PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Study protocol for a real-world evaluation of an integrated child and family health hub for migrant and refugee women
AUTHORS	Hodgins, Michael; Ostojic, Katarina; Hu, Nan; Lawson, K; Samir, Nora; Webster, Amanda; Rogers, Helen; Henry, Amanda; Murphy, Elisabeth; Lingam, Raghu; Raman, Shanti; Mendoza Diaz, Antonio; Dadich, Ann; Eapen, Valsamma; Rimes, Tania; Woolfenden, Susan

VERSION 1 – REVIEW

REVIEWER	Murad Alrashdi Qassim University
REVIEW RETURNED	01-Apr-2022

GENERAL COMMENTS	The paper looked at the A non-randomised control trial, implementation evaluation, and economic evaluation of an integrated child and family health hub (FDCC) for migrant and refugee women . It is very well-done protocol and deserve to be published in the BMJ Open, well written and straight to the point in addition to the great topic that is much needed for migrants and refugees' health. I have suggested few comments, which I think will improve the study. ..... Title The title is long, it needs to be shortened. What does FDCC stands for, try to avoid abbreviation in the title Abstract Please separate the aim from the introduction part in the abstract, it can be in eperate section since this is a protocol study. In the material and analysis, it is better to be called material and methods, I don't see any analysis. Second, please mention that this is a protocol study in the abstract, so to avoid confusion to the reader. Third, I don't see any measures of the outcomes, how are you going to do your measurements, please mention them briefly in the abstract. Introduction Page 5, line 47: Please define " developmentally vulnerable" Page 5, line 48: "Families with greater disadvantage are at greater risk of developmental vulnerability and poorer maternal mental health "This is so true, not only mental healthy but also has affected oral health. Please add to mental health "other health problem" and cite this article "Alrashdi M, Hameed A, Cervantes Mendez MJ, Farokhi M. Education intervention with respect to the oral health

	knowledge, attitude, and behaviors of refugee families: A randomized clinical trial of effectiveness. J Public Health Dent. 2021 Jun;81(2):90-99. doi: 10.1111/jphd.12415. Epub 2020 Oct 20. PMID: 33084019; PMCID: PMC8246856." Page 5, line 34: Please cite this new study to support this finding, it is also affect their quality of life "Murad Alrashdi, Maria Jose Cervantes Mendez, Moshtagh R. Farokhi, A Randomized Clinical Trial Preventive Outreach Targeting Dental Caries and Oral-Health-Related Quality of Life for Refugee Children, International Journal of Environmental Research and Public Health, 10.3390/ijerph18041686, 18, 4, (1686), (2021)." Page 6, line 23: Add reference toward the end of the sentence that ends "Hubs", please. Materials and Methods Recruitment and consent: How did you determine that you will recruit 240 women? any sample size calculation, please specify that and add it in the protocol. Was it supposed to be 240 children not women per you sample size estimation? Clarify this please Page 11, line 22: Please correct " (Error! Reference source not found) Primary and secondary measures: I see primary measure will explained, but there is no information about secondary measure in the text or table 5. Please specify what are your secondary measures.

REVIEWER	Tan Nguyen Deakin University
REVIEW RETURNED	11-May-2022

GENERAL COMMENTS	Dear authors, Overall, the paper is well written. There are elements of the economic evaluation that is unclear, and requires consideration. I have added these comments in the PDF version. Kind regards, The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

REVIEWER 1 COMMENTS	
1. The title is long, it needs to be shortened. What does FDCC stands for, try to avoid abbreviation in the title.	The title has been revised: *'Study protocol for a real-world evaluation of an integrated child and family health hub for migrant and refugee women'*.
2. Please separate the aim from the introduction part in the abstract, it can be in separate section since this is a protocol study. In the material and analysis, it is better to be called material and methods, I	The abstract has been revised accordingly.

	don't see any analysis. Second, please mention that this is a protocol study in the abstract, so to avoid confusion to the reader. Third, I don't see any measures of the outcomes, how are you going to do your measurements, please mention them briefly in the abstract.	
3.	Page 5, line 47: Please define "developmentally vulnerable"	We have explicated the domains of developmental vulnerability according to the Australian Early Development Census.
4.	Page 5, line 48: "Families with greater disadvantage are at greater risk of developmental vulnerability and poorer maternal mental health "This is so true, not only mental healthy but also has affected oral health. Please add to mental health "other health problem" and cite this article "Alrashdi M, Hameed A, Cervantes Mendez MJ, Farokhi M. Education intervention with respect to the oral health knowledge, attitude, and behaviors of refugee families: A randomized clinical trial of effectiveness. J Public Health Dent. 2021 Jun;81(2):90-99. doi: 10.1111/jphd.12415. Epub 2020 Oct 20. PMID: 33084019; PMCID: PMC8246856."	We have added this detail and citation as suggested.
5.	Page 5, line 34: Please cite this new study to support this finding, it is also affect their quality of life "Murad Alrashdi, Maria Jose Cervantes Mendez, Moshtagh R. Farokhi, A Randomized Clinical Trial Preventive Outreach Targeting Dental Caries and Oral-Health-Related Quality of Life for Refugee Children, International Journal of Environmental Research and Public Health, 10.3390/ijerph18041686, 18, 4, (1686), (2021)."	We have added this citation as suggested.
6.	Page 6, line 23: Add reference toward the end of the sentence that ends "Hubs", please.	We have added this reference as suggested.
7.	Recruitment and consent: How did you determine that you will recruit 240 women? any sample size calculation, please specify that and add it in the protocol. Was it supposed to be 240 children not women per you sample size estimation? Clarify this please	We have already provided a sample size calculation in the Data Analysis Plan (p.16).
8.	Page 11, line 22: Please correct " (Error! Reference source not found)	We have corrected this error as suggested.
9.	Primary and secondary measures: I see primary measure will explained, but there is no information about secondary measure in the text or table 5. Please specify what are your secondary measures.	We have identified our secondary measures as suggested.
REVIEWER 2 COMMENTS		
10.	Move reference to end of sentence.	These references have been moved as suggested.

11. Inserted comment: Project officer? (as opposed to an implementation scientist)	The project has a funded dedicated implementation scientist who will be completing this piece of work.
12. What is a keyworker, please describe?	We have described the role of the Key Worker as suggested.
13. Please correct “Error! Reference source not found.”	We have corrected this error as suggested.
14. This reads as healthcare perspective and should be explicitly stated. The outcomes is not clear, and need to mention QALY as outcome measure derived from EQ-5D. Trial-based economic evaluation should also be mentioned using a decision-tree analysis I presume. Cost-effectiveness should also consider what is the willingess to pay threshold. Sensitivity analysis needs to be incorporated such as one-way deterministic or probabilistic. I would suggest CEA also consider alternative outcome measures given the short duration of the study. Changes to EQ-5D may be minimal such attendance/completion of CFH checks.	We have updated the text make clear that the analysis is aligned with the reviewer comments. For clarity, a within-trial economic evaluation from health sector perspective is made explicit. The analysis combines a cost consequence analysis (CCA) and cost-utility analysis (CUA) in a complimentary approach. The CCA will include all trial outcomes (e.g. well-being measures, attendance). The EQ5D is still included as the main generic measure as this is the main generic measure routinely used in Australia, and the willingness of pay threshold is varied using values from a recent Australian study. A value of information analysis (VOI) is included to assess uncertainty and value of further research (post-trial) including longer follow-up.
15. One-way or multi-way deterministic?	The latter - specifically a Probability Sensitivity Analysis (PSA) following international best practice.

VERSION 2 – REVIEW

REVIEWER	Murad Alrashdi Qassim University
REVIEW RETURNED	20-Jul-2022

GENERAL COMMENTS	The authors addressed all the previous comments in a great way. I belief the study protocol well written and deserve to be published in this current way. I have no further comments and give my heist recommendation to be accepted for publication.

REVIEWER	Tan Nguyen Deakin University
REVIEW RETURNED	22-Jul-2022

GENERAL COMMENTS	Dear authors, I have minor comments regarding the economic evaluation plan. 1) I would rephrase 'probability sensitivity analysis' with 'probabilistic sensitivity analysis', as the generally accepted term. 2) Change in health utility should be explicitly reported as QALYs if this is the case. Health utility weights also are varied, so an explicit reference is required to justify which health utility set will be used for

	the analysis. 3) VOI would only be required if the CUA does not show cost-effectiveness based on the WTP. I would suggest remove this approach, and only consider if the economic evaluation results is insufficient to make clear judgement based on the cost-effectiveness acceptability curve. The same would apply for the BIA, as it not a worthwhile investment in performing this evaluation if the intervention is not cost-effective. Alternatively, you can suggest the VOI and BIA would be performed, contingent if the CUA determines the intervention is cost-effective. Kind regards, Peer-reviewer

VERSION 2 – AUTHOR RESPONSE

REVIEWER 2 COMMENTS	
16. I would rephrase 'probability sensitivity analysis' with 'probabilistic sensitivity analysis', as the generally accepted term.	We have made this change as suggested.
17. Change in health utility should be explicitly reported as QALYs if this is the case. Health utility weights also are varied, so an explicit reference is required to justify which health utility set will be used for the analysis.	We have added an explicit reference to justify the health utility set used as suggested.
18. VOI would only be required if the CUA does not show cost-effectiveness based on the WTP. I would suggest remove this approach, and only consider if the economic evaluation results is insufficient to make clear judgement based on the cost-effectiveness acceptability curve. The same would apply for the BIA, as it not a worthwhile investment in performing this evaluation if the intervention is not cost-effective. Alternatively, you can suggest the VOI and BIA would be performed, contingent if the CUA determines the intervention is cost-effective.	We recognise the intent behind the reviewer's sentiment, which is the sensible point to undertake an analysis if it's worthwhile to do so. Such considerations are inherent to the approach and methods themselves. Nonetheless, some additional text has been added to more clearly convey that, where there is uncertainty, a VOI will be undertaken and, where positive changes are found in primary and/or secondary outcomes, a BIA will be undertaken. Some additional context may be worthwhile regarding these small changes recognising the reviewer comments were also minor, though welcomed to make the text clearer. Regarding VOI, rarely if ever, would inferences regarding the cost effectiveness (or otherwise) of an intervention have zero uncertainty, and by extension there is value in undertaking a VOI. This is the authors choice to do so. Further, the time cost to undertake the VOI is relatively minimal given this is a natural and quick extension of the PSA (uncertainty analysis) which already contains 90% of the work required for a VOI assessment.

	Regarding the BIA, knowing the cost of scaling-up, will be of interest to both policymakers and applied researchers to inform such policy decisions. The value of undertaking a BIA is not solely contingent on whether the intervention is found to be cost-effective in a CUA. It is worth restating that orthodox approaches to CUA were derived for health technology assessment (HTA) and have challenges being advocated as the sole metric of value for any health and social service interventions. Health utility or QALYs is not the primary outcome for the study overall, but rather one important consideration amongst many; and a CUA does not capture nor value all key potential impacts. This is why the economic analysis begins with a CCA where all attributable changes in major outcome measures are listed, including and alongside utilities & QALYs. This again follows methodological guidance. As has been well written about, the policy decision to scale-up an intervention will involve multiple considerations beyond that solely captured in a cost effectiveness analysis. That is, priority setting for policymakers is not equivalent to cost effectiveness analysis for health economists, and a BIA can be an essential element to inform such decisions.