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The Children and Young People's Health Partnership (CYPHP) Evelina London Model of Care: Protocol for an Opportunistic Cluster Randomised Evaluation (cRCT) to Assess Child Health Outcomes, Healthcare Quality, and Health Service Use

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Abstract

Introduction

Children and young people (CYP) in many high-income settings, especially those with long-term conditions (LTCs), have poor health outcomes. Emergency and outpatient hospital service use is increasing unsustainably. To address these problems, the Children and Young People's Health Partnership (CYPHP) has developed and is evaluating an integrated model of care as part of a health systems strengthening programme across two boroughs of London, UK. The CYPHP Evelina London model of care comprises proactive case-finding and triage, specialist clinics, and transformative education and training for professionals working with CYP. Services are delivered by multidisciplinary health teams with an emphasis on increased coordination across primary, community, and hospital settings and integration of physical and mental healthcare that accounts for the CYP's social context.

Methods and analysis

The phased roll-out of the CYPHP Evelina London model allows an opportunistic population-based evaluation using a cluster randomised controlled trial design. Seventy GP practices across two London boroughs, grouped into 23 clusters, were randomised to provide either the CYPHP model of care (n=11) or enhanced usual care (n=12).

The evaluation will measure the impact of the CYPHP Evelina London model of care on child and parent health and wellbeing, healthcare quality, and health service use up to two years post-implementation. A population-level evaluation will utilise routinely collected pseudonymised healthcare data to conduct a service-use analysis for all CYP registered with a participating GP (n=~90,000) with the rate of non-elective admissions as the primary outcome. We will seek consent from a subset of this population, with specific conditions (target n=2138) to assess the impact on patient-reported outcomes using the PedsQL as the primary outcome.

Ethics and dissemination

Ethics approval obtained from South West - Cornwall & Plymouth Research Ethics Committee. Results will be submitted for publication in peer-reviewed journals.

Trial registration number: Clinicaltrials.gov Identifier: NCT03461848; Pre-results.

Keywords: Child health, integrated care, cluster randomised controlled trial

Strengths and limitations of this study

- The Children and Young People's Health Partnership (CYPHP) Evelina London model of care is a new model of integrated, comprehensive, coordinated and tailored care that will be delivered to a population catchment of over 90,000 children and young people across a large and diverse area of south London, UK.
- The opportunistic cluster randomised controlled trial design enables unique and rigorous testing of a new model of care, as a population level health services intervention, for child health in the UK.
- Patient-reported and routine service use data will provide information on effectiveness and cost-effectiveness of the CYPHP model of care on outcomes relating to CYP health and wellbeing, healthcare quality, and health services and systems. Linkage of pseudo-anonymised health service use data will allow population level impact to be assessed.
- While it is anticipated that not all eligible CYP will participate in the evaluation, we aim to identify barriers and enablers to accessing the new model of care through a nested process evaluation study providing detailed information about implementation.

Introduction

Approximately 20% of childhood deaths across the USA, England, Australia, and New Zealand are thought to be preventable through better clinical care and patient self-management, with higher proportions in specific categories such as children and young people (CYP) with chronic conditions.[1] Between 60 and 70% of children who died in the UK between 2001 and 2010 had a chronic condition requiring frequent contact with the health system.[2]

Chronic, non-communicable disease accounts for 79% of all disability adjusted life years lost (DALYS), in young people aged 1-14 years across Europe, with respiratory diseases (mainly asthma), neuropsychiatric disorders, congenital abnormalities and musculoskeletal disorders the predominant causes of morbidity.[3] This is mirrored in data from North America and Australia.[4-5]

The current model of hospital-centered paediatric care in high-income countries was developed to deliver acute inpatient and high intensity specialist services, rather than high quality care for CYP with LTCs who need multidisciplinary, coordinated planned care to prevent illness and disease complications, and to maximize wellbeing and developmental potential.[6] The current healthcare model, in the context of the wider health and social care system in the UK, has resulted in suboptimal health outcomes for both acute and chronic illness.[7-8] Finally, current services are not as responsive to families' needs as they should be, and are often inefficient with a reliance on high-cost emergency department attendance and acute admissions.[3,6,9] This is mirrored by inefficiencies seen in other high-income countries.[10] There is an urgent need to develop new evidence-based, cost-effective and sustainable health care services to meet the increasing demands caused by the rising prevalence of chronic illness across the life course.[3,11-13]

The CYPHP Evelina London model was conceived in response to the evolving health care needs of CYP, and the dearth of evidence for health service commissioners and planners on how to address these needs. The CYPHP Evelina London model is an innovative approach to reshaping everyday healthcare services, expanding on the principles of integrated care.[14-15] CYPHP Evelina London brings together physical and mental healthcare, and delivers services taking into account the social context of the family. It integrates primary and secondary healthcare, and links healthcare with local government efforts to improve the wider determinants of health. A major focus of the CYPHP Evelina London model is improving front line care for all CYP. This is vital as primary care and accident and emergency departments are where the majority of healthcare is delivered in the UK context, and act as the gateway to other services. Front line care can therefore be an enabler or barrier for the rest of the system to function well. In particular, effective and efficient urgent care is important to ensure that sufficient resources are available for the planned, proactive, comprehensive care that CYP with LTC need. This evaluation of the CYPHP Evelina London model of care is designed to generate robust evidence on effectiveness and cost-effectiveness of an integrated model of care for CYP when delivered at scale to inform local, national, and international service providers and commissioners.

Evaluation overview

The evaluation, a population-based cluster randomised controlled trial (cRCT) with over 90,000 CYP has four component parts: 1) a pseudonymised population-based evaluation for all CYP in participating GP practices, 2) an evaluation of patient-reported outcomes from CYP with one of four specific (or 'tracer') conditions, 3) a process evaluation, and 4) an economic evaluation. The broad evaluation aims are:

(i) To evaluate the impact of the Children and Young People's Health Partnership (CYPHP) Evelina London model of care on the health, healthcare, and health service use of CYP; at the population level and for CYP with tracer conditions.

(ii) To understand through the process evaluation how and why the CYPHP Evelina London model is effective or ineffective, and to identify contextually relevant strategies for successful implementation as well as practical difficulties in adoption, delivery, and maintenance to inform wider implementation.

(iii) To assess the costs of delivery and cost-effectiveness of the CYPHP Evelina model of care compared with enhanced usual care (EUC), through the economic evaluation.

Differences in outcomes will be compared (i) between practices delivering the CYPHP model compared with practices delivering EUC up to two years' post-implementation of the service and (ii) before implementation of the model compared with up to 2 years after.

Methods and analysis

Study design

The implementation of the CYPHP Evelina London model of care across Lambeth and Southwark will occur in stages. This phased roll-out allows the application of an opportunistic cRCT, where for the first stage (lasting for approximately two years) GP practices are randomised to either the full CYPHP Evelina London model (intervention) or enhanced usual care (EUC - control). The results of this evaluation will inform local decision-makers about whether and/or how to roll out the CYPHP Evelina London model to the EUC GP practices.

Population evaluation

A population-level evaluation will use routinely collected, pseudonymised primary and secondary healthcare data to conduct a service-use and economic analysis for all CYP registered with a participating GP. The model will be evaluated at a population level by comparing health service use (i) between CYP from the CYPHP Evelina London model and EUC clusters, and (ii) to historical data within the CYPHP Evelina London model and EUC arms (i.e. before-after comparison). This before-and-after analysis will allow us to compare the CYPHP Evelina London model to the healthcare offered before any enhanced care was introduced.

Objectives of the population evaluation are:

- To compare health service use (including non-elective admissions, emergency department attendance, outpatient appointments, GP attendances) over time, before and after intervention implementation, and between the CYPHP Evelina London model and EUC practices.
- To examine the impact of socio-demographic determinants, specifically measures of deprivation, on health service use over time and between the CYPHP Evelina London model and EUC practices.

Tracer condition evaluation

A subset of the population with specific conditions (asthma, epilepsy, constipation, eczema) will be invited to consent for follow-up, as part of our tracer condition evaluation, to assess the impact of the CYPHP Evelina London model on patient-reported outcomes. These tracer conditions were chosen as they are examples of long term and common conditions, which will provide generalisable lessons about improving outcomes through healthcare for CYP with ongoing conditions.

Objectives of the tracer condition evaluation are:

- To assess the impact of the CYPHP Evelina London model on CYP's health-related quality of life, parent-reported disease severity, prevalence and severity of mental health difficulties, and mental wellbeing among parents over time, before and after intervention implementation, and compared with EUC practices.
- To assess the equity of service access and delivery (activity, costs, outcomes) across socioeconomic backgrounds

Process evaluation

A nested process evaluation will explore how well the CYPHP Evelina London model has been implemented and its impact on quality of care (e.g. patient/family experience, case notes audits, prescribing rates). Objectives relating specifically to the process evaluation and details of methods are presented in our accompanying process evaluation protocol entitled *'The Children and Young People's Health Partnership Evelina London Model of Care: Process Evaluation Protocol'.*

Economic evaluation

We will assess the cost of delivering the CYPHP Evelina London model, cost savings in relation to any decrease in health service use, and cost effectiveness of the model in terms of utility in relation to health-related quality of life of CYP with tracer conditions.

Objectives of the economic evaluation are:

- To quantify the differences in resource use and costs linked to professional contacts and services delivered in managing the tracer conditions between the CYPHP Evelina London model and EUC.
- To assess secondary healthcare contacts and costs.
- To evaluate cost-effectiveness by combining evidence on cost impacts and health-related quality of life outcomes for CYP with tracer conditions.

Hypothesis

We hypothesise that patients from both the CYPHP Evelina London model and EUC practices will show improvement in health outcomes between baseline and follow-up up to two years post-implementation.

However, we hypothesise that the impact on health outcomes will be significantly greater in patients from CYPHP Evelina London practices compared with patients from EUC practices. In addition, we anticipate that savings attributed to service activity reductions at a population level will outweigh the costs of running the service and that the service will be cost-effective at the tracer condition level.

Study setting

The study is being run in two inner-city boroughs of South London in the UK, Lambeth and Southwark. Child health outcomes for these two inner city boroughs are worse in many instances than average in England (Fingertips). There are high and rising A&E attendance rates for CYP, emergency hospital admissions, and hospital outpatient use.[16] The CYPHP Evelina model of care components are being rolled out across GP practices, schools, and hospitals within Lambeth and Southwark.

Interventions

The CYPHP Evelina London model aims to provide comprehensive coordinated care for CYP, and tailored care that is responsive to patients' needs. In practice this means integrating primary and secondary healthcare, physical and mental healthcare, healthcare with public health, and improving the age appropriateness of care. Providing tailored care that is responsive to patients' needs will be achieved through roll-out of several universal and targeted services, and through health system strengthening initiatives including intra- and inter-sectoral partnerships, workforce training, technology, and analytics. Further details of the underlying theory and activities involved in the model of care, and the health needs it seeks to address, are described in our model of care paper.[17] During phased roll out and the evaluation trial, the CYPHP Evelina London model comprises two groups: 1) interventions that are being implemented across both arms of the trial, that we term "enhanced usual care" (EUC) and 2) The CYPHP Evelina London model comprising EUC plus additional interventions. Thus EUC serves as the control arm, and the full CYPHP Evelina London model serves as the intervention arm. Services include care for CYP and support for parents and GPs; described in detail below.

Enhanced usual care (control arm)

All practices within Lambeth and Southwark will begin to receive:

- Decision support tools for GPs comprising guidelines (in line with national evidence-based guidelines), algorithms, and referral guidance for common conditions such as constipation, eczema, urinary tract infection, enuresis, headache and food allergies. They are in an electronic format, embedded into local GP data systems so that they can be accessed easily during a consultation.
- Paediatric hotline enabling rapid communication between GPs and paediatricians to discuss urgent support, management, or referral of an individual child or young person.
- School-based emotional resilience building and mental health first aid.
- Minor illness and wellness support and services for the most common problems and illnesses, to help parents and professionals to keep CYP well at home.
- CYPHP Health Checks for CYP with tracer conditions (asthma, epilepsy, eczema, constipation) and their parents – a biopsychosocial questionnaire which supports tailored care planning.

- CYPHP Health Packs for CYP and their parents, comprising self-management support, health promotion, and health education material.

Parents of patients with tracer conditions are invited to complete a condition-specific biopsychosocial questionnaire (CYPHP Health Check) about disease severity, emotional wellbeing, and social factors. Invitation to complete the Health Check will happen by one of four methods. First, eligible families will be identified by their GP and sent a letter and text messages that invites them to complete an online CYPHP Health Check. Second, GP practices and secondary care sites (e.g. specialist clinics, outpatient departments) will have paper copies of the Health Check available with pre-paid envelopes. Third, patients may self-direct to the Health Check web page which is promoted widely, for example through schools, community events, pharmacists, and social media. Finally, healthcare providers may directly refer patients to the service. Information from the CYPHP Health Check will be added to patients' GP records, and families will be sent a summary of their scores on the questionnaire and a CYPHP Health Pack.

CYPHP Evelina London model (intervention arm)

In addition to the components of the EUC arm, the CYPHP Evelina London model comprises two types of clinical services: targeted care for CYP with ongoing (tracer) conditions, and universal care for CYP with any condition.

CYP with tracer conditions are eligible for a tailored clinical service delivered by the multidisciplinary CYPHP Health team in primary and community care settings and in patient's homes. CYP and families complete a CYPHP Health Check which provides information for triaging and tailoring care. The CYPHP Health Team comprises specialist children's nurses, a children's pharmacist, mental health workers, linked with school nurses, and backed up by Consultant Paediatrician, Child and Adolescent Psychiatrist, and GP. Care includes health promotion, preventive, and reactive care, and integrates services both vertically across primary and secondary care and horizontally between sectors.

CYP with any condition are eligible for "in-reach" CYPHP clinics. These clinics are integrated child health clinics jointly run by GPs and local "Patch Paediatricians" who are linked to a cluster of GP practices. Clinics are held in primary care settings. They offer generalist and specialist advice co-located and coordinated conveniently close to home for patients. In-reach clinics will typically be for CYP who would otherwise have been referred to hospital for an outpatient appointment with a general paediatrician. In-reach clinics also aim to improve clinical decision-making, provide shared learning opportunities, and through building trust, cooperation, and team-working between GPs and Patch Paediatricians, integrates services vertically across primary and secondary care.

Study eligibility criteria

For the population level evaluation, using pseudonymised data, there are very broad eligibility criteria, as the purpose of the evaluation is to include as many CYP as possible. The only criteria are that the CYP is (i) <16 years of age at the time of service roll out, and (ii) registered with a participating practice in Lambeth and Southwark. For the tracer condition evaluation, the same eligibility criteria as the

population evaluation apply, and in addition CYP must be diagnosed or identified as having one or more of the four tracer conditions (constipation, eczema, epilepsy, asthma), express interest in the study when completing a CYPHP Health Check (described below) and give informed consent (described below).

Participants will be excluded from the evaluation if any of the following applies:

- If during the evaluation period, the patient diagnosis changes and a tracer condition no longer applies.
- If the patient is no longer registered with a participating practice (Of the total 89 practices in Lambeth and Southwark, all are participating except 19 pilot practices).
- If the patient moves their primary residence outside of Lambeth or Southwark.

Randomisation and blinding

As part of the implementation of the CYPHP Evelina London model within Lambeth and Southwark, GP practices were grouped into virtual clusters. Where possible, clusters were created aligned to GP Federation "neighbourhoods" or other existing groupings. These primary care practice clusters consist of 2-4 GP practices grouped together to allow the practices to share resources and hold "in-reach" CYPHP clinics with a local "Patch Paediatrician".

Of the 89 GP practices within Lambeth and Southwark, 19 practices took part in pilot testing of some components of the CYPHP Evelina London model of care. As such these 19 practices were not randomised.

Randomisation was at the level of primary care practice cluster. Seventy GP practices were grouped into 23 clusters and were randomised to receive either the CYPHP Evelina London model of care (n=12) or enhanced usual care (EUC) (n=11). Clusters were initially stratified by borough. A restricted randomisation was then carried out on the 23 clusters. Restriction ensured minimal difference between intervention and control arms with regard to:

- Baseline Index of Multiple Deprivation (IMD) - difference in mean IMD score <2.5 (mean IMD 30, range of IMD mean score by cluster 20-37)
- Income Deprivation affecting children index (IDACI) - difference in mean IDACI < 2.5 (mean IDACI 29, range 17-37)
- CYP population under-16 per GP cluster - difference in mean population < 1000 (mean under-16 population 3914, range 2951-5674)
- OutPatient clinic referrals - difference in mean number of referrals <100 (mean number of OP referral 373, range of 256-505)

We generated 56,580 unique randomisations which met the restriction criteria. We checked that cluster pairs were not always grouped together. From these 56,580 randomisations we selected one at random.

The evaluation will not be blinded at the level of the service delivery or participant. Study personnel are blinded to allocation at the time of recruitment and assessment. Stages of identification, recruitment, randomisation and assessment are highlighted in Figure 1 using a cluster trial timeline diagram.[18]

Recruitment and Consent

For the population evaluation, data sharing agreements have been established for access to pseudonymised data for all CYP across the two boroughs. Individual-level recruitment and consent is not required for the population evaluation since administrative data are provided to the research team in pseudononymised form. The data is termed pseudonymised as it is only identifiable by a third party (data custodian) who has access to the "pseudonymisation key" which allows record linkage.

For the tracer condition evaluation, at completion of the Health Check, parents of CYP with a tracer condition will be provided with written information for both the parent and CYP about the evaluation and invited to participate in the evaluation. The informed consent process to participate in the evaluation and follow-up can take place through the web-based portal, in person, or by post. Parents will be asked to: (i) provide informed consent for the evaluation team to access their child's clinical details including Health Check information, and have access to, and link, the child's GP and hospital data to assess the impact of CYPHP on both primary and secondary health service use, (ii) complete an evaluation questionnaire at baseline (including health related quality of life measured by PedsQL and CHU9D, and parental wellbeing measured by the Warwick-Edinburgh Mental Wellbeing Scale), and (iii) give informed consent to be contacted to participate in qualitative studies evaluating the service. Information sheets will make it clear that parents can consent or refuse consent to any of these components. Participants will be free to withdraw consent without prejudice at any time. A parent/carer alone or with their child may be involved in the recruitment process. If the CYP is under 12 years of age the parent/carer will be asked to provide, on behalf of the child, informed consent, if they are happy to take part in the evaluation. If the CYP is between 12 and 16 years of age, the parent will be asked to provide informed consent and if the CYP is available at the time when parental consent is requested, the CYP will be asked to provide assent if they wish to participate. Questionnaire data for patients with epilepsy is not eligible for the primary comparison between intervention and EUC practices because these patients are primarily managed under secondary care and are found through a different case finding procedure. As such, their experiences of the CYPHP Evelina model of care may be different than the other three conditions. However, their questionnaire data will be used for a before-after, epilepsy-specific comparison and they are still included in the process evaluation so that we can understand their experience of care (see Figure 2). To compensate parents/carers for their time in completing the questionnaires, they will be provided with a £5 gift voucher on completion of the baseline and final follow-up assessments. In addition, following completion of the second assessment, participants will be enrolled into a draw for a tablet computer. Details of recruitment of participants for the process evaluation are outlined in the accompanying paper entitled *'The Children and Young People's Health Partnership (CYPHP) Evelina London Model of Care: Process Evaluation Protocol'.*

Follow-up

Participants who consent to take part in the tracer condition evaluation will be followed for up to two years and will be asked to complete two questionnaires about the health of their child during the follow-up period. Questionnaire completion may occur up to four months after the end of the follow-up period.

Outcomes

Outcome measures include parent-reported child health, health service use, and economic impact. Process outcomes, including quality of care, are described in the accompanying process evaluation protocol entitled *'The Children and Young People's Health Partnership Evelina London Model of Care: Process Evaluation Protocol'.* The methods to assess outcomes are both quantitative and qualitative. "Self"-reported outcomes collected include parent-reported and child-related, and parent-related, and child self-reported outcomes, where appropriate. Self-report outcomes will be completed at baseline and up to two years' post-implementation of the service. For all outcomes, differences in outcomes will be compared between practices delivering the CYPHP Evelina London model compared with practices delivering EUC, up to two years' post-implementation of the service. In addition, the impact of the CYPHP Evelina London model will be assessed by comparing outcomes before implementation of the model compared with up to 2 years after.

Population evaluation outcomes

The primary outcome of the population evaluation is the difference in the rate of non-elective hospital admissions (count per patient-year) among CYP from practices delivering the CYPHP Evelina London model compared with practices delivering EUC. Secondary outcomes of the population evaluation will be rates of primary and secondary health service use, including GP attendances, emergency department attendance, outpatient appointment referrals, outpatient appointment attendances, ambulatory care sensitive admissions, proportion of non-elective admissions that are ambulatory care sensitive, and rate (sum per patient-year) of non-elective admissions and outpatient appointment referrals, combined. Table 2 lists the indicators of healthcare use that will be measured using routinely collected health services data, in pseudonymised format.

Table 2. Population evaluation outcome measures

Primary Outcome:
Rate of non-elective admissions
Secondary Outcomes:
GP attendances
Emergency department attendances
Outpatient appointment referrals
Outpatient appointment attendances
Ambulatory care sensitive admissions
Proportion of non-elective admissions that are ambulatory care sensitive
Rate (sum per patient-year) of non-elective admissions and outpatient appointment referrals

Tracer condition evaluation outcomes

The primary outcome measure of the tracer condition evaluation is health-related quality of life (HRQOL), as measured by PedsQL.[19] The PedsQL is a brief, standardized, generic assessment instrument that systematically assesses patients' and parents' perceptions of health-related quality of life in paediatric patients. The PedsQL is based on a modular approach to measuring HRQOL and consists of a 15-item core measure of global HRQOL and eight supplemental modules assessing specific symptom or treatment domains. The survey integrates generic core scales and disease-specific modules.

Secondary outcomes of the tracer condition evaluation include health service use, physical condition symptom severity, mental health, and parental wellbeing. Health service use will be analysed using individual data with consent, and aggregate pseudonymised data. Consent will be requested to link patient-level primary and secondary healthcare use data to analyse the impact of the CYPHP Evelina London model on both primary and secondary health service use. In addition, pseudonymised data on healthcare use will be aggregated for all CYP with tracer conditions allowing analysis of the impact of the model on all patients in this population. A further benefit in using pseudonymised data is that it will help to characterise (but not identify) patients that declined to participate, or did not engage. This will identify distributional equity issues by examining the differential impact on costs and outcomes for different patient and social groupings.

Physical condition symptom severity, mental health, and parental wellbeing will be analysed using data derived from the CYPHP Health Check questionnaires which are used by clinicians for biopsychosocial assessment and tailoring care, and if consent is given data will also be used for evaluation (Table 3). The CYPHP Health Check includes a condition-specific disease severity questionnaire for each of the four tracer conditions, the Strengths and Difficulties Questionnaire (SDQ) to measure of mental health, and a bespoke measure of social conditions (e.g. parental mental health, social deprivation). The Strengths and Difficulties Questionnaire (SDQ) is being used as part of clinical practice to assess child mental health symptoms and help tailor care specific to need.[20] The SDQ is a standardised screening questionnaire used extensively in mental health research with young people.[21] The SDQ consists of 25 questions arranged to create four subscales (measuring emotional symptoms, conduct, hyperactivity and inattention and peer relationship difficulties). The impact supplement will also be completed. A version can be completed by the parent/carer for CYP aged 2-17. The Asthma Control test is being used to assess severity of physical symptoms in patients with asthma. The ACT is a self-report measure designed for adults and adolescents 12 years or older.[22] The Childhood Asthma Control Test is used for CYP aged 4 to 11 years old. The ACT has 5 items asking about patients' symptoms over the past 4 weeks; which are each scored on a 5-point scale. The Childhood ACT has 7 items which use a 5-point scale but where 4 questions are answered by the child and 3 questions are answered by the parent/carer using the same 4 weeks' reference frame. Patients with eczema (or their parents/carers) complete the Patient Oriented Eczema Measure (POEM).[23] The POEM is a tool used for monitoring atopic eczema severity. It focuses on the illness as experienced by the patient. The scale includes 7 items with a one-week reference frame, and produces a score (0 to 28) and severity level ("clear or almost clear" to "very severe eczema"). Patients with constipation and/or epilepsy (or their parents/carers) will be asked to complete bespoke condition-specific measures created for the purposes of the clinical service. Measures were created by CYPHP clinicians and researchers based on NICE guidelines and clinical utility.

Additional measures, for evaluation only, are asked of parents/carers who have given their consent. The Child Health Utility 9D (CHU 9D) is a generic measure of quality of life that can be applied to paediatric populations.[24] The measure consists of items with preference weights that give utility values for each health state described, allowing the calculation of Quality Adjusted Life Years (QALYs) for use in cost utility analysis. The scale has 9 dimensions and each item is scored on a 5-point scale. The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) is a 14-item scale of mental well-being, validated for adults. WEMWBS covers subjective well-being and psychological functioning, in which all items are worded positively and address aspects of positive mental health.[25]

Table 3. Tracer condition outcome measures used as part of clinical service and study evaluation

Domain measured	**Outcome measure**
Self-report measures used for clinical service and evaluation (CYPHP Health Check)	
Asthma severity	Asthma Control Test (ACT)
Eczema severity	Patient Oriented Eczema Measure (POEM)
Constipation severity	Bristol Stool Chart (BSC)
	Bespoke constipation questionnaire
Epilepsy severity	Bespoke epilepsy questionnaire
Mental health concerns	Strengths & Difficulties Questionnaire (SDQ)
Social context	Bespoke social screen questionnaire - Social Deprivation (3 items) - Parent mental health (1 item) - Employment (1 item) - Ethnicity (1 item)
Self-report measures used for evaluation	
Primary outcome: Health-related quality of life	Pediatric Quality of Life Inventory (PedsQL)
Economic data on child quality of life	Child Health Utility 9D (CHU-9D)
Parental wellbeing	Warwick-Edinburgh Mental Wellbeing Scale
Health service use (individual level data linked with consent)	
Rate of non-elective admissions	
GP attendances	
Emergency department attendances	
Outpatient appointment referrals	
Outpatient appointment attendances	
Ambulatory care sensitive admissions	
Proportion of non-elective admissions that are ambulatory care sensitive	
Rate (sum per patient-year) of non-elective admissions and outpatient appointment referrals	

The economic evaluation includes assessment of implementation, and primary care and hospital services, primarily from a National Health Service perspective. Implementation inputs will be measured through activity logs used to record time, equipment, and building space and costed using national and locally relevant unit costs. Resource use and costs of services delivered in primary care will be evaluated through use of CYP contact data with specific professionals and services delivered within primary care settings, combined with national and locally relevant unit costs. Hospital-based service contacts will be identified through linkage between primary care and HES data systems. Appropriate national and local unit costs estimates will be applied to cost hospital service contacts. QALY outcomes relating to acute and nonacute impacts on CYP health and quality of life will be estimated from the Child Health Utility (CHU-9D) measure.

Sample size calculation

For the population evaluation, pseudonymised data from all CYP (<16 years) within participating practices will be used to analyse the impact of the CYPHP Evelina London model on health service use. 11 clusters in each arm, and an average of 3800 CYP per cluster, provides over 87% power to detect a reduction of 20% in the rate of non-elective admissions, assuming a coefficient of variation of 0.142, and baseline rate of 56 admissions per 1000 person-years. The number of CYP per cluster is estimated conservatively based on the 89382 CYP (age 0-15) registered in 2015 in the GP practices in the 23 randomised clusters. The baseline rate of non-elective admissions and the coefficient of variation were estimated using counts of non-elective admissions per cluster from financial years 2013-14 – 2015-16, and counts of CYP enrolled per cluster during 2013-2015. The coefficient of variation used in the sample size calculation was the mean of these three estimates. The rate of non-elective admissions was the total rate estimated by combining data from the three financial years 2013-2016.

For the tracer condition evaluation, with 11 clusters in each study arm, the study team will need to recruit a minimum of 1068 CYP with a tracer condition (asthma, constipation, or eczema) per arm (total 2138). This number of participants will give the study 90% power to detect a mean minimum clinically important difference (MCID) of 4.5 points (standard deviation 16.5) in the primary outcome tool (parental reported PedsQL[19], as used previously with CYP with chronic health conditions such as asthma.[26] The intraclass correlation coefficient (ICC) is assumed to be 0.02 based on a study of quality of life in CYP with a related condition, hay fever.[27] The between cluster coefficient of variation in cluster size is assumed to be 0.03 based on the harmonic mean and variance of cluster size derived from GP registrations. The recruitment target also accounts for a 30% loss to follow up. In total there are 23 clusters, 12 in one arm and 11 in the other; as such the outlined sample size underestimates the total power as we have assumed 11 clusters in each arm.

Data analysis and reporting

A detailed analysis plan will be finalised before receipt of study data. Findings will be reported according to the CONSORT guidelines for cluster randomized controlled trials. Flow charts will show the numbers of clusters, the numbers of CYP recruited and followed up to each time point post recruitment. Balance between CYPHP Evelina London and EUC clusters will be presented for a pre-defined set of potential

confounding factors, and analyses adjusted for any major imbalances. All analyses will take into account the cluster design.[28] Summary values (of each outcome) will be presented for each cluster, and for CYPHP Evelina London and EUC groups compared using t-tests and chi squared tests for continuous outcomes and binary outcomes respectively.

Random-effects regression analyses using individual-level data will be used to simultaneously adjust for the clustered design and any imbalances between CYPHP Evelina London and EUC arms; logistic regression models will be used for binary outcomes, Poisson regression for rates (e.g. admission rates) and linear regression for continuous outcomes (e.g. PedsQL scores). Effect sizes will be presented as odds ratios for binary outcomes, rate ratios for rates and as mean differences for continuous outcomes; 95% confidence intervals (CI) will also be given. Regression analyses will also be used to assess whether the impact of the intervention differs by wealth quintile.

Primary analyses will be intention-to-treat and include all data from participants regardless of their exposure to intervention activities. Per-protocol analyses will also be carried out to examine the impact of the intervention taking into account engagement with the respective clinical services of the universal EUC services and services specific to patients with tracer condition.

Ethics and dissemination

We plan to use the MATRICS (Method for Aggregating the Reporting of Interventions in Complex Studies)[29] approach to bring together complex data from multiple sources to evaluate this complex intervention. Results will be disseminated through publication in peer-reviewed articles, through presentation at national and international meetings, and via websites including CYPHP programme, partners, funder, and sponsor. Results, including a lay summary, will be shared with participants through publicly accessible websites, and participants who gave consent will receive information about their contribution to the evaluation. Participant identifiable data will be removed from all publications.

Ethics approval was obtained from South West - Cornwall & Plymouth Research Ethics Committee and NHS Health Research Authority. Approval was granted on the 14th December 2017

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Authors' contributions

JN was responsible for writing the first draft of the protocol and JF was responsible for drafting the second version. JN, JF, MH, SC, CL, ME, RS, RL, IW were involved in the study design and in obtaining ethical approvals. RL and IW were responsible for study conception. All authors commented on the manuscript and agreed with the final version.

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Competing interests statement.

No authors have any conflicts of interest to declare

Figure 1. Timeline of cluster randomised control trial process

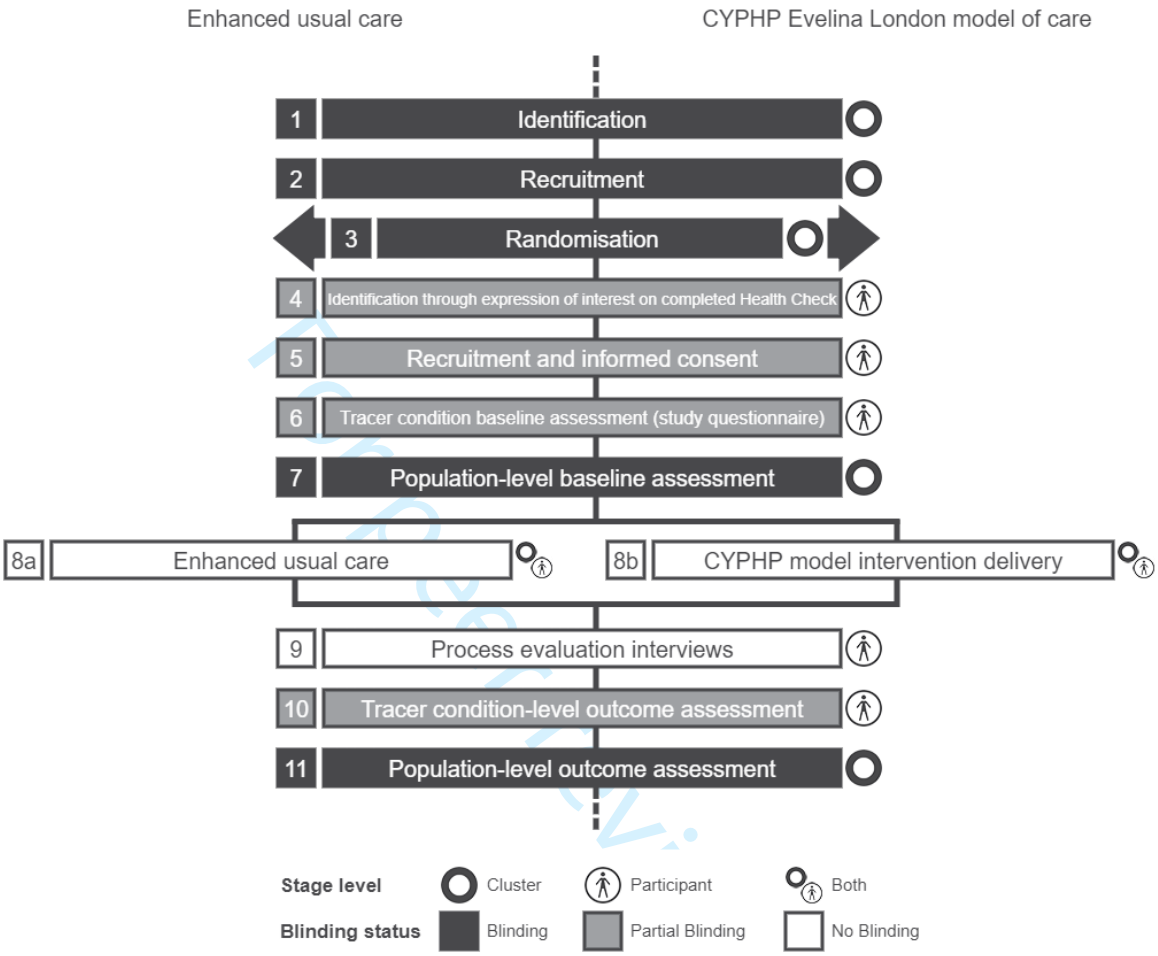
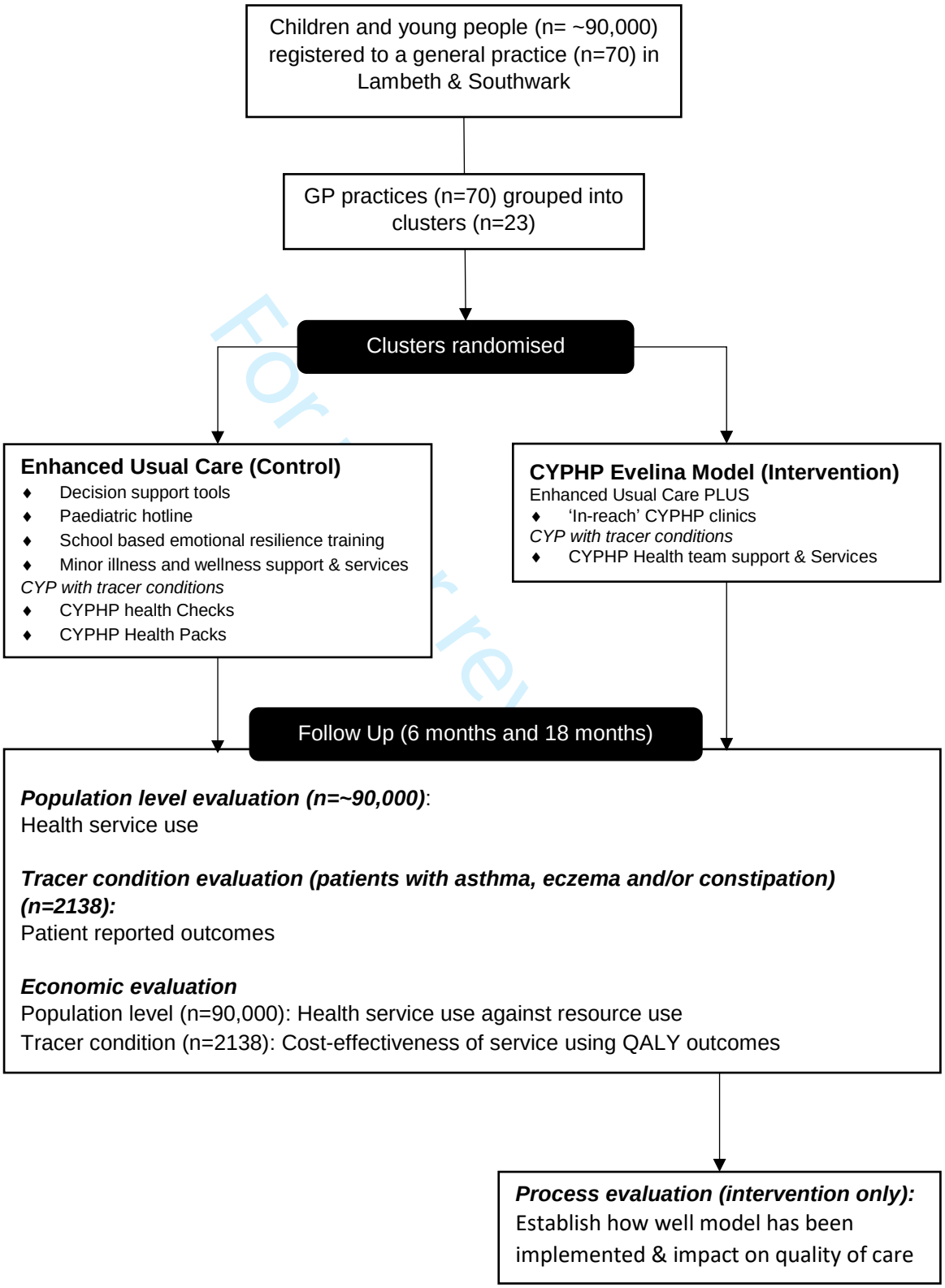


Figure 2. Diagram of patients, services, and levels of the evaluation



CONSORT Guidelines	
1a Identification as a randomised trial in the title	✓
1b Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	✓
2a Scientific background and explanation of rationale	✓
2b Specific objectives or hypotheses	✓
3a Description of trial design (such as parallel, factorial) including allocation ratio	✓
3b Important changes to methods after trial commencement (such as eligibility criteria), with reasons	✓
4a Eligibility criteria for participants	✓
4b Settings and locations where the data were collected	✓
5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	✓
6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	✓
6b Any changes to trial outcomes after the trial commenced, with reasons	N/A
7a How sample size was determined	✓
7b When applicable, explanation of any interim analyses and stopping guidelines	✓
8a Method used to generate the random allocation sequence	✓
8b Type of randomisation; details of any restriction (such as blocking and block size)	✓
9 Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	✓
10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	✓
11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those CONSORT 2010 checklist Page 2 assessing outcomes) and how	✓

11b If relevant, description of the similarity of interventions	✓
12a Statistical methods used to compare groups for primary and secondary outcomes	✓
12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	✓
Results and Discussion Sections from CONSORT not reported as this is a protocol	
23 Registration number and name of trial registry	✓
24 Where the full trial protocol can be accessed, if available	✓
25 Sources of funding and other support (such as supply of drugs), role of funders	✓

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The Children and Young People's Health Partnership (CYPHP) Evelina London Model of Care: Protocol for an Opportunistic Cluster Randomised Evaluation (cRCT) to Assess Child Health Outcomes, Healthcare Quality, and Health Service Use

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TITLE: The Children and Young People's Health Partnership (CYPHP) Evelina London Model of Care: Protocol for an Opportunistic Cluster Randomised Evaluation (cRCT) to Assess Child Health Outcomes, Healthcare Quality, and Health Service Use

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Abstract

Introduction

Children and young people (CYP) in many high-income settings have poor healthcare outcomes, especially those with long-term conditions (LTCs). Emergency and outpatient hospital service use is increasing unsustainably. To address these problems, the Children and Young People's Health Partnership (CYPHP) has developed and is evaluating an integrated model of care as part of a health systems strengthening programme across two boroughs of London, UK that are characterised by mixed ethnic populations and varying levels of deprivation. The CYPHP Evelina London model of care comprises proactive case-finding and triage, specialist clinics, and transformative education and training for professionals working with CYP. Services are delivered by multidisciplinary health teams with an emphasis on increased coordination across primary, community, and hospital settings and integration of physical and mental healthcare that accounts for the CYP's social context.

Methods and analysis

The phased roll-out of the CYPHP Evelina London model allows an opportunistic population-based evaluation using a cluster randomised controlled trial design. Seventy GP practices across two London boroughs, grouped into 23 clusters, were randomised to provide either the CYPHP model of care (n=11) or enhanced usual care (n=12).

The evaluation will measure the impact of the CYPHP Evelina London model of care on child and parent health and wellbeing, healthcare quality, and health service use up to two years post-implementation. A population-level evaluation will utilise routinely collected pseudonymised healthcare data to conduct a service-use analysis for all CYP registered with a participating GP (n=~90,000) with the rate of non-elective admissions as the primary outcome. We will seek consent from a subset of this population, with specific conditions (target n=2138) to assess the impact on patient-reported outcomes using the PedsQL as the primary outcome.

Ethics and dissemination

Ethics approval obtained from South West - Cornwall & Plymouth Research Ethics Committee. Results will be submitted for publication in peer-reviewed journals. Findings will be generalisable to community-based models of care, especially in urban settings. Our process evaluation will identify barriers and enablers of implementation and delivery of care salient to the context and condition.

Trial registration number: Clinicaltrials.gov Identifier: NCT03461848; Pre-results.

Keywords: Child health, integrated care, cluster randomised controlled trial

Strengths and limitations of this study

- The Children and Young People's Health Partnership (CYPHP) Evelina London model of care is a new model of integrated, comprehensive, coordinated, and tailored care that will be delivered to a population catchment of over 90,000 children and young people across a large and diverse area of south London, UK.
- The opportunistic cluster randomised controlled trial design enables unique and rigorous testing of a new model of care, as a population level health services intervention, for child health in the UK.
- Patient-reported and routine service use data will provide information on effectiveness and cost-effectiveness of the CYPHP model of care on outcomes relating to CYP health and wellbeing, healthcare quality, and health services and systems. Linkage of pseudo-anonymised health service use data will allow population level impact on patterns of service use to be assessed.
- It is anticipated that not all eligible CYP will participate in the intervention or evaluation; our population-based approach to case finding, and recruitment through a patient portal, may present challenges for some patients, for example with language, literacy, or technology barriers. These factors mean that interventions may not reach those most in need. However, we will assess population level factors, including equity, and through a robust process evaluation that aims to identify barriers and enablers to accessing the new model of care and gain detailed information about implementation.

Introduction

Approximately 20% of childhood deaths across the USA, England, Australia, and New Zealand are thought to be preventable through better clinical care and patient self-management, with higher proportions in specific categories such as children and young people (CYP) with chronic conditions.[1] Between 60 and 70% of children who died in the UK between 2001 and 2010 had a chronic condition requiring frequent contact with the health system.[2]

Chronic, non-communicable disease accounts for 79% of all disability adjusted life years lost (DALYS), in young people aged 1-14 years across Europe, with respiratory diseases (mainly asthma), neuropsychiatric disorders, congenital abnormalities and musculoskeletal disorders the predominant causes of morbidity.[3] This is mirrored in data from North America and Australia.[4-5]

The current model of hospital-centered paediatric care in high-income countries was developed to deliver acute inpatient and high intensity specialist services, rather than high quality care for CYP with LTCs who need multidisciplinary, coordinated planned care to prevent illness and disease complications, and to maximize wellbeing and developmental potential.[6] The current healthcare model, in the context of the wider health and social care system in the UK, has resulted in suboptimal health outcomes for both acute and chronic illness.[7-8] Finally, current services are not as responsive to families' needs as they should be, and are often inefficient with a reliance on high-cost emergency department attendance and acute admissions.[3,6,9] This is mirrored by inefficiencies seen in other high-income countries.[10] There is an urgent need to develop new evidence-based, cost-effective and sustainable health care services to meet the increasing demands caused, in part, by the rising prevalence of chronic illness across the life course.[3,11-13]

The CYPHP Evelina London model was conceived in response to the evolving health care needs of CYP, and the dearth of evidence for health service commissioners and planners on how to address these needs. The CYPHP Evelina London model is an innovative approach to reshaping everyday healthcare services, expanding on the principles of integrated care.[14-15] CYPHP Evelina London brings together physical and mental healthcare, and delivers services taking into account the social context of the family. It integrates primary and secondary healthcare, and links healthcare with local government efforts to improve the wider determinants of health. A major focus of the CYPHP Evelina London model is improving front line care for all CYP. This is vital as primary care and accident and emergency departments are where the majority of healthcare is delivered in the UK context, and act as the gateway to other services. Front line care can therefore be an enabler or barrier for the rest of the system to function well. In particular, effective and efficient urgent care is important to ensure that sufficient resources are available for the planned, proactive, comprehensive care that CYP with LTC need. This evaluation of the CYPHP Evelina London model of care is designed to generate robust evidence on effectiveness and cost-effectiveness of an integrated model of care for CYP when delivered at scale to inform local, national, and international service providers and commissioners.

Evaluation overview

The evaluation, a population-based cluster randomised controlled trial (cRCT) with over 90,000 CYP has four component parts: 1) a pseudonymised population-based evaluation for all CYP in participating GP practices, 2) an evaluation of patient-reported outcomes from CYP with one of four specific (or 'tracer') conditions, 3) a process evaluation, and 4) an economic evaluation. The broad evaluation aims are:

(i) To evaluate the impact of the Children and Young People's Health Partnership (CYPHP) Evelina London model of care on the health, healthcare, and health service use of CYP; at the population level and for CYP with tracer conditions.

(ii) To understand through the process evaluation how and why the CYPHP Evelina London model is effective or ineffective, and to identify contextually relevant strategies for successful implementation as well as practical difficulties in adoption, delivery, and maintenance to inform wider implementation.

(iii) To assess the costs of delivery and cost-effectiveness of the CYPHP Evelina model of care compared with enhanced usual care (EUC), through the economic evaluation.

Differences in outcomes will be compared (i) between practices delivering the CYPHP model compared with practices delivering EUC up to two years' post-implementation of the service and (ii) before implementation of the model compared with up to 2 years after.

Methods and analysis

Study design

The implementation of the CYPHP Evelina London model of care across Lambeth and Southwark will occur in stages. This phased roll-out allows the application of an opportunistic cRCT, where for the first stage (lasting for approximately two years) GP practices are randomised to either the full CYPHP Evelina London model (intervention) or enhanced usual care (EUC - control). The results of this evaluation will inform local decision-makers about whether and/or how to roll out the CYPHP Evelina London model to the EUC GP practices.

Population evaluation

A population-level evaluation will use routinely collected, pseudonymised primary and secondary healthcare data to conduct a service-use and economic analysis for all CYP registered with a participating GP. The model will be evaluated at a population level by comparing health service use (i) between CYP from the CYPHP Evelina London model and EUC clusters, and (ii) to historical data within the CYPHP Evelina London model and EUC arms (i.e. before-after comparison). This before-and-after analysis will allow us to compare the CYPHP Evelina London model to the healthcare offered before any enhanced care was introduced.

Objectives of the population evaluation are:

- To compare health service use (including non-elective admissions, emergency department attendance, outpatient appointments, GP attendances) over time, before and after intervention implementation, and between the CYPHP Evelina London model and EUC practices.
- To examine the impact of socio-demographic determinants, specifically measures of deprivation, on health service use over time and between the CYPHP Evelina London model and EUC practices.

Tracer condition evaluation

A subset of the population with specific conditions (asthma, epilepsy, constipation, eczema) will be invited to consent for follow-up, as part of our tracer condition evaluation, to assess the impact of the CYPHP Evelina London model on patient-reported outcomes. These tracer conditions were chosen as they are examples of long term and common conditions, which will provide generalisable lessons about improving outcomes through healthcare for CYP with ongoing conditions.

Objectives of the tracer condition evaluation are:

- To assess the impact of the CYPHP Evelina London model on CYP's health-related quality of life, parent-reported disease severity, prevalence and severity of mental health difficulties, and mental wellbeing among parents over time, before and after intervention implementation, and compared with EUC practices.
- To assess the equity of service access and delivery (activity, costs, outcomes) across socioeconomic backgrounds

Process evaluation

A nested process evaluation will explore how well the CYPHP Evelina London model has been implemented and its impact on quality of care (e.g. patient/family experience, case notes audits, prescribing rates). Objectives relating specifically to the process evaluation and details of methods are presented in our accompanying process evaluation protocol entitled *'The Children and Young People's Health Partnership Evelina London Model of Care: Process Evaluation Protocol'.*

Economic evaluation

We will assess the cost to the NHS of delivering the CYPHP Evelina London model, cost savings in relation to any decrease in health service use, and cost effectiveness of the model in terms of utility in relation to health-related quality of life of CYP with tracer conditions.

Objectives of the economic evaluation are:

- To quantify the differences in resource use and costs linked to professional contacts and services delivered in managing the tracer conditions between the CYPHP Evelina London model and EUC.
- To assess secondary healthcare contacts and costs to the NHS.
- To evaluate cost-effectiveness by combining evidence on cost impacts and health-related quality of life outcomes for CYP with tracer conditions.

Hypothesis

We hypothesise that patients from both the CYPHP Evelina London model and EUC practices will show improvement in health outcomes between baseline and follow-up up to two years post-implementation. However, we hypothesise that the impact on health outcomes will be significantly greater in patients from CYPHP Evelina London practices compared with patients from EUC practices. In addition, we anticipate that savings attributed to service activity reductions at a population level will outweigh the costs of running the service and that the service will be cost-effective at the tracer condition level.

Study setting

The study is being run in two inner-city boroughs of South London in the UK, Lambeth and Southwark. Child health outcomes for these two inner city boroughs are worse in many instances than average in England, with high and rising A&E attendance rates for CYP, emergency hospital admissions, and hospital outpatient use.[16] The CYPHP Evelina model of care components are being rolled out across GP practices, schools, and hospitals within Lambeth and Southwark.

Interventions

The CYPHP Evelina London model aims to provide comprehensive coordinated care for CYP, and tailored care that is responsive to patients' needs. In practice this means integrating primary and secondary healthcare, physical and mental healthcare, healthcare with public health, and improving the age appropriateness of care. Providing tailored care that is responsive to patients' needs will be achieved through roll-out of several universal and targeted services, and through health system strengthening initiatives including intra- and inter-sectoral partnerships, workforce training, technology, and analytics. CYPHP intervention functions have been designed to target barriers to effective management of physical, mental and social determinants of health at both a service-provider and patient-level to maximise behaviour change. Further details of the underlying theory and activities involved in the model of care, and the health needs it seeks to address, are described in our model of care paper.[17] During phased roll out and the evaluation trial, the CYPHP Evelina London model comprises two groups: 1) interventions that are being implemented across both arms of the trial, called "enhanced usual care" (EUC) and 2) The full CYPHP Evelina London model, comprising EUC plus additional interventions. Thus, EUC serves as the control arm, and the full CYPHP Evelina London model serves as the intervention arm. Services include care for CYP and support for parents and GPs; described in detail below.

Enhanced usual care (control arm)

All practices within Lambeth and Southwark will receive:

- Decision support tools for GPs comprising guidelines (in line with national evidence-based guidelines), algorithms, and referral guidance for common conditions such as constipation, eczema, urinary tract infection, enuresis, headache and food allergies. They are in an electronic format, embedded into local GP data systems so that they can be accessed easily during a consultation.
- Paediatric hotline enabling rapid communication between GPs and paediatricians to discuss urgent support, management, or referral of an individual child or young person.
- School-based emotional resilience building and mental health first aid.
- Minor illness and wellness support and services for the most common problems and illnesses, to help parents and professionals to keep CYP well at home.
- CYPHP Health Checks for CYP with tracer conditions (asthma, epilepsy, eczema, constipation) and their parents – a biopsychosocial questionnaire which supports tailored care planning.
- CYPHP Health Packs for CYP and their parents, comprising self-management support, health promotion, and health education material.

Parents of patients with tracer conditions are invited to complete a condition-specific biopsychosocial questionnaire (CYPHP Health Check) about disease or condition status, emotional

wellbeing, and social factors. Invitation to complete the Health Check will happens by one of four methods. First, eligible families are identified by their GP and sent a letter and text messages that invites them to complete an online CYPHP Health Check. Second, GP practices and secondary care sites (e.g. specialist clinics, outpatient departments) have paper copies of the Health Check available with pre-paid envelopes. Third, patients may self-direct to the Health Check web page which is promoted widely, for example through schools, community events, pharmacists, and social media. Finally, healthcare providers may directly refer patients to the service. Information from the CYPHP Health Check will be added to patients' GP records, and families will be sent a summary of their scores on the questionnaire and a CYPHP Health Pack.

CYPHP Evelina London model (intervention arm)

In addition to the components of the EUC arm, the CYPHP Evelina London model comprises two types of clinical services: targeted care for CYP with ongoing (tracer) conditions, and universal care available for CYP with any condition.

CYP with tracer conditions are eligible for a tailored clinical service delivered by the multidisciplinary CYPHP Health team in primary and community care settings and in patient's homes. CYP and families complete a CYPHP Health Check which provides information for triaging and tailoring care. The CYPHP Health Team comprises specialist children's nurses, a children's pharmacist, mental health workers, associated school nurses, and backed up by Consultant Paediatrician, Child and Adolescent Psychiatrist, and GP. Care includes health promotion, preventive, and reactive care, and integrates services both vertically across primary and secondary care and horizontally between sectors.

CYP with any condition are eligible for "in-reach" CYPHP clinics. These clinics are integrated child health clinics jointly run by GPs and local "Patch Paediatricians" who are linked to a cluster of GP practices. Clinics are held in primary care settings. They offer generalist and specialist advice co-located and coordinated conveniently close to home for patients. In-reach clinics will typically be for CYP who would otherwise have been referred to hospital for an outpatient appointment with a general paediatrician. In-reach clinics also aim to improve clinical decision-making, provide shared learning opportunities, and through building trust, cooperation, and direct and virtual team-working between GPs and Patch Paediatricians, integrates services vertically across primary and secondary care.

The hypothesised active components of interventions available in each arm have been mapped against the 12 domains of the Theoretical Domains Framework (TDF) to evidence the proposed mechanism through which the intervention becomes effective (Table 1, end of manuscript). The TDF is a synthesis (from across existing theories) of the different behavioural domains which interventions may target to influence behaviour change.[18] Thus, the TDF is useful for aiding intervention design and for process evaluations that aim to determine whether mechanisms of actions were as anticipated. While some services are available in both arms and are hypothesised to improve outcomes (e.g. education & training), we hypothesise patients receiving the CYPHP Evelina London model will have significantly improved outcomes than patients receiving EUC by the additive behavioural domains targeted and the increased intensity through which domains are targeted due to the mode of administration. For example, Health Packs received in EUC target 'Motivation and Goals' by novel goal setting and action planning exercises. However, while this material is delivered passively through written material in EUC, 'Motivation and goals' will be targeted in patients

receiving CYPHP care through goal-based outcome measures for children and nurses being able to talk through the material face-to-face and provide feedback on meeting those goals.

Study eligibility criteria

For the population level evaluation, using pseudonymised data, there are very broad eligibility criteria, as the purpose of the evaluation is to include as many CYP as possible. The only criteria are that the CYP is (i) <16 years of age at the time of service roll out, and (ii) registered with a participating practice in Lambeth and Southwark. For the tracer condition evaluation, the same eligibility criteria as the population evaluation apply, and in addition CYP must be diagnosed or identified as having one or more of the four tracer conditions (constipation, eczema, epilepsy, asthma), express interest in the study when completing a CYPHP Health Check (described below) and give informed consent (described below).

Participants will be excluded from the evaluation if any of the following applies:

- If during the evaluation period, the patient diagnosis changes and a tracer condition no longer applies.
- If the patient is no longer registered with a participating practice (Of the total 89 practices in Lambeth and Southwark, all are participating except 19 pilot practices).
- If the patient moves their primary residence outside of Lambeth or Southwark.

Randomisation and blinding

As part of the implementation of the CYPHP Evelina London model within Lambeth and Southwark, GP practices were grouped into virtual clusters. Where possible, clusters were created aligned to GP Federation "neighbourhoods" or other existing groupings. These primary care practice clusters consist of 2-4 GP practices grouped together to allow the practices to share resources and hold "in-reach" CYPHP clinics with a local "Patch Paediatrician".

Of the 89 GP practices within Lambeth and Southwark, 19 practices took part in pilot testing of some components of the CYPHP Evelina London model of care. As such these 19 practices were not randomised.

Randomisation was at the level of primary care practice cluster. Seventy GP practices were grouped into 23 clusters and were randomised to receive either the CYPHP Evelina London model of care (n=12) or enhanced usual care (EUC) (n=11). Clusters were initially stratified by borough. A restricted randomisation was then carried out on the 23 clusters. Restriction ensured minimal difference between intervention and control arms with regard to:

- Baseline Index of Multiple Deprivation (IMD) - difference in mean IMD score <2.5 (mean IMD 30, range of IMD mean score by cluster 20-37)
- Income Deprivation affecting children index (IDACI) - difference in mean IDACI < 2.5 (mean IDACI 29, range 17-37)
- CYP population under-16 per GP cluster - difference in mean population < 1000 (mean under-16 population 3914, range 2951-5674)
- OutPatient clinic referrals - difference in mean number of referrals <100 (mean number of OP referral 373, range of 256-505)

We generated 56,580 unique randomisations which met the restriction criteria. We checked that cluster pairs were not always grouped together. From these 56,580 randomisations we selected one at random.

The evaluation will not be blinded at the level of the service delivery or participant. Study personnel are blinded to allocation at the time of recruitment and assessment. Stages of identification, recruitment, randomisation and assessment are highlighted in Figure 1 using a cluster trial timeline diagram.[19]

Recruitment and Consent

For the population evaluation, data sharing agreements have been established for access to pseudonymised data for all CYP across the two boroughs. Individual-level recruitment and consent is not required for the population evaluation since administrative data are provided to the research team in pseudononymised form. The data is termed pseudonymised as it is only identifiable by a third party (data custodian) who has access to the "pseudonymisation key" which allows record linkage.

For the tracer condition evaluation, at completion of the Health Check, parents of CYP with a tracer condition will be provided with written information for both the parent and CYP about the evaluation and invited to participate in the evaluation. The informed consent process to participate in the evaluation and follow-up can take place through the web-based portal, in person, or by post. Parents will be asked to: (i) provide informed consent for the evaluation team to access their child's clinical details including Health Check information, and have access to, and link, the child's GP and hospital data to assess the impact of CYPHP on both primary and secondary health service use, (ii) complete an evaluation questionnaire at baseline (including health related quality of life measured by PedsQL and CHU9D, and parental wellbeing measured by the Warwick-Edinburgh Mental Wellbeing Scale), and (iii) give informed consent to be contacted to participate in qualitative studies evaluating the service. Information sheets will make it clear that parents can consent or refuse consent to any of these components. Participants will be free to withdraw consent without prejudice at any time. A parent/carer alone or with their child may be involved in the recruitment process. If the CYP is under 12 years of age the parent/carer will be asked to provide, on behalf of the child, informed consent, if they are happy to take part in the evaluation. If the CYP is between 12 and 16 years of age, the parent will be asked to provide informed consent and if the CYP is available at the time when parental consent is requested, the CYP will be asked to provide assent if they wish to participate. Questionnaire data for patients with epilepsy is not eligible for the primary comparison between intervention and EUC practices because these patients are primarily managed under secondary care and are found through a different case finding procedure. As such, their experiences of the CYPHP Evelina model of care may be different than the other three conditions. However, their questionnaire data will be used for a before-after, epilepsy-specific comparison and they are still included in the process evaluation so that we can understand their experience of care (see Figure 2). To compensate parents/carers for their time in completing the questionnaires, they will be provided with a £5 gift voucher on completion of the baseline and final follow-up assessments. In addition, following completion of the second assessment, participants will be enrolled into a draw for a tablet computer. Details of recruitment of participants for the process evaluation are outlined in the accompanying paper entitled *'The Children and Young People's Health Partnership (CYPHP) Evelina London Model of Care: Process Evaluation Protocol'.*

Follow-up

Participants who consent to take part in the tracer condition evaluation will be followed for up to two years and will be asked to complete two questionnaires about the health of their child during the follow-up period. Questionnaire completion may occur up to four months after the end of the follow-up period.

Outcomes

Outcome measures include parent-reported child health, health service use, and economic impact. Process outcomes, including quality of care, are described in the accompanying process evaluation protocol entitled *'The Children and Young People's Health Partnership Evelina London Model of Care: Process Evaluation Protocol'.* The methods to assess outcomes are both quantitative and qualitative. "Self"-reported outcomes collected include parent-reported and child-related, and parent-related, and child self-reported outcomes, where appropriate. Self-report outcomes will be completed at baseline and up to two years' post-implementation of the service. For all outcomes, differences in outcomes will be compared between practices delivering the CYPHP Evelina London model compared with practices delivering EUC, up to two years' post-implementation of the service. In addition, the impact of the CYPHP Evelina London model will be assessed by comparing outcomes before implementation of the model compared with up to 2 years after.

Population evaluation outcomes

The primary outcome of the population evaluation is the difference in the rate of non-elective hospital admissions (count per patient-year) among CYP from practices delivering the CYPHP Evelina London model compared with practices delivering EUC. Secondary outcomes of the population evaluation will be rates of primary and secondary health service use, including GP attendances, emergency department attendance, outpatient appointment referrals, outpatient appointment attendances, ambulatory care sensitive admissions, proportion of non-elective admissions that are ambulatory care sensitive, and rate (sum per patient-year) of non-elective admissions and outpatient appointment referrals, combined. Table 2 lists the indicators of healthcare use that will be measured using routinely collected health services data, in pseudonymised format.

Table 2. Population evaluation outcome measures

Primary Outcome:
Rate of non-elective admissions
Secondary Outcomes:
GP attendances
Emergency department attendances
Outpatient appointment referrals
Outpatient appointment attendances
Ambulatory care sensitive admissions
Proportion of non-elective admissions that are ambulatory care sensitive
Rate (sum per patient-year) of non-elective admissions and outpatient appointment referrals

Tracer condition evaluation outcomes

The primary outcome measure of the tracer condition evaluation is health-related quality of life (HRQOL), as measured by PedsQL.[20] The PedsQL is a brief, standardized, generic assessment instrument that systematically assesses patients' and parents' perceptions of health-related quality of life in paediatric patients. The PedsQL is based on a modular approach to measuring HRQOL and consists of a 15-item core measure of global HRQOL and eight supplemental modules assessing specific symptom or treatment domains. The survey integrates generic core scales and disease-specific modules.

Secondary outcomes of the tracer condition evaluation include health service use, physical condition symptom severity, mental health, and parental wellbeing. Health service use will be analysed using individual data with consent, and aggregate pseudonymised data. Consent will be requested to link patient-level primary and secondary healthcare use data to analyse the impact of the CYPHP Evelina London model on both primary and secondary health service use. In addition, pseudonymised data on healthcare use will be aggregated for all CYP with tracer conditions allowing analysis of the impact of the model on all patients in this population. A further benefit in using pseudonymised data is that it will help to characterise (but not identify) patients that declined to participate, or did not engage. This will identify distributional equity issues by examining the differential impact on costs and outcomes for different patient and social groupings.

Physical condition symptom severity, mental health, and parental wellbeing will be analysed using data derived from the CYPHP Health Check questionnaires which are used by clinicians for biopsychosocial assessment and tailoring care, and if consent is given data will also be used for evaluation (Table 3). The CYPHP Health Check includes a condition-specific disease severity questionnaire for each of the four tracer conditions, the Strengths and Difficulties Questionnaire (SDQ) to measure mental health, and a bespoke measure of social conditions (e.g. parental mental health, social deprivation). The Strengths and Difficulties Questionnaire (SDQ) is completed as part of the Health Check to provide an estimate of the prevalence and severity of mental health difficulties of CYP with tracer conditions, as measurement of mental health is not routinely collected by (physical) health services within the UK. Scores on the SDQ is being used as part of clinical practice to assess child mental health symptoms and help tailor care specific to need.[21] The SDQ is a standardised screening questionnaire used extensively in mental health research with young people.[22] The SDQ consists of 25 questions arranged to create four subscales (measuring emotional symptoms, conduct, hyperactivity and inattention and peer relationship difficulties). The impact supplement will also be completed. A version can be completed by the parent/carer for CYP aged 2-17. The Asthma Control test is being used to assess severity of physical symptoms in patients with asthma. The ACT is a self-report measure designed for adults and adolescents 12 years or older.[23] The Childhood Asthma Control Test is used for CYP aged 4 to 11 years old. The ACT has 5 items asking about patients' symptoms over the past 4 weeks; which are each scored on a 5-point scale. The Childhood ACT has 7 items which use a 5-point scale but where 4 questions are answered by the child and 3 questions are answered by the parent/carer using the same 4 weeks' reference frame. Patients with eczema (or their parents/carers) complete the Patient Oriented Eczema Measure (POEM).[24] The POEM is a tool used for monitoring atopic eczema severity. It focuses on the

illness as experienced by the patient. The scale includes 7 items with a one-week reference frame, and produces a score (0 to 28) and severity level ("clear or almost clear" to "very severe eczema"). Patients with constipation and/or epilepsy (or their parents/carers) will be asked to complete bespoke condition-specific measures created for the purposes of the clinical service. Measures were created by CYPHP clinicians and researchers based on NICE guidelines and clinical utility.

Additional measures, for evaluation only, are asked of parents/carers who have given their consent. The Child Health Utility 9D (CHU 9D) is a generic measure of quality of life that can be applied to paediatric populations.[25] The measure consists of items with preference weights that give utility values for each health state described, allowing the calculation of Quality Adjusted Life Years (QALYs) for use in cost utility analysis. The scale has 9 dimensions and each item is scored on a 5-point scale. The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) is a 14-item scale of mental well-being, validated for adults. WEMWBS covers subjective well-being and psychological functioning, in which all items are worded positively and address aspects of positive mental health.[26]

Table 3. Tracer condition outcome measures used as part of clinical service and study evaluation

Domain measured	Outcome measure
Self-report measures used for clinical service and evaluation (CYPHP Health Check)	
Asthma severity	Asthma Control Test (ACT)
Eczema severity	Patient Oriented Eczema Measure (POEM)
Constipation severity	Bristol Stool Chart (BSC)
	Bespoke constipation questionnaire
Epilepsy severity	Bespoke epilepsy questionnaire
Mental health concerns	Strengths & Difficulties Questionnaire (SDQ)
Social context	Bespoke social screen questionnaire - Social Deprivation (3 items) - Parent mental health (1 item) - Employment (1 item) - Ethnicity (1 item)
Self-report measures used for evaluation	
Primary outcome: Health-related quality of life	Pediatric Quality of Life Inventory (PedsQL)
Economic data on child quality of life	Child Health Utility 9D (CHU-9D)
Parental wellbeing	Warwick-Edinburgh Mental Wellbeing Scale
Health service use (individual level data linked with consent)	
Rate of non-elective admissions	
GP attendances	
Emergency department attendances	
Outpatient appointment referrals	
Outpatient appointment attendances	
Ambulatory care sensitive admissions	
Proportion of non-elective admissions that are ambulatory care sensitive	
Rate (sum per patient-year) of non-elective admissions and outpatient appointment referrals	

The economic evaluation includes assessment of implementation, and primary care and hospital services, primarily from a National Health Service perspective. Implementation inputs will be measured through activity logs used to record time, equipment, and building space and costed using national and locally relevant unit costs. Resource use and costs of services delivered in primary care

will be evaluated through use of CYP contact data with specific professionals and services delivered within primary care settings, combined with national and locally relevant unit costs. Hospital-based service contacts will be identified through linkage between primary care and HES data systems. Appropriate national and local unit costs estimates will be applied to cost hospital service contacts. QALY outcomes relating to acute and nonacute impacts on CYP health and quality of life will be estimated from the Child Health Utility (CHU-9D) measure.

Patient and Public Involvement (PPI)

The CYPHP Evelina London model was developed with key stakeholders including CYP, carers, front line practitioners and providers, and health service commissioners. Stakeholders were involved in the development of the theoretical framework for CYPHP, identification of research questions and refining the research methodology. A specific CYPHP PPI group was developed with CYP and their families and allowed us to consult with regard to all aspects of the evaluation design; including appropriateness of outcome measures, consent procedures, and self-management material that was developed as part of enhanced usual care.

Sample size calculation

For the population evaluation, pseudonymised data from all CYP (<16 years) within participating practices will be used to analyse the impact of the CYPHP Evelina London model on health service use. 11 clusters in each arm, and an average of 3800 CYP per cluster, provides over 87% power to detect a reduction of 20% in the rate of non-elective admissions, assuming a coefficient of variation of 0.142, and baseline rate of 56 admissions per 1000 person-years. The number of CYP per cluster is estimated conservatively based on the 89382 CYP (age 0-15) registered in 2015 in the GP practices in the 23 randomised clusters. The baseline rate of non-elective admissions and the coefficient of variation were estimated using counts of non-elective admissions per cluster from financial years 2013-14 – 2015-16, and counts of CYP enrolled per cluster during 2013-2015. The coefficient of variation used in the sample size calculation was the mean of these three estimates. The rate of non-elective admissions was the total rate estimated by combining data from the three financial years 2013-2016.

For the tracer condition evaluation, we hypothesise that the intervention will have an effect on both infant health and parent health but we believe that the mechanisms may be theoretically different and we believe that parental wellbeing may be a potential mediator. Therefore, we have included both a child- and parent-based health outcome in our sample size calculations. With 11 clusters in each study arm, the study team will need to recruit a minimum of 1068 CYP with a tracer condition (asthma, constipation, or eczema) per arm (total 2138) (see 'Recruitment and Consent' for rationale why epilepsy not included in sample size calculation). This number of participants will give the study 90% power to detect a mean minimum clinically important difference (MCID) of 4.5 points (standard deviation 16.5) in the primary outcome tool for child health-related quality of life (parental reported PedsQL),[20] as used previously with CYP with chronic health conditions such as asthma.[27] The intraclass correlation coefficient (ICC) is assumed to be 0.02 based on a study of quality of life in CYP with a related condition, hay fever.[28] The between cluster coefficient of variation in cluster size is assumed to be 0.03 based on the harmonic mean and variance of cluster size derived from GP registrations. The recruitment target also accounts for a 30% loss to follow up. In total there are 23 clusters, 12 in one arm and 11 in the other; as such the outlined sample size underestimates the

total power as we have assumed 11 clusters in each arm. This same sample size provides over 90% power to detect a mean MCID of 3 points (standard deviation 8.4) in the parental primary outcome tool, WEMWBS.[26] Here the intraclass coefficient (ICC) is assumed to be 0.03, based on pilot data from the WISE trial.[29] Again, this allows for 30% loss to follow up.

Data analysis and reporting

A detailed analysis plan will be finalised before receipt of study data. Findings will be reported according to the CONSORT guidelines for cluster randomized controlled trials. Flow charts will show the numbers of clusters, the numbers of CYP recruited and followed up to each time point post recruitment. Balance between CYPHP Evelina London and EUC clusters will be presented for a pre-defined set of potential confounding factors, and analyses adjusted for any major imbalances. All analyses will take into account the cluster design.[30] Summary values (of each outcome) will be presented for each cluster, and for CYPHP Evelina London and EUC groups compared using t-tests and chi squared tests for continuous outcomes and binary outcomes respectively.

Random-effects regression analyses using individual-level data will be used to simultaneously adjust for the clustered design and any imbalances between CYPHP Evelina London and EUC arms; logistic regression models will be used for binary outcomes, Poisson regression for rates (e.g. admission rates) and linear regression for continuous outcomes (e.g. PedsQL scores). Effect sizes will be presented as odds ratios for binary outcomes, rate ratios for rates and as mean differences for continuous outcomes; 95% confidence intervals (CI) will also be given. Regression analyses will also be used to assess whether the impact of the intervention differs by wealth quintile.

Primary analyses will be intention-to-treat and include all data from participants regardless of their exposure to intervention activities. Per-protocol analyses will also be carried out to examine the impact of the intervention taking into account engagement with the respective clinical services of the universal EUC services and services specific to patients with tracer condition.

Ethics and dissemination

We plan to use the MATRICS (Method for Aggregating the Reporting of Interventions in Complex Studies)[31] approach to bring together complex data from multiple sources to evaluate this complex intervention. Results will be disseminated through publication in peer-reviewed articles, through presentation at national and international meetings, and via websites including CYPHP programme, partners, funder, and sponsor. Results, including a lay summary, will be shared with participants through publicly accessible websites, and participants who gave consent will receive information about their contribution to the evaluation. Participant identifiable data will be removed from all publications.

Ethics approval was obtained from South West - Cornwall & Plymouth Research Ethics Committee and NHS Health Research Authority. Approval was granted on the 14th December 2017

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Authors' contributions

JN was responsible for writing the first draft of the protocol and JF was responsible for drafting the second version. JN, JF, MH, SC, CL, ME, RS, RL, IW were involved in the study design and in obtaining ethical approvals. RL and IW were responsible for study conception. All authors commented on the manuscript and agreed with the final version.

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Competing interests statement.

No authors have any conflicts of interest to declare

Figure legends

Figure 1: Timeline of cluster randomised control trial process

None

Figure 2: Diagram of patients, services, and levels of the evaluation

None

Table 1 Mapping CYPHP components to the constructs of the Theoretical Domains Framework

Domain	CYPHP model of care		Enhanced usual care		
	CYPHP care for tracer conditions	CYPHP 'in-reach' clinics	CYPHP Health Checks for tracer conditions	Support tools and services for health professionals	Education and training
Knowledge: an awareness of the existence of something	One-to-one appointments where patients can ask specific questions	One-to-one learning in joint clinics where opportunity to learn knowledge	Health packs describe to patients the causes and triggers of their condition	Evidence-based guidelines, algorithms, and referral guidance for common conditions (e.g. urinary tract infection, headache, allergies)	Training to improve awareness of difficulties within CYP's health to: • GPs • Personal advisors • Teaching staff
Skills: ability or proficiency acquired through practice	• Multidisciplinary working within health team fosters improved competence to tackle mental and social concerns of CYP • One-to-one visits with CYP helps improves self-management skills (e.g. use inhaler correctly)	GPs working with consultant to impart skills in managing certain conditions	Health packs designed to provide valuable skills-based techniques in managing condition rather simply provide information		Training for: • GPs on how to communicate more effectively with CYP • Personal advisors to better support CYP leaving care • teachers on promoting emotional resilience in CYP
Social or professional role and identity: a coherent set of behaviours and displayed personal qualities of an individual in a social or work setting	Multidisciplinary culture of health staff team places emphasis and responsibility on treating social and mental health concerns in addition to focusing on physical condition				
Beliefs about capabilities: self-efficacy or acceptance of the truth, reality, or validity about an ability, talent or facility that a person can put to constructive use	Encouraging CYP and families to better self-manage the child's condition	Teaching other GPs how they can better manage a child's presentation of illnesses			
Beliefs about consequences: acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation	Routine visits help encourage positive patterns of behaviour and deter negative patterns of behaviour by providing feedback by health team		Information about what will happen if CYP do not better manage their condition		Training on the lasting impact of not treating CYP mental and physical health early to GPs, teachers and personal advisors
Motivation and goals: Intention or mental representations of outcomes or end states that an individual wants to achieve	Goal based outcomes used routinely as part of clinical care to help encourage CYP to manage condition for a reason that is salient to them		Goal setting exercises help CYP realise why managing their condition is relevant		
Memory attention and decision processes: the ability to retain information, focus selectively on aspects of the environment, and choose between alternatives	Clinical templates to aid nurses to talking through physical, mental and social barriers for CYP not self-managing their condition effectively		Health pack material for CYP focuses on self-monitoring techniques (e.g. take medication, plan for likely triggers)	• Clinical templates guide GPs on how to talk about issues commonly faced by teens • Guidelines advise appropriate actions	
Environmental context and resources: any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour	CYPHP nurses are flexible to allow some patients home visits so that they can better understand the triggers for poor health symptoms. Appointments also longer to allow time for CYP to express their concerns	Patients can receive specialist advice, with their GP, within practices close to home rather than having to go to secondary or tertiary settings		Resources embedded into local GP data systems so that they can be accessed easily during a consultation to help GPs provide evidence based best practice	

Social influences: those interpersonal processes that can cause individuals to change their thoughts, feelings or behaviours		CYPHP clinics designed to encourage interaction with health professional peers to gain better understanding of condition			
Emotion: a complex reaction pattern, involving experiential, behavioural and physiological elements, by which the individual attempts to deal with a personally significant matter or event	CYPHP health team is trained to focus on the emotional impact of the condition and treat with equal emphasis as the physical condition		Health pack material has sections focused on techniques to manage mood and emotional concerns	Clinical templates to guide care place focus on asking about any emotional concerns the CYP may be experiencing	All training is focused on the emotional concerns of CYP
Behavioural regulation: anything aimed at managing or changing objectively observed or measured actions	Clinical templates promote standardised way of documenting care delivered and received			Clinical templates and guidelines provide framework to guide clinical care	
Nature of the behaviours: description of how the behaviour is conducted	Documented procedures on how to manage the physical, social and emotional concerns of CYP	Behaviours taught through collaborative clinics will be taken by GPs to utilise in regular practice	Visual information on how to conduct positive self-management behaviours	Guidance on appropriate behaviours to follow in providing support	Training to discourage maladaptive behaviours and foster new patterns

Green = Active delivery (e.g. face-to-face, guided demonstration)

Yellow= Passive delivery (e.g. written text, leaflet)

Figure 1. Timeline of cluster randomised control trial process

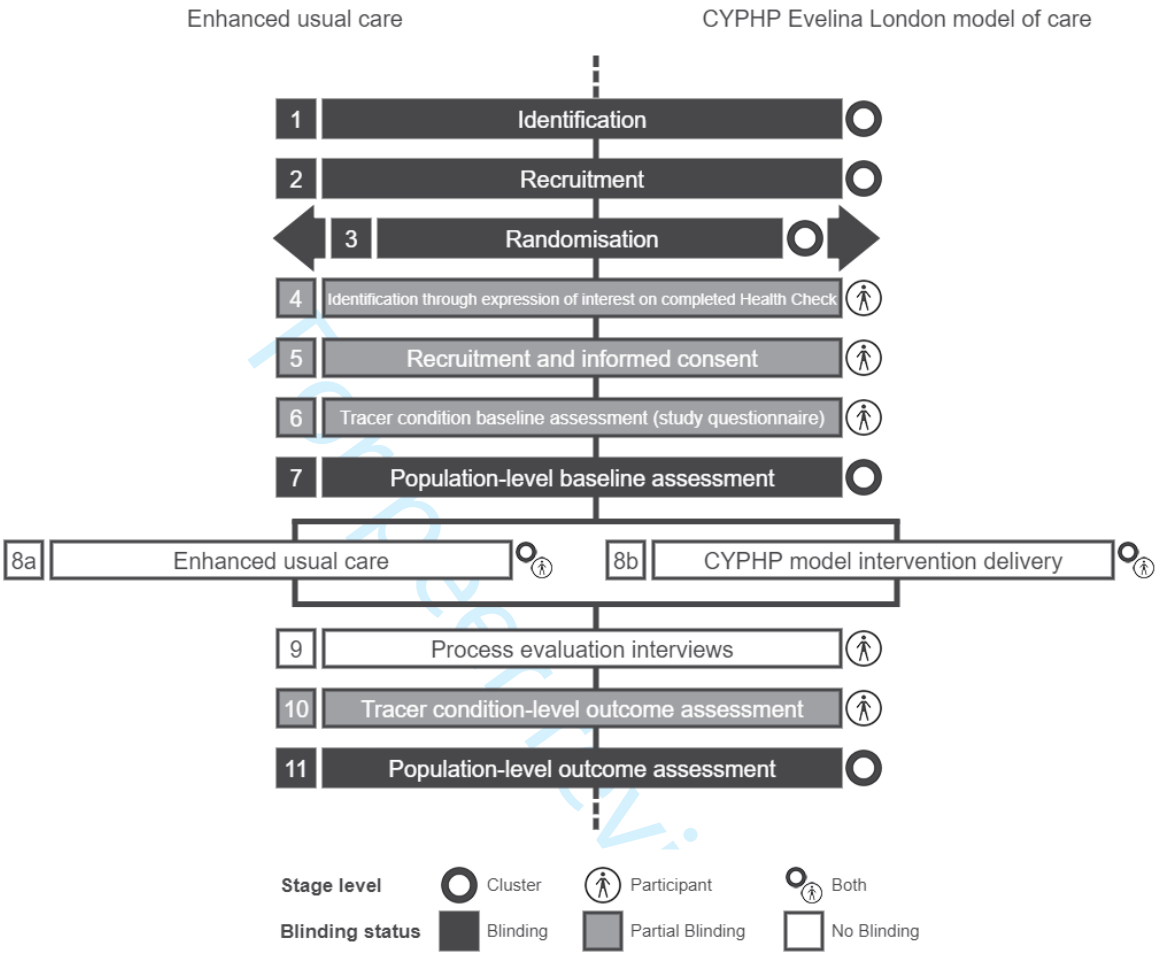
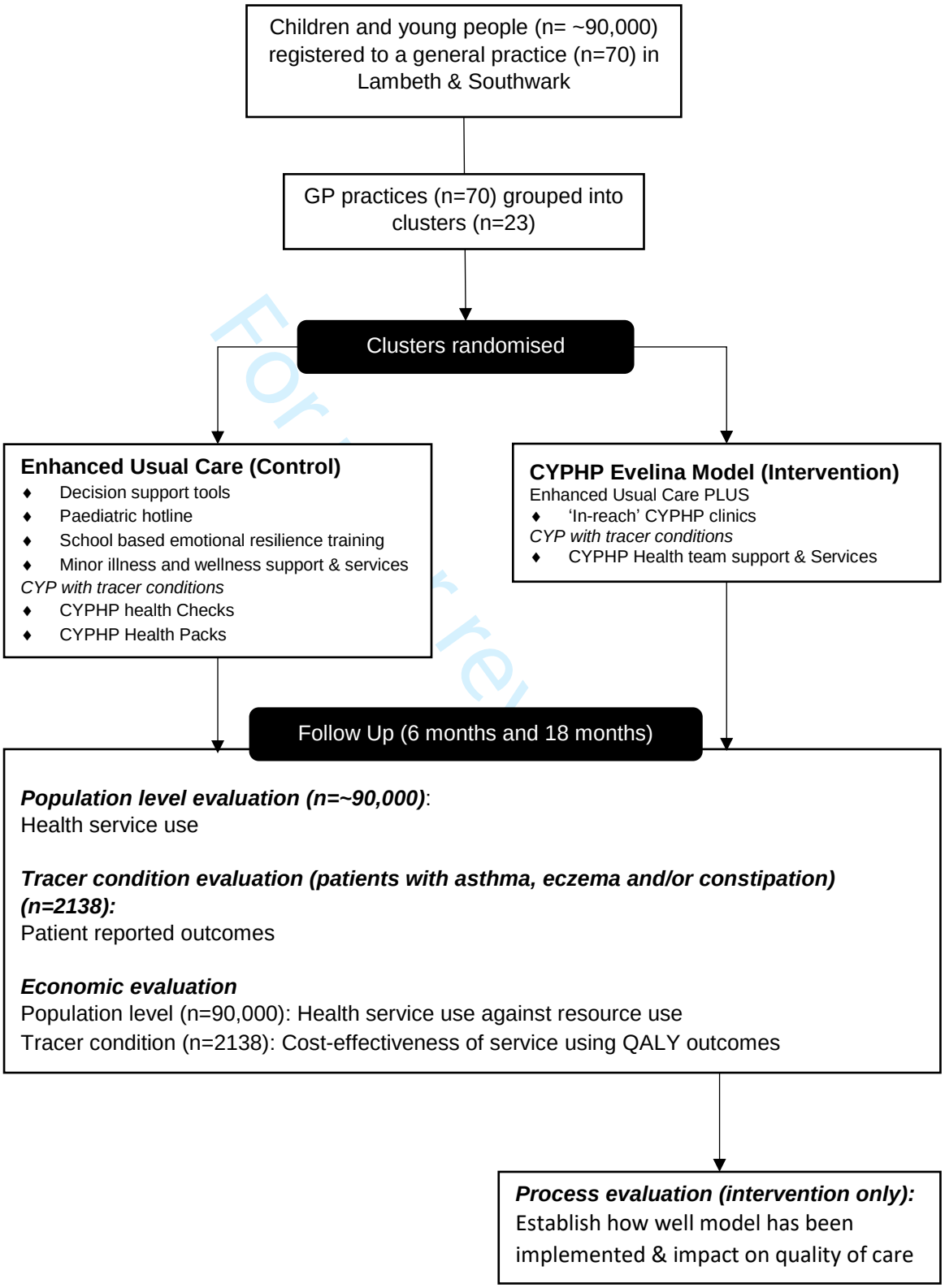


Figure 2. Diagram of patients, services, and levels of the evaluation



CONSORT Guidelines	
1a Identification as a randomised trial in the title	✓
1b Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	✓
2a Scientific background and explanation of rationale	✓
2b Specific objectives or hypotheses	✓
3a Description of trial design (such as parallel, factorial) including allocation ratio	✓
3b Important changes to methods after trial commencement (such as eligibility criteria), with reasons	✓
4a Eligibility criteria for participants	✓
4b Settings and locations where the data were collected	✓
5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	✓
6a Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	✓
6b Any changes to trial outcomes after the trial commenced, with reasons	N/A
7a How sample size was determined	✓
7b When applicable, explanation of any interim analyses and stopping guidelines	✓
8a Method used to generate the random allocation sequence	✓
8b Type of randomisation; details of any restriction (such as blocking and block size)	✓
9 Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	✓
10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	✓
11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those CONSORT 2010 checklist Page 2 assessing outcomes) and how	✓

11b If relevant, description of the similarity of interventions	✓
12a Statistical methods used to compare groups for primary and secondary outcomes	✓
12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	✓
Results and Discussion Sections from CONSORT not reported as this is a protocol	
23 Registration number and name of trial registry	✓
24 Where the full trial protocol can be accessed, if available	✓
25 Sources of funding and other support (such as supply of drugs), role of funders	✓