

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	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
AUTHORS	Newham, James Joseph; Forman, Julia; Heys, Michelle; Cousens, Simon; Lemer, Claire; Elsherbiny, Mohamed; Satherley, Rose-Marie; Lingam, Raghu; Wolfe, Ingrid

VERSION 1 - REVIEW

REVIEWER	Pamela Collins University of Washington USA
REVIEW RETURNED	26-Dec-2018

GENERAL COMMENTS	<p>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</p> <p>This manuscript presents a protocol to study the implementation of The Children and Young People's Health Partnership Evelina London Model of Care. The authors propose a rigorous, complex and comprehensive 4-part evaluation with 3 primary evaluation aims to examine population-level outcomes of the model, outcomes for 4 specific conditions, as well as process and cost evaluations. The mixed-methods approach that will complement the cluster randomized trial is a strength.</p> <p>The paper is well-written and the methods are well described. Given that the findings will be used to inform health policy and practice, it would be interesting to understand what active ingredients of this model the authors feel will make it superior to enhanced usual care in the various domains of care utilization. Since both conditions are expected to lead to improved outcomes, what hypotheses can the authors articulate about specific components of the model that should lead to better outcomes in the experimental group? This may become evident in the process evaluation, but specifying the proposed mediators might help inform implementation directions in the future.</p> <p>The authors will include an assessment of CYP and parental mental health—another strength given the prevalence of mental health conditions among young people as well as the importance of parental mental health on CYP wellbeing. One of the objectives of the tracer condition evaluation is to assess the impact of the model on the “prevalence and severity of mental health conditions.” While parents and CYP will be screened and</p>
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	presumably referred for co-located mental health services in the experimental model, it would be extremely useful to fully characterize mental health service utilization in these contexts, too.
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REVIEWER	David Keller MD University of Colorado, School of Medicine Aurora, Colorado, USA
REVIEW RETURNED	07-Jan-2019

GENERAL COMMENTS	<p>I applaud the authors and the journal for taking the initiative to prepare and publish for peer review a plan for the carefully designed evaluation of novel population-based child health initiative. The paper clearly lays out an initiative that has the potential to change the approach to child health care provision and chronic disease management for children in the United Kingdom. My specific comments follow:</p> <p>Abstract: Clear and concise description of both the intervention and the evaluation plan. The limitations of the study are not well described. As the study is planned for two urban boroughs in London, it is not clear how generalizable the results will be to the rest of the UK. ALoS, since the 4 tracer conditions do not include common developmental or behavioral health problems, it is not clear the evaluation will adequately assess the ability of GPs to manage these problems in the community.</p> <p>Introduction: Clear and precise, documenting the need for new model of primary care that moves chronic disease management for children out of hospital.</p> <p>Evaluation overview: Clearly delineates the four focuses of the evaluation, including the process evaluation (not the topic of this paper) and the economic evaluation. 4 tracer conditions are identified here to assess the impact of shared care between a pediatrician and a GP on pediatric chronic disease management. Only 3 of those conditions are mentioned in the sample size analysis later in the paper. Why were seizures omitted from the sample size analysis? The 3 study aims are clear, including the aim for the process analysis, which is stated more clearly here than in the companion paper. I may be more consistent to have 4 study aims to be consistent with the earlier arguments in favor of this evaluation.</p> <p>Note: I reviewed the other paper on the process analysis first; the writing and thinking in this paper is much more clear. I believe that this would all make more sense if the process analysis protocol were included in this paper.</p> <p>Methods and analysis: Clear and easy to follow. See notes above re: the process evaluation. The economic evaluation requires some clarify- the “cost of delivering the ...model” need to be defined as “costs to whom?”- the family, the clinic, the local government or the National Health Service. The detailed description of the intervention makes it relatively straightforward to align this evaluation with the work to be conducted. Concerns regarding the use of seizures as a tracer condition were noted above.</p>
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	Thanks again for the opportunity to review this paper. Look forward to seeing the results of the evaluation.
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VERSION 1 – AUTHOR RESPONSE

Response to Reviewers' comments on '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'

	Reviewer 1 comments	Author's response	Location
1	The paper is well-written and the methods are well described. Given that the findings will be used to inform health policy and practice, it would be interesting to understand what active ingredients of this model the authors feel will make it superior to enhanced usual care in the various domains of care utilization. Since both conditions are expected to lead to improved outcomes, what hypotheses can the authors articulate about specific components of the model that should lead to better outcomes in the experimental group? This may become evident in the process evaluation, but specifying the proposed mediators might help inform implementation directions in the future.	Thank you for these kind comments. We agree with the very well-made points about describing active components. To try and clarify this we have included an additional table that maps the intervention components of enhanced usual care and the full CYPHP model of care to the Theoretical Domains Framework. We hope this details sufficiently clearly how we believe the interventions will have an effect and why there will be an incremental benefit in those receiving the full range of services.	Pg. 7 and Pg. 8-9 under Interventions
2	The authors will include an assessment of CYP and parental mental health—another strength given the prevalence of mental health conditions among young people as well as the importance of parental mental health on CYP wellbeing. One of the objectives of the tracer condition evaluation is to assess the impact of the model on the “prevalence and severity of mental health conditions.” While parents and CYP will be screened and presumably referred for co-located mental health services in the experimental model, it would be extremely useful to fully characterize mental health service utilization in these contexts, too.	We agree that mental health is an important aspect of this work, and are aiming to address mental health needs among children with physical health conditions, mostly below the level of usual referral thresholds. CYPHP's services are primarily about early intervention so we anticipate a preventive effect and are not anticipating an impact on short to medium term mental health service use. One of the novel aspects of this study is obtaining estimates of the prevalence and severity of mental health concerns by asking consenting patients from both groups to complete the SDQ. To clarify our intentions the following phrase was changed (edits in bold): “The Strengths and Difficulties Questionnaire (SDQ) is completed as part of the Health Check to provide an	Pg. 12 under Tracer condition evaluation outcomes

		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 health services within the UK. Scores on the SDQ will be 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	
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Reviewer 3's comments	Author's response	Location
1 I applaud the authors and the journal for taking the initiative to prepare and publish for peer review a plan for the carefully designed evaluation of novel population-based child health initiative. The paper clearly lays out an initiative that has the potential to change the approach to child health care provision and chronic disease management for children in the UK.	Thank you for your kind comments. We appreciate the reviewer's recognition of why this work is so important, and the approach we have taken to ensure its rigour and policy-relevance.	Not applicable
2 Abstract: Clear and concise description of both the intervention and the evaluation plan. The limitations of the study are not well described. As the study is planned for two urban boroughs in London, it is not clear how generalizable the results will be to the rest of the UK. ALoS, since the 4 tracer conditions do not include common developmental or behavioral health problems, it is not clear the evaluation will adequately assess the ability of GPs to manage these problems in the community.	We have strived to explain the varied levels of the evaluation within the allowed word count, and have tried to improve this section through addressing these helpful comments by: <ul style="list-style-type: none"> - Including the phrase 'that are characterised by mixed ethnic populations and varying levels of deprivation' to give a clearer idea on the sociodemographic mix of the boroughs. - Asthma, constipation and eczema are experienced by 8%, ~15%, and 16%, respectively, of the paediatric population; and thus were chosen as tracer conditions because of their high prevalence and need for effective self-management to prevent exacerbation. We feel this evaluation will be able to determine how effectively GPs are managing these conditions in the community by comparing the health service use of infant who were primarily managed by GPs against those in the intervention group who have access to refer to the CYPHP health team and CYPHP 	'Abstract' and 'Strengths and limitations'

		<p>clinics for skills training. However we have adapted the sentence accordingly with the phrase: '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.'</p>	
3	<p>Evaluation overview: Clearly delineates the four focuses of the evaluation, including the process evaluation (not the topic of this paper) and the economic evaluation. 4 tracer conditions are identified here to assess the impact of shared care between a pediatrician and a GP on pediatric chronic disease management. Only 3 of those conditions are mentioned in the sample size analysis later in the paper. Why were seizures omitted from the sample size analysis?</p>	<p>Each of the four tracer conditions was chosen to fit with specific criteria about generalisability in learning. We evaluate epilepsy as part of our tracer condition cohort for lessons regarding how the service was implemented and acceptability (process evaluation) but do not include in the analysis of the effectiveness of the model of care (tracer condition evaluation).</p> <p>Asthma, eczema and constipation are comparable in how they are managed in a community setting by the new model of care. Epilepsy is distinct in that its management and treatment is primarily through secondary care. Thus, it was not appropriate to include patients with epilepsy in the same tracer condition cohort for the outcome-based sample size. We had included an explanation for this in the Recruitment and Consent section but we appreciate this may be confusing so we have included the following line in the Sample size calculation section: '(see 'Recruitment and Consent' for rationale why epilepsy not included in sample size calculation)'</p>	<p>See 'Recruitment and Consent' for rationale why epilepsy not included in sample size calculation</p>
5	<p>The 3 study aims are clear, including the aim for the process analysis, which is stated more clearly here than in the companion paper. I may be more consistent to have 4 study aims to be consistent with the earlier arguments in favor of this evaluation. Note: I reviewed the other paper on the process analysis first; the writing and thinking in this paper is much more clear. I believe that this would all make more sense if the process</p>	<p>We have adapted both papers to express the aims more clearly and hope this is now improved. We plan to publish the pair of papers together, as linked publications, so that it is clear they are part of an overarching evaluation plan.</p>	<p>Both papers' aims</p>

	analysis protocol were included in this paper.		
6	Methods and analysis: Clear and easy to follow. See notes above re: the process evaluation. The economic evaluation requires some clarify- the “cost of delivering the ...model” need to be defined as “costs to whom?”- the family, the clinic, the local government or the National Health Service. The detailed description of the intervention makes it relatively straightforward to align this evaluation with the work to be conducted. Concerns regarding the use of seizures as a tracer condition were noted above.	<p>Thank you, yes that is an important point. We have clarified throughout the manuscript that the cost is to the NHS.</p> <p>Thank you, yes. We hope the description and explanation above is sufficient; that we are accounting for epilepsy in our population level analysis but are not including it in the tracer condition analysis of effectiveness.</p>	Pg.5, 6

Although not requested, we have decided to introduce a parent-based primary outcome in addition to a child-based primary outcome. A sample size calculation has been estimated for this. We have made these changes on pages 14-15.

VERSION 2 – REVIEW

REVIEWER	David Keller Department of Pediatrics, University of Colorado School of Medicine, Aurora, CO, USA
REVIEW RETURNED	07-Apr-2019

GENERAL COMMENTS	The paper remains strong, and have adequately addressed my concerns. No additional comments. Thank you for the opportunity to reread this paper.
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