerns arise.

3.4 Co-enrolment Guidance

Participants can be concurrently enrolled in any other interventional trial. This trial will use maintain screening and enrolment logs to track currently enrolled participants to ensure that each participant can only be enrolled once. The online randomisation service used for this trial (www.sealedenvelope.com) also prohibits the same participant from being randomised twice.

3.5 Screening Procedures and Informed Consent

3.5.1 Ways of obtaining consent to participate in HWFinEL

Informed consent will be obtained by a UCL Researcher in the following ways using a secure encrypted electronic consent (e-consent) facility, via REDCap:

1) By the participant completing and signing the e-consent form via a secure online link
2) By the participant giving verbal consent over the telephone to a member of the recruiting team, followed by completing and signing the e-consent form via a secure online link
3) Occasionally face to face consent may be used if assistance is required via a secure online link.

All researchers will have completed NIHR Good Clinical Practice training and those obtaining consent will additionally have completed NIHR Informed Consent Training.

Participants will be provided with a PIS and given time to read it fully. Following a discussion with a suitably trained and authorised delegate, any questions will be satisfactorily answered and if the participant is willing and has the capacity to consent and wishes to participate, informed e-consent will be obtained. Once the participant has signed the consent form, an email is generated to the delegated member of the research team, allowing them to countersign the consent form. A fully executed consent form is sent to all parties (including the participant) and is stored within REDCap (UCL Data Safe Haven). The copy within REDCap is only accessible to UCL.

Only the UCL research team can view and check the e-consent forms. UCL and CFCs will be able to view the participant's email address, telephone number and address details. This information is encrypted. Signatures are timestamped by audit trail within REDCap and cannot be altered. All actions involved in the e-consent process are recorded in the software audit trail.

If a participant has capacity and is willing to provide verbal consent, but is physically unable to sign the consent form, a witness independent of the trial team will be identified and asked to sign the witness signature field in the consent form, to attest to the participant's verbal consent to participate.

For all participants, consent will be re-sought if new information becomes available that affects the participant's consent in any way. This will be documented in a revision to the appropriate format of the Participant Information Sheet and the participant will be asked to sign an updated corresponding consent form (via a secure online link on REDCap). These will be approved by

the REC prior to their use. A copy of the approved consent form is available from the HWFinEL trial team.

Informed consent to enter and be randomised into the trial must be obtained from participants, after explanation of the aims, methods, benefits, and potential hazards of the trial and **BEFORE** any trial-specific procedures are performed.

It must be made completely and unambiguously clear that the participant is free to refuse to participate in all or any aspect of the trial, at any time and for any reason, without incurring any penalty or affecting the services available to them.

Signed consent forms must be kept by the researcher and a copy given to the participant. The consent process should be documented in the participants records.

For details on all assessments performed at each visit, please refer to Section 5.2 for Participant Timeline.

4 Trial Intervention

4.1 Introduction

The intervention is welfare advice sessions which will run alongside routine service within HV services rather than council offices or online. Co-located WBA with health appointments is an example of a Health Justice Partnership (HJP)[8], found to be an effective tool in addressing health equity.

Successful implementation relies on collaborative working, characterised by willingness to work together, confidence in and trust between teams, and workability of systems. Establishing the intervention requires active promotion, ongoing opportunities to learn about the partnership, informal and formal interactions to build shared knowledge and understandings, and regular feedback between the teams involved[9]. To achieve this we will adapt the Glasgow model[10] and set up and coordinate intervention oversight groups to provide strategic direction, operational guidance and facilitate local collaboration at the site level.

4.2 Intervention Arm

Parents randomised into the intervention arm will be offered an appointment with the borough's WBA. WBA appointments will be scheduled by the UCL researchers to coincide their baby's/babies' 6-8 week check, when possible. HVs deliver 6-8 week checks at the CFCs in Tower Hamlets. The researcher will book this appointment as they will be responsible for checking consent has been obtained, the baseline questionnaire has been completed, and then randomising the participant. They will also check which of the CFC sites are most suitable for the participant to attend for their appointment at the time of booking. There are 12 CFCs in Tower Hamlets, but we will use 8 of these. Each site will host a WBA one day a week. These centres are ideally placed to co-locate WBA as they are universally accessible to parents and children.

Advice (including welfare benefits, employment, housing, debt) will be provided by Local advice provider (WBA) under subcontract to the study (Mary Ward Legal Centre) and will proceed as per service standard. For straightforward cases this is a one off appointment; for others with multiple needs it may include subsequent appointments or referral to a more specialist advice service. The WBA will determine this on a case-by-case basis. As per service standard the advisor will work with the client until optimum financial change has been achieved. A translator will be available during advice sessions when necessary utilising the usual service in that CFC. We have recruited Mary Ward Legal Centre to add capacity in the borough. At present there are approximately 24 advice services run by voluntary and public sector organisations but none are targeted at parents of newborn children by being delivered alongside routine health appointments. Accessing WBA at present requires a high level of digital literacy and information is fragmented across various delivery organisations and websites. Two new full-time members of WBA staff will run in CFCs on days to coincide with child health checks. Approximately 20 x 1 hour appointments will be provided per working week, including some additional follow up work, suggesting that 12-15 new parents could be seen each working week. The service will run for 12-16 months or until sample size has been reached and final participant has completed their participation in the trial.

Enrolment in the trial does not preclude participants seeking financial support from other sources. We will record access to financial support on follow-up to explore uptake of financial support from any service irrespective of randomisation arm.

4.3 Control Arm

Parents randomised into the control arm will receive signposting to LBTH and voluntary sector welfare benefits advice service, national websites and helplines.

4.4 Unblinding

Participants and researchers are unblinded. Statisticians and health economists will remain blinded until after database lock and primary analysis has been completed. An unblinded statistician will be appointed when required to support the oversight of the trial.

4.5 Protocol Intervention Discontinuation

In consenting to the trial, participants are consenting to the trial intervention, trial follow-up and data collection.

As participation in the trial is entirely voluntary, the participant may choose to discontinue the trial intervention at any time without penalty or loss of benefits to which they would otherwise be entitled. Although not obliged to give a reason for discontinuing their trial intervention, a reasonable effort should be made to establish this reason, whilst remaining fully respectful of the participant's rights.

It should be clear to the participant and recorded in the trial database what aspect(s) of the trial the participant is discontinuing their participation. These could include:

- Early cessation **from questionnaires**
- Early cessation **from further trial follow-up**
- Early cessation **from electronic social care record use.**

Participants should remain in the trial for the purpose of follow-up and data analysis (unless the participant withdraws their consent from all stages of the trial). If a participant ceases follow-up early, refer to Section 5.4.

Data on participants who stop follow-up early will be kept and included in analysis, unless the participant requests their data to be deleted.

4.6 Eligibility Criteria for Individuals Performing the Interventions

The intervention will be delivered by experienced Welfare and Benefits Advisors within three months of randomisation. The UCL Researcher will arrange a WBA appointment at the participant's local CFC (where possible this will be in conjunction with the participant's 6-8 week postnatal check-up). Advice (including welfare benefits, employment, housing, debt) will be provided by LBTH's WBA and will proceed as per service standard. For straightforward cases this is a one off appointment; for others with multiple needs it may include subsequent appointments or referral to a more specialist advice service. As per service standard the advisor will work with the client until optimum financial change has been achieved. A translator will be available during advice sessions when necessary.

5 Assessments & Follow-Up

5.1 Outcomes

5.1.1 Primary Outcome(s)

Difference in depression (PHQ-8[11]) scores at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values and adjusted for stratification variables (if any). The outcome will be examined to ensure that it meets the assumptions for regression analyses and transformed, if necessary, to an appropriate scale so that the resultant distribution approaches normality.

5.1.2 Secondary Outcomes

Financial gain

Difference in household financial income at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values and adjusted for stratification values (if any). The outcomes will be examined to ensure that it meets the assumptions for regression analyses and transformed, if necessary, to an appropriate scale so that the resultant distribution approaches normality.

Anxiety

Difference in GAD-7[12] scores at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values.

Quality of life

Difference in SWEMWBS[13] scores at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values.

Quality of life (economic evaluation measure)
Difference in EQ-5D-5L[14] scores at 6 months' follow-up in the intervention arm compared with the control arm accounting for baseline values.

5.2 Participant Timeline

Table 2: Schedule of Assessments

Visit Number	Screening	Baseline	Control Group	Intervention group	6-month follow up	Additional follow-up (subsample of participants)
Day/week	**Day 0**	**2 weeks**	**1-3 months**	**1-3 months**	**6 months**	**6 months**
Protocol visit window						
[1]Eligibility screen	X					
[1]Verbal Informed consent	X					
[2]Written informed e-consent		X				
[2]Eligibility confirmation	X	X				
Demographics data	X					
[2]Randomisation / Group allocation		X				
SAE review		X	X	X	X	
Interventions:						
[3]Post card detailing LBTH services			X			

[4]WBA appointment				X		
[5]Questionnaires:						
EQ-5D-5L		X			X	
GAD-7		X			X	
PHQ-8		X			X	
SWEMWBS		X			X	
Subjective financial situation		X			X	
Self-reported household income		X			X	
[6]Qualitative Interview						X

[1]Initial eligibility screening will be performed by a health visitor and they will obtain verbal consent from interested participants for their contact details to be passed on to the UCL research team who can explain the study.

[2]Written informed e-consent, eligibility re-confirmation and randomisation will be performed by a UCL Researcher.

[3]Post card detailing LBTH services (information on where to access welfare benefits advice) to control group only.

[4]WBA appointment to be arranged for intervention group only (where possible to coincide with 6-8 week health check of newborn infant).

[5]Questionnaires will be completed at Baseline and 6-month follow-up. At each time point participants will be chased every 2 weeks for 2 months if the questionnaires have not been completed.

[6]A subsample of 45 participants from both groups will be purposively selected at random to complete an in-depth interview at 6 months.

5.3 Participant Transfers

If a participant moves address they will continue to be followed-up. Relating to participants in the intervention group (receiving WBA at the CFC) if they move address before or during receiving the intervention, every effort should be made for them to be seen by a WBA at a participating CFC which is most convenient for them.

5.4 Early Stopping of Follow-up

If a participant chooses to discontinue their trial intervention, they should always be followed up providing they are willing, that is, they should be encouraged to not leave the whole trial; if they do not wish to remain on trial follow-up, however, their decision must be respected, and the participant will be withdrawn from the trial completely. The CCTU should be informed of this in writing using the appropriate HWFinEL trial documentation. Participants stopping early may have a negative impact on trial data integrity and the ability to reach the stated endpoints.

Data already collected during the participant's participation in the trial will be kept for analysis, unless the participant requests deletion.

Participants may change their minds about stopping trial follow-up at any time and re-consent to participation in the trial. Their original randomisation allocation will stand.

Participants who withdraw from the trial will not be replaced and cannot re-enter the trial.

(See also Section 4.5 Protocol discontinuation)

5.5 Loss to Follow-up

If a participant is no longer contactable and has not completed their follow-up questionnaire within the protocol defined window, then UCL researchers should attempt to contact the participant at least three times via two different methods of contact (i.e., telephone and letter) before they are declared as lost to follow-up. We have assumed an attrition rate of 10-20% (section 8.1).

5.6 Completion of Protocol Follow-Up

Participants will complete protocol follow-up upon the completion of the questionnaire/and the in-depth interview at 6 months (if they consent to take part in this).

6 Safety reporting

This trial is very low risk as the trial intervention groups are non-invasive (i.e. money advice being offered). As such, serious adverse events are not anticipated in the HWFinEL trial; if any Serious Adverse Events (SAEs) occur to a participant during the trial, these will be recorded and appropriate action taken (i.e. intervention discontinuation or withdrawal, as deemed appropriate by the researchers).

SAEs that are **related** to the study (i.e. they resulted from any of the research procedures) and **unexpected** will be reported to the REC using the relevant documentation.

These should be sent within 15 days of the Chief Investigator becoming aware of the event.

6.1 Definitions

Definitions of harm of the European Union (EU) Directive 2001/20/EC Article 2 based on the principles of GCP apply to this trial.

Table 3: Definitions

Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical trial subject to whom an intervention is being given that are not necessarily caused by or related to that product.
Serious Adverse Event (SAE)	Respectively any adverse event, adverse reaction or unexpected adverse reaction that: • results in death • is life threatening* • requires hospitalisation or prolongation existing hospitalisation** • results in persistent or significant disability or incapacity • consists of a congenital anomaly or birth defect • is another significant medical condition***

* The term life threatening here refers to an event in which the patient is at risk of death at the time of the event; it does not refer to an event that might hypothetically cause death if it was more severe (e.g., a silent myocardial infarction)

** Hospitalisation is defined as an in-patient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisation for pre-existing conditions (including elective procedures that have not worsened) do not constitute an SAE

*** Medical judgement should be exercised in deciding whether an AE is serious in other situations. The following should also be considered serious: important AEs that are not immediately life threatening or do not result in death or hospitalisation but may jeopardise the participant or may require intervention to prevent one of the other outcomes listed in the definition above.

Only events that are clearly **related** and **serious** will be considered a reportable SAE and should be reported in this study.

6.2 Investigator responsibilities

SAEs should be notified to CCTU immediately and no later than **24 hours** after the CFC staff becomes aware of the event by email to the HWFinEL trial team using the trial specific SAE form.

6.2.1 Assessment of AEs

6.2.1.1 Seriousness

When an AE occurs, the researcher responsible for the care of the participant must first assess whether or not the event is serious using the definition given in Table 3. If the event is classified as 'serious' then an SAE form must be completed and CCTU (or delegated body) notified immediately (within 24 hours).

6.2.1.2 Causality

The researcher must assess the causality of all serious events in relation to the trial intervention using the definitions in Table 4. There are five categories: unrelated, unlikely, possibly, probably, and definitely related. If the causality assessment is unrelated or unlikely to be related, the event is classified as an '**unrelated** SAE'. If the causality is assessed as possibly, probably or definitely related, then the event is classified as a '**related** SAE'.

Table 4: Assigning Causality

Relationship	Description
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out
Probably	There is evidence to suggest a causal relationship and the influence of other factors is unlikely
Possibly	There is some evidence to suggest a causal relationship (e.g., because the event occurs within a reasonable time after administration of the trial intervention). However, the influence of other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events)
Unlikely	There is little evidence to suggest that there is a causal relationship (e.g., the event did not occur within a reasonable time after administration of the trial intervention). There is another reasonable explanation for the event (e.g., the participant's clinical condition, other concomitant event)
Unrelated	There is no evidence of any causal relationship

6.2.1.3 Severity or Grading of Adverse Events

The severity of all 'related' SAEs in this trial should be graded using the toxicity gradings in the Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 (2017). Grades for SAEs according to the CTCAE are as per Table 5 (next page).

Table 5: Toxicity Gradings for Adverse Events

Grade	Description
1	Mild; asymptomatic or mild symptoms; clinical diagnostic observations only; intervention not indicated
2	Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL)*
3	Sever or medically significant but not life threatening; hospitalisation or prolongation of hospitalisation indicated; disabling; limiting self-care ADL**
4	Life threatening consequences; urgent intervention required
5	Death related to AE or AR

**Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money etc.*

*** Self-care AD refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications and not bedridden.*

Where no specific grading criteria exist for an event, the event should be graded according to the CTCAE general guidelines.

6.2.1.4 Expectedness

If there is at least a possible involvement of the trial intervention (or comparator), the expectedness of the event should be assessed by the CCTU delegated clinical reviewer. The Sponsor has the overall responsibility for determination of expectedness.

Table 6: Expectedness

Expectedness	Description
Expected	An adverse event which is consistent with the information about the trial procedures/intervention defined in this protocol
Unexpected	An adverse event which is not consistent with the information about the trial procedures/intervention defined in this protocol

6.2.1.4 Urgent Safety Measures

The CCTU or Chief Investigator may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. These should be reported to the REC within 3 days via email notification.

7 Quality Assurance & Control

7.1 Risk Assessment

The Quality Assurance (QA) and Quality Control (QC) considerations for the HWFinEL trial are based on the standard CCTU Quality Management Policy that includes a formal Risk

Assessment, and that acknowledges the risks associated with the conduct of the trial and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on the rights and safety of participants; project concept including trial design, reliability of results and institutional risk; project management; benefit risk of the trial (see section 1.4); and other considerations.

QA is defined as all the planned and systematic actions established to ensure the trial is performed and data generated, documented and/or recorded and reported in compliance with the principles of GCP and applicable regulatory requirements. QC includes the operational techniques and activities performed within the QA system to verify that the requirements for quality of the trial related activities are fulfilled.

The HWFinEL Risk Assessment has been reviewed by the CCTU's Quality Management Group (QMG).

7.2 Central Monitoring at CCTU

CCTU staff will review data and other information provided by investigators to identify trends, outliers, anomalies, protocol deviations and inconsistencies. The frequency and type of central monitoring will be detailed in the HWFinEL QMMP.

7.3 Monitoring

The frequency, type and intensity of routine on-site monitoring and the requirements for triggered on-site monitoring will be detailed in the HWFinEL QMMP, including any provision for remote or self-monitoring. The QMMP will detail the procedures for review and sign-off of monitoring reports. In the event of a request for a trial site inspection by any regulatory authority UCL CCTU must be notified as soon as possible.

7.3.1 Direct access to Participant Records

CFCS must agree to allow trial-related monitoring, including audits, and EC review, by providing access to source data and other documents as required. Participant consent for this must be obtained as part of the informed consent process for the trial.

7.3.2 Confidentiality

CCTU plan to follow the principles of the UK DPA regardless of the countries where the trial is being conducted.

Participant's data will be collected and kept securely. Confidentiality of participant's personal data is ensured by not sharing participant names and other personally identifiable information on CRFs and receiving only pseudonymised data. Pseudonymised data will be stored in the REDCap database (separate to the administrative database). At trial enrolment, participants will be allocated a Participant Identification Number (PIN), which will be used on all trial related paperwork sent to UCL CCTU and in the trial database. Any documents (e.g. screening and enrolment logs) linking PIN to participant's personally identifiable information will be kept securely at the CFC; only redacted copies will be sent to Sponsor if requested.

Copies of participant's trial data will be kept at the participating CFC in a secure location with restricted access. Unless working at a site, CCTU staff will only have access to the data collected on the trial CRFs (i.e. they will not have access to any other personal data) and

applicable source data, moreover only staff working on the trial will have access to these data. Where paper copies of CRFs have been sent to CCTU (due to central database unavailability, e.g., system updates, system failure), all CCTU copies of CRF data on paper are stored securely in locked filing cabinets at the UCL CCTU office. Data stored electronically are held on secure servers, that have restricted access.

The informed consent form will carry the participant's name and an appropriate signature; these will be retained on the REDCap database as it will be completed electronically with restricted access. The consent forms will only be accessed by UCL CCTU staff for purposes of monitoring the consent procedure.

7.4 Source Data

The investigator/institution should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial participants. Source data are contained in source documents and are defined by EU guidelines as all information in original records that are used for the reconstruction and evaluation of the clinical trial. Source documents are the first place where the source data are recorded. These can include hospital records, clinical and office charts, laboratory notes, X-rays, questionnaires, source data worksheets and pharmacy dispensing records.

Source data should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail). Each data element should only have one source.

For this trial, the majority of datapoints will be recorded directly into CRFs/eCRFs and therefore the CRF/eCRF will be regarded as source data. However, a minority of datapoints will be recorded in the participant's notes. In such cases, the participants notes will be regarded as source data. The location of each datapoint will be detailed in the HWFinEL Data Management Plan.

Paper CRFs will be provided to the CFC to be used as a back-up for instances when the EDC is unavailable (e.g., system updates, build maintenance, system failures). Paper CRFs will be provided to CFCs and should only be used as a temporary measure until the EDC is restored.

A Source Data Agreement will be put in place as part of the activation process with each CFC. This will define the source documents and the data therein, together with location of these source documents and any applicable plans for transmission of source data between the CFC and CCTU.

All trial data will be verifiable from source documents, which may include CRFs/eCRFs, and paper notes.

7.5 Data Collection and Transfer Methods

Each CFC will be allocated a unique site code and enrolled participants will be given a unique randomisation Participant Identification Number (PIN), which will be used for all data collection

forms. At the point of screening, the participants will be assigned a unique Screening ID number in sequential order following consent.

The preferred method of data collection is direct online entry of data onto the Electronic Data capture (EDC) system sponsor central database REDCap. Paper CRFs can be used as an intermediary (i.e. as CRF worksheets, if CFCs wish to) between the source data and the EDC, however, ultimately all data are to be entered into the EDC.

Trial specific CRFs will be designed by the HWFinEL trial team. The approved CRFs will be provided to CFCs/used by UCL Researchers.

Training on data collection, secure data transfer and storage for CFC staff listed on the delegation of responsibilities log will be provided at the site initiation meeting or prior to green light activation.

7.6 Data Management

Data will be collected at the time-points indicated in the Schedule of Assessments Participant Timeline (Section 5.2). Data will be entered remotely under the assigned unique PINs onto the central database. The database software provides a number of features to help maintain data quality, including maintaining an audit trail, allowing custom validations on data, allowing users to raise data query requests, and search facilities to identify validation failure and missing data.

Data collection, data entry, data queries (raised by a member of the HWFinEL trial team), data coding and database lock(s) will be conducted in line with the CCTU Standard Operating Procedures (SOPs) and trial-specific Data Management Plan.

The database will be password protected and only accessible to members of the HWFinEL trial team at CCTU/UCL Researchers, delegated CFC staff and external regulators if requested. Database users will only be granted permissions to use the database functionality appropriate to their role in the clinical trial. The servers are protected by firewalls and are patched and maintained according to best practice. The physical location of the servers is protected by CCTV and security door access.

Identification logs, screening logs and enrolment logs will completed and held securely at the CFC/UCL CCTU.

All data will be handled in accordance with the Data Protection Act 2018, the EU General Data Protection Regulation (GDPR) 2016 (and subsequent updates and amendments).

7.7 Data Storage

Trial data will be stored in a database created specifically for the HWFinEL trial.

The database is created using REDCap, hosted by UCL. The data are stored on secure, GDPR-compliant, cloud-based servers held within the UK:
https://projectredcap.org/software/mobile-app/privacypolicy/

The randomisation service is hosted by Sealed Envelope LTD. The data are stored on a secure, GDPR-compliant, cloud based servers held within the EEA/EU: https://www.sealedenvelope.com/security/

The identification, screening and enrolment logs, linking personally identifiable information to the PIN, will be held by the CFC and in the separate secure admin database. This will either be held in written form in a locked filing cabinet or electronically in password protected form on REDCap Data Safe Haven. After completion of the trial the identification, screening and enrolment logs will be stored securely by the sites for 5 years after trial closure unless otherwise advised by CCTU.

7.8 Data Archiving

Once all primary and secondary analysis has been completed the trial data will be archived. Once the trial data has been archived the trial database will be decommissioned and will no longer be available. Any subsequent/ further analysis will be performed using the archived data.

7.9 Quality Issues

Quality Issues are issues that can have an impact on participant safety, rights, and well-being; data integrity and/or scientific rigor; and compliance with regulatory requirements; these can be classified as protocol deviations, potential serious breaches, near misses etc.

A protocol deviation is any departure from procedures documented in this protocol, this includes deviations that cannot be predicted. If a protocol deviation is identified the HWFinEL trial team should be contacted and CCTU's protocol deviation reporting process will be followed.

A 'serious breach' is a deviation from procedures documented in this protocol, GCP or other clinical trial regulations that is likely to affect to a significant degree:

1. The safety or physical or mental integrity of the participants in the trial, or
2. The scientific value of the trial.

If a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the CI, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the REC committee within 7 days.

8 Statistical Considerations

8.1 Sample Size

We make the following assumptions:

I. We take the Minimum Clinically Important Difference (MCID) in PHQ-8[11] scores to be half of the usual value of 3. We have chosen this conservative estimate because the population at risk in this study is not known to have a high prevalence of depressive illness (unlike the other environments in which the PHQ-8 has been validated). Additionally, we are not convinced that this population, which encompasses a high proportion of migrants and people of minority ethnicity, will volunteer symptoms of a depressive disorder because of cultural sigma against mental illness. Further, those participants who experience symptoms of low mood may report different symptoms from those elicited on the PHQ scale due to cultural differences in the way they experience low mood. We therefore do not think the PHQ is an appropriately sensitive instrument in this environment and have estimated the sample size with a conservative estimate of the MCID.

II. We have provided a conservative estimate of the correlation between baseline and follow-up values. This means that the study may be overpowered.

III. We assume a standard deviation of 7.25 for the change score (which derives from the Born in Bradford study)[16].

IV. This is a very experienced research team which has conducted substantial research in this area. We have consulted extensively with our PPIE partners, and they do not think that we will encounter high dropout rates. We anticipate that we will have an approximate dropout rate of 10% but are prepared for a 20% dropout rate in our sample size calculations.

V. We have used the ANCOVA method to calculate the sample size. This method results in a smaller sample size (if we account for baseline adjustment for PHQ-8 scores in the final analysis of the effect of the intervention) than that which would obtain otherwise.

We estimate that we will be able to detect a difference of 1.5 units in the PHQ-8 scale between the two arms with a two-sided alpha of 5% and with 90% power (assuming a nominal correlation of 0.25 between baseline and follow-up scores, a standard deviation of the change score of 7.25 and an anticipated 20% drop-out rate) with a sample size of 1153 participants.

If the dropout rate is only 10% (as anticipated), leaving all the other parameters as specified above, we expect that the study will have an increased power of 93% to find a difference in PHQ-8 scores of a magnitude of at least 1.5 units between the arms if such a difference exists.

8.2 Assignment of Intervention

8.2.1 Randomisation Procedures

An independent, concealed, online randomisation service provider (www.sealedenvelope.com) will be used to divide participants equally into the two trial groups.

We will perform individual participant randomisation using stratification factors, detailed in the prespecified SAP, to attempt to balance allocation to both study arms for these variables. We will use a biased coin technique to ensure that the groups are approximately equal but still retaining some component of randomness in the allocation. Randomisation will be performed either by CCTU/UCL Researchers or by a delegated entity via Sealed Envelope (who will use industry standard validated randomisation and/or minimisation algorithms to achieve the aim of 1:1 allocation ratio with the 70% biased coin element of randomness). The Trial Statisticians conducting the trial analyses and involved in the conduct of the study will be blinded to trial group allocation until the end of the trial when data analysis and unblinding occurs.

Following the Baseline visit, the UCL Researcher or delegate will enter minimisation factors as well as the necessary data to re-confirm participant eligibility on the SealedEnvelope.com secure online system and then allocate the appropriate PIN to the participant.

Delegated staff (at CCTU/UCL Researchers or appropriate designee) will be provided with a secure login to the SealedEnvelope.com Website, according to their role in the trial. The randomisation result will be shown directly online as the intervention allocation, with an email confirmation sent to the user and to the CCTU trial team. If allocated to the intervention group, the UCL Researcher will book a WBA appointment and provide details to the participant.

Randomisation will be considered completed after allocation has been generated from the randomisation system.

8.2.2 Randomisation Method

Participants will be randomised 1:1 to the intervention group (WBA appointment) or the control group (standard of care, where they will be given information on where to access welfare benefits advice).

8.2.3 Sequence generation

Randomisation will be performed with stratification factors to attempt to achieve equal allocation to both study arms.

8.2.4 Allocation concealment mechanism

Treatment allocation will be masked to the trial statisticians during the conduct of the study by Sealed Envelope who will restrict access to the variable which encodes for allocation.

8.2.5 Allocation Implementation

After the participant's eligibility for the trial has been confirmed, they have provided informed consent, and baseline measures have been recorded, randomisation will be performed by

the CCTU or a delegated entity, using the Sealed Envelope randomisation service stated above. Eligibility and consent will be verified before each participant is randomised. Eligibility decisions will be made in line with the approved protocol.

8.2.6 Blinding

This is a randomised controlled trial with appropriately blinded statisticians and health economists during the conduct of the study. All analyses will be conducted by suitably qualified and experienced statisticians according to a detailed prespecified SAP. Investigators, participants, health visitors at the CFCs, and the WBAs will be unblinded. Process evaluation researchers, who will support participant recruitment and conduct the qualitative interviews, will not be blinded to group allocation.

Allocation concealment will be maintained by providing alternative Welfare Benefits advice to those who have been allocated to the control group. Participants who are randomised to the control group will be emailed or mailed a card detailing LBTH's existing 'service as usual' WBA services which reproduces what is available on their website (signposting to LBTH and voluntary sector welfare benefits advice service, national websites and helplines) after their follow up data is obtained and when sending on their thank you voucher.

The blinded intervention allocation identity will be maintained in the online Sealed Envelope randomisation service and the trial statistician will not have access to the variable which codes for intervention allocation.

8.3 Statistical Considerations

8.3.1 Statistical Analysis Plan

A detailed analysis plan will be finalised prior to database lock, below is a brief outline.

8.3.2 Interim Analyses

There are no planned interim analyses.

8.3.3 Statistical Methods – Outcomes

The primary analyses will be a generalised mixed model with identity link and Gaussian / mixed error structures, accounting for baseline scores using a repeated measures framework. There will be two observations for each participant, the baseline and final outcome scores. These will be linked within a participant using a random intercept term. The model will be parameterised to identify baseline and post randomisation observation as one parameter, and random allocation as the second parameter. For the latter, all baseline measures will be coded as no intervention, and the post randomisation values will be classified as active or control. We will not make adjustments for repeated testing but will discuss the possibility that type 1 errors would have increased in the discussion.

We will employ a treatment policy estimand in the primary analysis with inclusion defined as that population of participants who were randomised.

8.3.4 Additional Analyses

Secondary analyses will choose the appropriate analogous generalised mixed model, for the outcome and account for the baseline measurement of the outcome. We will describe randomised groups at baseline. Summary statistics for continuous variables will be mean, median, SD, lower quartile, upper quartile and reported appropriately according to distribution. Summary statistics for binary and categorical variables will be n (%).

We will carry out supportive analyses including the minimisation variables as explanatory variables.

We will carry out, if indicated, a threshold analysis of the primary outcome where missing values in the control group are assigned the best possible outcome values and missing values in the intervention group are assigned the worst possible outcome values to assess the stability of the primary outcome to missingness.

In addition, we will carry out these additional analyses:
Provide the point estimates and standard errors for (1) parental depression (PHQ-8), (2) parental anxiety (GAD-7) and (3) household income. We will also carry out exploratory sub-group analyses by income and by IMD quintile group.

9 Economic Evaluation (WP2)

The aim of WP2 is to apply a novel longitudinal individual-level microsimulation modelling approach to understand how improvements in short-term family income and parental mental health will impact children's long-term health, economic, social, and wellbeing outcomes.

Research questions (RQ):

RQ1. Do increases in family income and improvements in parental mental health during infancy lead to improved long-term health, economic, social, and wellbeing outcomes for children over the lifecourse?

RQ2. Will referral to a co-located WBA in LBTH be cost-effective in the long-term, compared with no referral to a co-located WBA?

RQ3. Would national roll-out of co-located money advice and health services across the whole of England be cost-effective and reduce inequalities in the long-term?

We will conduct two model-based economic evaluations, one local and one national, using a lifecourse microsimulation model called "LifeSim[17]":

1. **Local model-based economic evaluation** – a long-term cost-effectiveness analysis of referral to co-located Welfare and Benefits Advice (WBA) in London Borough of Tower Hamlets (LBTH), compared with no referral to co-located WBA (RQ1, RQ2).

2. **National model-based economic evaluation** – a long-term distributional cost-effectiveness analysis of full national implementation of co-located WBA in England, compared with no co-located WBA in England (RQ3).

9.1 Health Economic Analysis Plan

Interventions being compared: See (1) and (2) above.

Cost perspective: public sector, including local and central government costs falling on the NHS, social care, education, criminal justice and taxes and benefits.

Effectiveness measure: the primary measure will be wellbeing adjusted life years (WELLBYs) as defined by the UK Treasury – i.e. a one-point improvement in life satisfaction for one year[18] – with quality adjusted life years (QALYs) as a secondary measure

Type of analysis: cost-effectiveness analysis for the local evaluation (1) and distributional cost-effectiveness analysis for the national evaluation (2).

Reported outcomes: model (1): incremental cost-effectiveness ratio and, for model (2), the reduction in lifetime inequality in health and wellbeing between babies born into the richest and poorest fifths of households in England. We will also report various policy-relevant secondary outcomes, including payback period and total discounted lifetime cost savings and benefits in terms of WELLBYs, QALYs and other policy-relevant outcomes (e.g. numbers of people achieving good General Certificate of Secondary Education (GCSE) results, lifetime income and poverty, employment, and crime outcomes). All outcomes derived from LifeSim will be interpreted as the long-term effects of referral, relative to non-referral, of parents to a co-located money advice service during the child's infancy, and will provide greater understanding of whether the intervention supports children's ability to achieve their fullest potential over the lifecourse.

Time horizon: Lifetime of the newborn babies.

Discounting: All costs and outcomes will be discounted at an annual rate of 3.5%, with sensitivity analysis using a 1.5% discount rate for health and wellbeing outcomes in line with HM Treasury "Green Book" guidance on economic appraisal in central government.

Statistical methods: Extrapolation of short-term trial outcomes (PHQ-8, GAD-7, household income) across the lifecourse using microsimulation, based on two linked LifeSim models: (1) LifeSim Childhood from 0 to 17, and (2) LifeSim Adulthood from 17 to the rest of life.

Sensitivity analyses: Probabilistic sensitivity analysis together with additional scenario analysis to handle structural uncertainties. These include the potential for "generational changes" in our data (e.g. the possibility that some of our model parameter estimates based on data from "Generation Z" born in 2000 may differ from those for babies born into "Generation A" in the 2020s).

9.2 Within-trial cost-effectiveness

This will be a long-term model-based evaluation.

9.3 Health economic modelling

RQ1. Figure 2 provides an overview of how WP1 links to WP2. Key trial outcomes that will inform long-term health, economic, social, and wellbeing outcomes for children include effects on parental depression (PHQ-8), parental anxiety (GAD-7) and household income. Given the following measures are based on similar concepts of anxiety and depression, we

will develop a mapping algorithm between the PHQ-8, GAD-7 and the Parental Malaise 9-item scale available through the Millennium Cohort Study (MCS) data and LifeSim.

Figure 2.

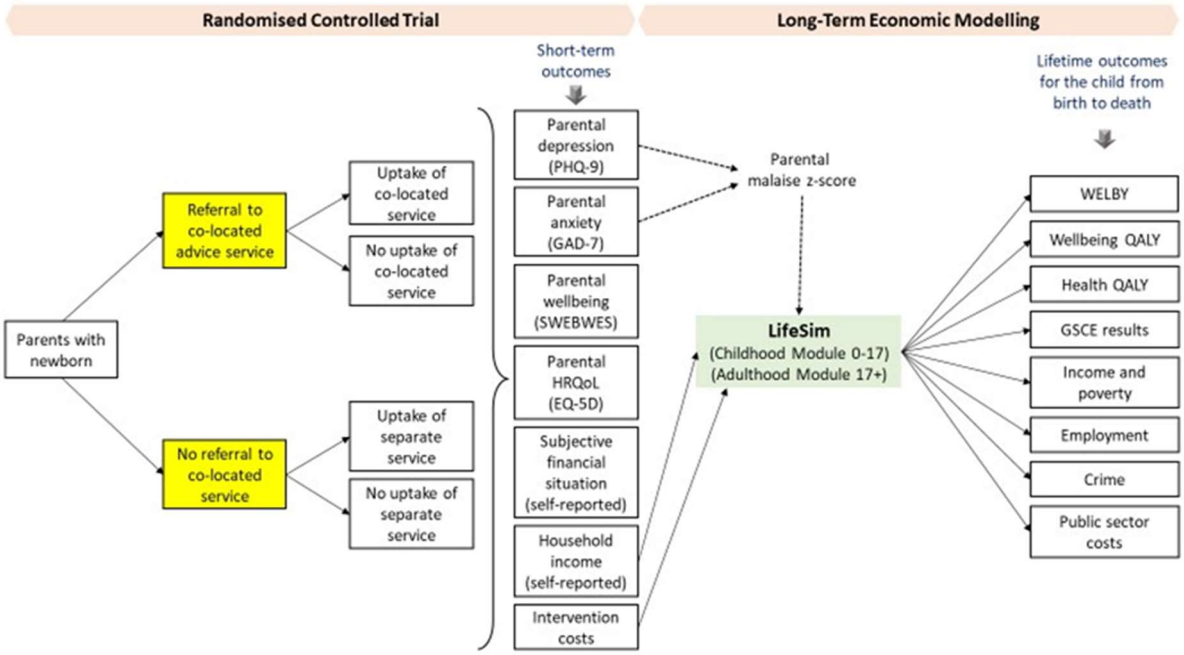


Figure 2. HWFinEL modelling approach

LifeSim will then be used to produce modelled individual-level simulated estimates of the long-term consequences for children of improvements in family income and parental mental health in infancy, including outcomes up to age 17 using the LifeSim Childhood module and outcomes for the rest of life using the LifeSim Adulthood module.

RQ2. To determine the long-term cost-effectiveness of a co-located WBA in LBTH, relative to no co-located WBA.

LifeSim will be used to extrapolate the long-term benefits for children, and related long-term cost savings to the public purse, of improvements in family income and parental mental health in infancy.

To harmonise the household income effects measured in the trial with the household income outcomes used in LifeSim, we will inflate year 2000 incomes using the standard gross domestic product (GDP) deflater used in UK central government economic appraisal. In further robustness checks we will harmonise our income variables using proportional changes and relative measures of income including income decile groups and the relative poverty line in both years (60% of median household income) to enable estimation of the consequences of shifting people from one decile group to another, and in and out of relative poverty.

Analysis will predict the long-term causal effects of changing family income alone, and parental mental health alone, and changing both outcomes together. To account for the potential reciprocal and mediating relationships between parental mental health and

household income, where improving household income may improve parental mental health, and vice versa, we will also conduct a mediation analysis using the first three sweeps of MCS data (at ages 0, 3 and 5). This will help us avoid double counting of long term benefits and clarify the direct effects of improvements in household income on parental mental health.

Long-term public costs are already programmed into LifeSim[17] and entail public costs across four sectors: National Health Service (NHS) England, social care, education, and criminal justice. Short-term costs entail those related to the intervention (referral) and comparator (no referral). These will be ascertained using data collected during the trial on the type and number of advice service appointments attended, the average length of appointment and known advice staff costs. We will also record the cost of organising the appointment, which will comprise the time spent making the appointment and the cost of this time in the health visitor enrolment service. We will also liaise with local authority finance officers to discuss the costs of organising and delivering the WBA service, compared with conventional services, to ensure we are not missing any important delivery costs.

RQ3. Baseline demographic and economic characteristics of the trial intervention and control groups (e.g., household income, ethnicity, index of multiple deprivation (IMD) area-based quintile groups), will be used to make suitable assumptions about how short-term effects might generalise from the trial population to different segments of the general population of England with similar economic characteristics and capacity to benefit from WBA services. Our assumptions will be based primarily on rapid literature review and feedback from experts in welfare policy and the tax-benefit system in England, and secondarily on sub-group analysis by income and IMD within the trial sample (section 8.3.4). Outcomes will inform the reduction in lifetime inequality in health and wellbeing between babies born into the richest and poorest fifths of households in England.

9.4 Sensitivity analyses

To estimate the general degree of uncertainty in cost-effectiveness estimates produced by LifeSim, we will conduct probabilistic sensitivity analysis based on empirical distributions around all the general causal effect parameters in LifeSim. To estimate the specific degree of uncertainty around key parameters of interest, such as a potential decline to the long-term sustained effect on maternal mental health, we will conduct scenario analysis using scenarios constructed in consultation with experts and informed by rapid literature review. We will also conduct scenario analysis around key assumptions about how the uptake of co-located money advice services varies among those with varying baseline economic circumstances (household income and IMD quintile group) and how the effect of uptake varies for those with varying levels of baseline economic circumstances (e.g. the richest fifth of households in England are less likely to be eligible for substantial unclaimed welfare benefits than the poorest fifth).

9.5 Additional considerations

If the trial does not meet the progression criteria (red traffic light), or referral to the co-located money advice service proves ineffective in improving short-term parental outcomes, LifeSim will be used to determine the minimum (threshold) level for which referral and uptake of the co-located money advice service is required to result in long-term cost-effectiveness. This

will inform the future design, implementation, and evaluation of co-located money advice service interventions.

10 Process Evaluation (embedded within WP1 trial)

Within the trial and WP1 will be an embedded process evaluation. The process evaluation will address key questions of implementation and delivery of the HWFinEL intervention.

This is an overview of the process evaluation. Process evaluation participant documentation, questionnaires, checklists and interview topic guides will be added as an amendment at a future date.

10.1 Theoretical framework

Theoretical frameworks from implementation science help clarify implementation questions, provide validated instruments to assess outcomes and barriers, and offer theory-driven explanations for success or failure. This evaluation will use the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance; Glasgow et al., 1999[19]), a widely used tool for translating research into practice and assessing public health impact. RE-AIM focuses on:

- **Reach**: the percentage of the target population that participates in a program
- **Effectiveness**: the positive and negative outcomes of the program
- **Adoption**: the percentage of settings and staff that participate
- **Implementation**: the extent to which the program is delivered as intended, including cost
- **Maintenance**: the sustainability of primary outcomes beyond six months.

We will explore the implementation of HWFinEL, through:

1) An implementation check list
2) Normalisation Process Theory (NPT; May et al., 2009[20]) will be used. NPT helps understand the adoption, implementation, and maintenance of practices by focusing on four mechanisms:

- **Coherence**: understanding the aims and logic of the intervention
- **Cognitive participation**: building and sustaining a community of practice
- **Collective action**: the operational work to embed the intervention
- **Reflexive monitoring**: assessing and evaluating the intervention's impact.

Together, RE-AIM and NPT provide a comprehensive approach to evaluating and understanding implementation processes and outcomes.

10.2 Methods

10.2.1 Data Collection

- Anonymised data recording the number of parents eligible for the trial and those that take up the offer, collected at 6-8 week appointment with their health visitor.
- Qualitative interviews with 45 purposively selected participants, selected at random to represent diverse (ethnicity, gender, household structure) backgrounds and locations in the borough, will provide data on the experience of using the service and will inform the effectiveness of the service in the eyes of the users

- Approximately 20 council staff who deliver, have oversight of, or host the intervention will be asked to take part in telephone or face to face interviews at the mid-point of the trial (approximately 8 months after recruitment begins) towards the end of the intervention period. Interview questions will include: facilitators and barriers to set up and continuous monitoring, contextual factors affecting intervention delivery and sustainability.
- An implementation check list at 2 time points
- Researcher observations and fieldnotes during the set up and support phases of the intervention about what worked (or did not), for whom and in what circumstances to produce implementation themes.
- Notes of meetings of intervention oversight groups which document evolving decision making will be thematically organised. These notes will be continuously monitored during the set up and implementation phase to inform the internal pilot (see section 3.3.4). Findings will document how adaptations had to be made and why, what feedback mechanisms were in place and how they worked, what, if any, were unintended consequences, and what possible forward trajectories for the intervention[21].

10.2.2 Analyses

- Our analytical approach will involve a structured and robust process of data collation, sorting, coding and thematic investigation against the evaluation questions (data analysis). An overview of the methods can be found in the table below.

Table 6: Process evaluation methods overview

REAIM domain	Data collection methods	Data collected	Data analysis methods
Reach	HVs appointment records All new mothers approached by HV	Anonymised data on Attendance, eligibility and interest in participation	Quantitative analysis
Reach	WBA administrative data	Attendances, benefits claimed	Quantitative analysis
Effectiveness	Trial	Participant questionnaires including financial gain and mental health outcomes	Quantitative analysis
Effectiveness	Parent interviews in person or virtual interview, recorded or notes taken	45 participants from intervention and control arms of the study. And 20 staff who deliver the intervention	Qualitative thematic analysis
Adoption/implementation/ maintenance	interviews with intervention stakeholders	20 staff who deliver, have oversight of, or host the intervention	Qualitative thematic analysis
Adoption/implementation	Pre- implementation checklist	Minimum of 8 CFCs managers/ staff	
Adoption/implementation	Post- implementation checklist	Minimum of 8 CFCs managers/ staff	
Adoption/implementation/ maintenance	In person observation, note taking	Minimum of 8 CFCs managers/ staff	Qualitative analysis of observation notes
Adoption/implementation/ maintenance	Notes of meetings of intervention oversight groups	All new mothers approached by HV	Quantitative analysis

Qualitative data will be recorded, transcribed and analysed thematically. There are two main lines of enquiry for this data. The first (focussed on in the 45 participant interviews) is about the participant's experience of the service and its impact on their lives, augmenting the quantitative analysis, while the second (focussed on in the 20 interviews with delivery staff and 8 CFC managers/ staff) is about the organisational arrangements for delivery. An initial coding structure will be developed in advance, building on earlier work by the team (feasibility study, PPI consultations), and by Reece's study in Bradford, but this will be flexible to modification as themes emerge from the data. Coding will be undertaken by two researchers, with a sample cross checked by a second coder. NVivo or similar software will be used to facilitate the coding and analysis. Analyses of experience will focus on how and in what ways the advice has been taken up, impacts on household, and child activities and wellbeing, while analyses of organisational arrangements will focus on how and in what ways implementation was consistent across centres, what challenges were raised and how overcome, and how the implementation might best be adapted. Preliminary interpretations will be checked with the PPI group. Findings will be compared with those from the Glasgow model[10], Beardon's work on HJP implementation[9] and Reece[7] to understand mechanisms of staff engagement, organisational arrangements and, indirectly, of families' health improvement.

10.2.3 Triangulation of findings

For all research questions, findings from interviews will be triangulated with findings from observations, participatory research etc to provide a rounded understanding of the implementation of the intervention model. The analysis will involve detailed thematic investigation based on the evaluation questions and themes identified in the analysis framework.

We will use thematic analysis to analyse transcripts. We use an inductive approach so that our findings are grounded in what participants have said and there is a clear link between themes and the data. We use NVivo software to help develop our analytical themes

In practice, the analysis will:

- Involve *familiarisation* with all data, to describe and interpret the findings across the main research aims and questions, by participant type. We will also identify any *unexpected themes* in terms of participant experiences or perceived outcomes/impacts.
- Assess *commonalities and differences* participant groups or data sources, unpicking the reasons for these. We will conduct within (e.g. CFCs) and between case analyses (e.g., across CFCs), triangulating the views of the different groups.
- Triangulate qualitative interview and quantitative data to help explain the impact findings.

11 Service Design for Marginalised Mothers (WP3)

The aim of WP3 is to co-design a draft toolkit for co-located WBA and health services aimed at marginalised mothers for whom there are particular difficulties of access to money advice.

11.1 Research questions

RQ3.1 What are the barriers and facilitators to accessing WBA (welfare benefits, employment, housing, debt) for marginalised mothers?

RQ3.2 How can a service to co-locate WBA with health services be designed to suit the circumstance of marginalised mothers?

11.2 Theoretical underpinning

The health of young children whose mothers are marginalised through social factors such as inadequate housing and income, and policy-related barriers such as access based on citizenship status is at risk[22]. Young mothers report that mental health is hard to achieve without stable foundations such as housing and having sufficient income to support children's basic needs[23].

Mothers who arrive in the UK seeking asylum are a highly vulnerable group whose antenatal care is often delayed, giving rising to poorer perinatal outcomes[24]. Children of migrant mothers are at risk of neurodevelopmental delays and missed interventions[24]. Recently arrived mothers face multiple service access barriers including ineligibility for routine health care until their citizenship status is resolved. Once it is resolved, employing a 'proportionate universalism' approach demands that particular effort is made to address health inequities, but there are no established models of co-located, integrated or streamlined WBA and health services that focus on the life circumstances and constraints of these mothers or similar groups. However, it seems likely that enhancing access to financial resources will not only improve financial and health and wellbeing outcomes for marginalised mothers and their children but will also ultimately reduce demand on the health service.

Understanding the specific service access barriers and needs of this group and how these might be addressed is thus very important in its own right. But focusing on this group will also act as an exemplar through which we can examine how WP1 findings on implementation and outcomes, and existing guidelines for implementing co-located WBA and health services, might be adapted in service planning.

11.2.1 The setting

A charity in the London Borough of Newham (LBN) supporting mothers with children under five who have limited or no recourse to public funds through their immigration status. When a right to remain in the UK is granted the charity offers this group, known as 'graduates', a series of workshops around rights, entitlements and financial literacy. The charity, Magpie , has agreed to work with us and their 'graduate' group, who are starting to establish themselves in an area, and provide for their children, and are in the process of acquiring financial and cultural knowledge. The charity provides activities and advice to those in temporary accommodation and signposts them to other sources of help. Approximately 300 families are known to the service at any one time, and ten new families arrive every week. Less than a fifth of the total are 'graduates'.

11.2.2 Design

WP3 will adopt a two-phase qualitative design, employing immersive ethnography and co-production workshops, to create an Experience Based Co-Design (EBCD) toolkit for co-located WBA and health services. EBCD in health care improvement has a six stage process (set up, engaging staff, engaging parents, co-design meeting, co-design teams, celebration event) but is often adapted to specific circumstances[25]. EBCD foregrounds the experience and participation of the target group as vital to developing effective services that improve accessibility and uptake[25]. Engaging marginalised groups in this process is often limited by power imbalances, lack of trust, and structural and practical constraints; addressing these requires an in-depth, relational approach[26] rather than rigid steps, hence we will use an adapted version of EBCD focusing on gathering experience in phase 1 and designing a service in phase 2.

To address RQ3.1: in phase 1 an embedded researcher (the project's qualitative Research Fellow) will volunteer with Magpie for a period of six months, two days a week, to observe and document the daily experience of accessing financial resources, which may be via welfare benefits, employment, debt or housing advice. Observation will follow an agreed framework, and will be participatory, in that the researcher will, when asked, provide in-kind assistance to help women to complete paperwork, prepare food, take part in discussions and activities. The researcher will record observations using fieldnotes (descriptive and interpretive). The aim of this phase is to build a 'rich picture' or 'thick description' of the everyday experience of accessing services. When trust is established, the researcher may be able to ask questions of the graduate group, such as about their financial and health strategies, child activities and aspirations for the future. Field data will be recursively examined with the research team (including the PPI group) to arrive at a set of common themes which will form the basis for the second phase of work.

To address RQ3.2: phase 2 will recruit a group of 8-10 graduates who have become accustomed to the embedded researcher and who agree to be the 'design team'. Following the co-design principle of participation, we will adapt the 5D procedure for appreciative inquiry using five sequential workshops with the same graduate group[27]. Each workshop will be held in the premises of the charity, and every effort will be made to ensure design team members feel safe and valued. Workshop 1 will introduce design principles and group work ground rules. Workshop 2 (5D 1 and 2: Define, Discover) will verify the themes gathered in phase 1 and add any new information including about evidence from HJPs. Workshop 3 (5D 3: Dream) will begin the process of imagining new possibilities for co-located WBA and health services. Workshop 4 (5D 4: Design) starts to develop the ideas from Workshop 3 into workable options. Workshop 5 (5D 5: Deliver) consolidates the process of implementation design taking into account the emerging evidence from WP1.

11.2.3 Analysis

Data (fieldnotes of observation sessions, recordings of conversations with graduates in phase 1, recordings and visualisations in phase 2) will be assembled by the qualitative Research Fellow using Nvivo software to describe everyday (barriers to) access to health services and money advice, whether co-located or not, and then to describe potential models for delivery of more streamlined, integrated or co-located models. The data collection

period will include researcher reflection sessions where observations and impressions can be subject to critical review with the research team on at least a monthly basis. As a volunteer, the Research Fellow will have access to the charities' workplace based reflection sessions to clarify understandings where necessary. A preliminary coding framework will be agreed with the graduate group and reviewed by the charity's leadership team. Next, thematic coding will be completed by the project Research Fellow and moderated with the team. Findings will be reviewed with the graduate group if they are still contactable.

11.2.4 Output

WP3 will result in a draft toolkit for local authorities, charities and HJPs that is grounded in the experiences, views, and participation of this specific group of marginalised mothers about how existing guidelines for implementing co-located WBA and health services might be adapted. This toolkit will be reviewed by the PPI group and in a WP4 workshop.

12 Knowledge Exchange and Policy Impact (WP4)

The aim of WP4 is to spread the learning from WP1-3 to local, regional, national and international audiences via multiple pathways. This WP will also include oversight of the PPI work of the project as detailed in the 'Application Details'.

The engagement strategy agreed with the borough is as follows:

Tower Hamlets council have in place an extensive network of parental engagement structures that we will be working through and with, with the assistance of our local authority partners. Aside from general groups there are more specific groups including a Dads Network, Somali Parents and Carers Network, SEND parents and carers group (each with approx. 100 individuals on mailing lists).

Initially we invited nominations to join a PPI standing group via the professional networks of the PPIE lead, Pratima Singh. We will expand this group to meet project needs using such forums as the Parent & Carer Council, and Newham public health officers. We plan to continue outreach about the project via established links with the Bromley by Bow Centre's social prescribing and social welfare advice work, via East London Foundation Trust's work that is building on our feasibility and acceptability pilot, and via established links with Tower Hamlets' councils' key governance boards (Every Chance for Every Child Forum, Children & Families Executive–) and, and at key operational partnership forums, including the Maternity & Early Years Working Group, to ensure that all key stakeholders are aware of the study.

12.1 Background and approach

This project was conceived and developed in partnership with local stakeholders (including the LBTH tackling poverty, early help, public health, maternal health and child health teams) under the auspices of UK Prevention Research Partnership (UKPRP) funded ActEarly (2019-2024), a city collaboratory promoting early health and life chances in Tower Hamlets and Bradford. We have developed strong collaborative networks with local health and community organisations in both Tower Hamlets and Newham through our HWFinEL

feasibility and acceptability study, and an 'impact project' coordinated by CC, to develop accessible materials for and with borough officers. LBTH is an NIHR HDRC (Health Determinants Research Collaboration) and committed to evidence partnerships. We are therefore well placed to disseminate our evidence to local council officers, voluntary sector organisations, parents and residents.

However, our research will also be of interest to a broader range of audiences, including our substantive findings about co-location of benefits but also our methodological approach in pioneering the use of the LifeSim long-term modelling platform to extrapolate short-term trial findings into the longer term, which will be of interest to numerous national stakeholders in potential future applications. We will therefore develop an impact strategy in the early months of the project tailored to these four distinct policy, practice and academic audiences: (1) local (LBTH and LBN); (3) regional (London); (3) national (UK) and (4) international, as described below in turn. We will tailor our dissemination activities appropriately to different audiences, and to help tie things together our central online communication platform will be the UCL webpage linked to UCL and University of York output digital storage. Social media, newsletters and networking activity will channel audiences to this webpage and invite audiences to interact with the project team. We will ensure regular communication throughout the project between the research team and diverse stakeholders.

12.2 Local knowledge exchange and impact activity

12.2.1 How

We will continue to build on our strong local collaborations with LBTH and LBN stakeholders. Year 1 researcher led inauguration of local project oversight groups will raise awareness among the multi-disciplinary professionals working with and in children and family centres. Researchers will present evidence about the potential impacts of the intervention at staff meetings and will channel materials through centre based 'champions'. Since this project aligns well with the activity of local Family Hubs now coming on stream, progress updates will be fed through to area managers, who meet with public health and children's services officers, who in turn feed through to the Children and Culture Directorate Leadership Team. These existing structures in both LBTH and LBN will thus enable early knowledge exchange about project progress.

12.2.2 What

Using snowballing techniques project Research Fellows will develop a database of relevant organisations and individuals in LBTH and LBN and invite them to join our mailing list and visit our webpage. Four visually appealing policy briefings covering different aspects of impact on local population and services: i) short term financial and health outcomes, ii) process of service organisation, iii) codesigned draft toolkit for co-located money and health advice for marginalised families, iv) longer term outcomes over childhood and adulthood.

Associated short video for wide distribution via LBTH and LBN borough communication channels to parents, residents, professionals and organisations. Study participants may also elect to receive these outputs.

12.2.3 Workshops

Three workshops focused thematically on translating findings into practice aimed at i) welfare benefits advisory services and tackling poverty teams; ii) health and community practitioners supporting families e.g. in family hubs, general practitioner (GP) practices, HV, schools, faith and other voluntary organisations; iii) specialist health and community services working with marginalised mothers and fathers (e.g., homelessness, refugees, domestic violence, those who are destitute and so on). Each workshop to outline findings on impact, and organisation of service delivery and aimed to draw up localised solutions guided by health justice partnership principles.

Workshop reports, videos and policy briefings will be freely available on the project webpage.

12.3 Regional

Local authorities in London will be interested in study findings especially where populations have a similar high child poverty profile to those in Tower Hamlets and Newham (all but three London boroughs have a child poverty rate at or above the national average). One of the London Mayor's top priorities is ameliorating the impact of the cost of living crisis on Londoners which is aligned with the aims of this project.

12.3.1 How

Building out from our existing advisory group; we already have links with similar projects in Camden and Hackney, with the UCL Centre for Health Justice, the London Office for Health Improvements and Disparities (OHID), the North East London CLARC, the health advisor to the London Mayor, the HDRC London group, and East London Foundation Trust, which is aiming to become a first Marmot Trust, focusing on actions to improve child wellbeing.

12.3.2 What

Develop a regional network of HWF interested regional organisations and representatives using internet searches, snowballing techniques and a short online survey tool.
Email newsletter to network members in years 2 and 3, signposting the four briefings, videos and workshop reports.

12.3.3 Invitation to a hybrid conference in year 3

Invitation to some members to join our TSC and ask them to distribute outputs via their networks. Presentation to the OHID chaired Health Equity Group, the pan London forum for overseeing and co-ordinating NHS action on healthcare inequalities and preventive care, and we will respond positively to invitations to present our findings to regional health and community services audiences.

12.4 National

Numerous national organisations are interested in at scale solutions to ameliorate impacts of poverty on child and family health and wellbeing. We will exchange knowledge about the co-location of money advice and health services for parents of newborns by liaising directly with national anti-poverty charities (e.g. Child Poverty Action Group, Action for Children and Save the Children), central government spending departments (e.g. Department for Work and Pensions, Department for Education, Department of Health and Social Care, OHID), national

knowledge mobilisation organisations (e.g. the Foundations What Works Centre for Children and Families), and other relevant national stakeholder organisations (e.g. the Royal College of Paediatrics and Child Health or National Centre for Family Hubs).

12.4.1 How

We will exploit and build on our broad existing national networks and links with all the above stakeholder groups with whom colleagues are connected, including the national advisory group for our LifeSim long-term childhood modelling programme (which has representatives from all the aforementioned central government spending departments and knowledge mobilisation organisations) and our links with the UCL Centre for Health Justice and the UCL Institute for Health Equity, Health Equity North, the Anti-Poverty Coordination Group of Bradford Metropolitan District Council, the Glasgow model team (Glasgow Centre for Population Health), Sian Reece (University of York), Nick Axford and Vashti Berry (ARC South West Peninsula.

12.4.2 What

We will coordinate and host a working group of interested academics operating within the current UK welfare contexts, with two aims: i) sharing general implementation knowledge in a changing service landscape; and ii) building knowledge about what works from our innovations in relation to co-located welfare advice services in health and community settings, particularly for fathers and very marginalised groups. Invite all the national level charities, government departments and knowledge mobilisation organisations to join our network.

In year 2, we will lead on a joint working group hosted webinar with major national child poverty and family support charities showcasing evaluations from across the UK and overall progress, with selected case studies, and a solution focused agenda. Webinar recording and report will be available on the project webpage.

As findings become available, we will produce academic papers focused on a) trial outcomes for parental mental health and finance; b) organisational delivery challenges and opportunities; c) toolkit for services aimed at enabling access to co-located health and money advice for highly marginalised parents; d) longer term childhood and adulthood outcomes, for submission to high profile journals aimed at the UK context.

12.5 International activity

Co-located money advice and health service as a means to address health inequity is becoming an international concern.

12.5.1 How

Via our membership of the HWF international working group led by Anna Price, Melbourne University, we have access to international scholars and networks.

12.5.2 What

- Use the international working group to discuss difficulties and present early findings.

- Host two online seminars focusing on a) intervention models and b) parent and child outcomes from studies in four countries. Consider whether a core outcomes set would benefit further studies in this field.
- In year 3 a final hybrid conference bringing together the HWF international network, local and regional stakeholders including from the Department of Work and Pensions, OHID, Institute of Health Visiting, Department for Education (DfE) and Department of Health and Social Care (DHSC) who jointly run the Family Hubs programme, Royal College of Midwifery

As a result of these activities, we anticipate that local, national and international stakeholders in health equity for families with newborn babies will have access to process and impact data about this form of HJP in formats acceptable to a range of audiences. If, as anticipated, East London families are substantially better off and their mental health has improved, and we have gathered robust information on the process of establishing this form of HJP, we will be able to promote models for replication in other NHS regions through the above tools and routes.

13 Regulatory & Ethical Issues

13.1 Compliance

13.1.1 Regulatory Compliance

This trial will adhere to the principles and conditions of Good Clinical Practice (GCP).

In conducting the trial, the Sponsor, UCL CCTU and CFCs shall comply with the protocol and with all relevant guidance, laws and statutes, as amended, applicable to the performance of clinical trials and research including, but not limited to:

- UK Policy Framework for Health and Social Care Research, issued by the Health Research Authority
- Declaration of Helsinki 1996
- Data Protection Act 2018 (DPA number: Z6364106),
- General Data Protection Regulation (EU)2016/679 (GDPR)

13.1.2 CFC Compliance

Agreements that include detailed roles and responsibilities will be in place between participating CFCs and CCTU.

Participating CFCs will inform CCTU as soon as they are aware of a possible serious breach of compliance, so that CCTU can fulfil its requirement to report the breach if necessary (see section 7.9).

13.1.3 Data Collection & Retention

Clinical notes and administrative documentation should be kept in a secure location (for example, locked filing cabinets in a room with restricted access) and held for a minimum of 5 years after the end of the trial. During this period, all data should be accessible, with suitable

notice, to the competent authorities, the Sponsor, and other relevant parties in accordance with the applicable regulations. The data may be subject to an audit by the competent authorities. Medical files of trial participants should be retained in accordance with the maximum period of time permitted by the CFC, or UCL CCTU.

13.2 Ethical Approvals

13.2.1 Ethical Considerations

The following ethical considerations relating to this trial have been considered extensively and every effort has been made to minimise them and their impact on participants:

- Any additional contact will be prioritised if there are safety concerns
- Any treatment/intervention that may be denied to the participant or withheld during the trial
- Any additional short-term or long-term risks of participating in the trial
- Effects on life insurance (sometimes known as assurance) policies
- Participants will not be able to choose their own treatment/intervention if this is a randomised controlled trial (RCT)
- Availability of trial intervention after the trial if the intervention is positive
- Reimbursement of time and expenses
- The collection of sensitive or personal data
- Publication of data and feedback of overall results (not individual results) to participants
- Coincidental findings: extra information may uncover some other previously unknown circumstances

13.2.2 Ethics Committee Approval

Within the UK, following main REC approval and Health Research Authority (in England) approvals and before initiation of the trial at each CFC, the local information pack will be submitted to each CFCs Research and Development (R&D) office or equivalent (if applicable) by UCL CCTU. The local information pack will contain the protocol, informed consent forms, and information materials to be given to the prospective participant, the Organisation Information Document (OID), and the validated Schedule of Events Cost Attribution Template (SoECAT). Any further substantial amendments will be submitted and approved by the main REC and HRA.

The rights of the participant to refuse to participate in the trial without giving a reason must be respected. After the participant has entered the trial, the researcher must remain free to give alternative treatment/intervention to that specified in the protocol, at any stage, if s/he feels it to be in the best interest of the participant. The reasons for doing so, however, must be recorded; the participant will remain within the trial for the purpose of follow-up and data analysis according to the intervention option to which they have been allocated. Similarly, the participant must remain free to change their mind at any time about the protocol intervention and trial follow-up without giving a reason and without prejudicing their further treatment/intervention.

13.3 Competent Authority Approvals

This is not a Clinical Trial of an Investigational Medicinal Product (IMP) as defined by The Medicines for Human Use (Clinical Trials) Regulations 2004/1031 for UK only. Therefore, a Clinical Trial Authorisation (CTA) is not required in the UK.

13.4 Other Approvals

The protocol will be submitted by those delegated to do so to the relevant R&D department of each participating CFCs (if applicable) or to other local authorities (LBTH council) for approval as required. A copy of the local permissions (or other relevant approval as above) and of the PIS and consent form on local headed paper must be forwarded to the CCTU before participants are entered.

13.5 Trial Closure

Trial closure is defined as the date when all data have been received, cleaned and all data queries resolved and the database locked for final analysis.

The REC/HRA will be notified within 90 days of trial completion. Within one year of the end of the trial, the CCTU will submit a final trial report with the results of the trial, including any publications/abstracts of the trial, to the HRA. In case the trial is ended prematurely, the CCTU will notify the HRA within 15 days, including the reasons for the premature termination.

14 Indemnity

UCL holds insurance to cover participants for injury caused by their participation in the clinical trial. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical trial is being carried out in a hospital, the hospital continues to have a duty of care to the participant in the clinical trial. UCL does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or not. This does not affect the participant's right to seek compensation via the non-negligence route.

Participants may also be able to claim compensation for injury caused by participation in this clinical trial without the need to prove negligence on the part of UCL or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in the first instance to the Chief Investigator, who will pass the claim to UCL's insurers, via the Sponsor's office.

Hospitals selected to participate in this clinical trial shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to UCL, upon request.

15 Finance

HWFinEL is fully funded by the National Institute for Health and Care Research (NIHR), grant number: NIHR158551. It is not expected that any further external funding will be sought.

16 Oversight & Trial Committees

Trial oversight is intended to preserve the integrity of the trial by independently verifying a variety of processes and prompting corrective action where necessary.

There is a number of committees involved with the oversight of the trial. These committees are detailed below, and the relationship between them expressed in the figure.

16.1 Trial Management Group

A TMG will be formed comprising the Chief Investigator, other lead investigators (clinical and non-clinical) and CCTU staff and PPI contributors. The TMG will be responsible for the design, coordination and strategic management of the trial. The membership, frequency of meetings, activity (including trial conduct and data review) and authority will be covered in the TMG Terms of Reference (ToR).

16.2 Trial Steering Committee

The Trial Steering Committee (TSC) is the independent group responsible for oversight of the trial in order to safeguard the interests of trial participants. The role of the TSC is to provide overall supervision for the trial and provide advice through its independent Chair. The ultimate decision for the continuation of the trial lies with the TSC. The membership, frequency of meetings, activity and authority will be covered in the TSC ToR.

16.3 Independent Data Monitoring Committee

An Independent Data Monitoring Committee (IDMC) will not be convened due to clinically low risk nature of the research; however, a DMEC function will be adopted within the TSC to oversee data, safety and ethics.

16.4 Trial Sponsor

The role of the sponsor is to take on responsibility for securing the arrangements to initiate, manage and finance the trial. UCL is the trial sponsor and has delegated the duties as sponsor to CCTU via a signed letter of delegation.

17 Patient & Public Involvement

Patient and Public Involvement (PPI) in research is defined by INVOLVE (an advisory group established by the NIHR) as research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them. INVOLVE intends ‘public’ to include patients, potential patients, carers and other users of health and social care services, as well as people from

organisations, that represent people who use services. In some cases, this may include involvement of a trial's participants in guidance or oversight of a trial.

Incorporating feedback from PPI members is crucial for ensuring that the study is relevant, ethical, and participant-centred. Their involvement should be meaningful, provide accountability and they should feel that they have been listened to. This may require some deviations from standard trial recommendations and processes. This is in line with the NIHR recommendations on PPI involvement, that there is no 'one size fits all' approach[28]. Taking on board this feedback is also important for motivating PPI contributors and building trust by demonstrating that their input is valued and considered, therefore encouraging continued involvement in the research process. If the feedback from the PPI cannot be adopted, a clear explanation of the reason why should be provided.

17.1 Potential Impact of PPI

PPI will help with recruitment strategies to improve recruitment where required. PPI will help with the trial design and be able to provide patient perspectives and promote the trial. PPI will review the participant information sheet and consent form to ensure it has been written in lay terms for the understanding of a participant enrolling in this trial. PPI will also help with developing the trial logo. PPI will help with the dissemination of trial results and feedback to participants and the public. PPI will be able to engage with stakeholders and monitor changes in response to PPI activities and comments.

17.2 Identifying PPI Contributors

In this trial a PPI lead has been appointed, who is familiar with the East London area and has worked with many local communities including parents of young children. She will be the main conduit of communication between the TMG and members of the public involved in helping shape the work as it progresses. Training for PPI members will be provided where required and courses identified as helpful. PPI members will be reasonably reimbursed for their time and travel as a PPI member.

17.3 Protocol Design & Trial Set Up

PPI has been considered from the start of the trial, where the PPI lead consulted parents attendees at children and family centres in Tower Hamlets about the need for and proposed mode of delivery of the intervention, via one to one interviews, a poster advertising the consultation, discussions with centre managers and a quiz activity at a community centre 'research day'. The PPI lead has already been appointed and was a co-applicant on the trial funding application. The PPI lead has been involved in the trial set-up and design and has had input in reviewing the trial protocol, participant information sheet and participant dosing diaries.

17.4 PPI in the Ongoing Running of the Trial

The PPI lead and CI will meet regularly with the Borough's Public Health research lead, to ensure communication with members of the public regarding this study are fed through to relevant members of the council. The PPI lead will also convene a standing group of 6-8 parents with young children recruited via the Borough's Parent Carer Council. The standing group will meet throughout the lifetime of the study and will review study materials. The PPI lead will be a member of the TMG and will report back to the TMG any outcomes of these

meetings. A monetary budget is available for any necessary training that PPI members require to fulfil their roles.

18 Publication & Dissemination of Results

18.1 Publication Policy

18.1.1 Trial Results

The results of the trial will be disseminated regardless of the direction of effect. The publication of the results will comply with the UCL CCTU Publication Policies.

A lay summary of the results will be produced and disseminated with participants who provide permission to keep their contact information for its provision. The results will also be communicated to the public, parents of young children and policymakers and practitioners via webinars.

A summary of results will be submitted to the REC via the HRA (https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/) and published through an open-access mechanism in a peer-reviewed journal within 12 months of the trial closure.

A summary of results will be published within one year of the end of study, in the registry where the clinical trial is registered.

18.1.2 Authorship

All individuals who have made substantial intellectual, scientific and practical contributions to the trial and the manuscript, where possible, should be credited as authors; all individuals credited as authors should deserve that designation. It is the responsibility of the CI and, ultimately, the Sponsor to ensure that these principles are upheld.

18.1.3 Reproducible Research

The latest version of the protocol will be made available as supplementary material upon publication of the final clinical investigation report.

Applications for access to the trial dataset at the end of the trial, should be submitted formally in writing to UCL CCTU and will be considered, and approved in writing after formal consideration by the TSC and the CI.

19 Data Sharing

Requests for access to trial data will be considered, and approved in writing where appropriate, after formal application to the TMG/TSC. Considerations for approving access are documented in the TMG/TSC ToR.

Data will be shared accordingly based on the following principles:

- No data should be released that would compromise an ongoing trial or study.

- There must be a strong scientific or other legitimate rationale for the data to be used for the requested purpose.
- Investigators who have invested time and effort into developing a trial or study should have a period of exclusivity in which to pursue their aims with the data before key trial data are made available to other researchers.
- The resources required to process requests should not be under-estimated, particularly successful requests which lead to preparing data for release. Therefore, adequate resources must be available in order to comply in a timely manner or at all, and the scientific aims of the study must justify the use of such resources.
- Data exchange complies with Information Governance and Data Security Policies in all of the relevant countries.

In order to reflect the NIHR's position on open access to research materials, where research materials recording the outcome of the Research or details of the progress of the Research are submitted for publication, UCL shall either: 1) subject to confidentiality requirements and to applicable data protection considerations, make all information and data on which the research materials are based available on an open access basis; or 2) include a statement with the research materials detailing how such information and data can be accessed.

UCL shall ensure that the outcome of the Research is prepared for publication in a suitable peer-reviewed journal and shall ensure that it, and any other publication, including patent applications, of or resulting from research caried out by the grant shall acknowledge the NIHR's financial support and carry a disclaimer relevant to the programmes set out in the NIHR's research outputs and publications guidance as amended from time to time. Data will be available for sharing after publication of the trial results. Researchers wishing to access the HWFinEL trial data should contact the TMG in the first instance. Requests will need to be approved by the CI and Sponsor.

20 Protocol Amendments

Table 7. Summary of Protocol Amendments

Protocol version	Protocol date	Summary of changes
1.0	26Mar2025	N/A - new version
2.0	27May2025	• Figure 1: Trial Diagram and Section 1.4 Benefit Risk Assessment updated to include safety netting information • Section 3.3.2 Process of recruitment updated to include the addition of a simplified, easy-read PIS • Section 18.1.1 Trial results updated to include permission to be sought from participants to retain their contact details to receive a lay summary of the results. • Administrative changes

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