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Interventions and Practice Models for Improving Health and Psychosocial Outcomes of Children and Young People in Out-of-Home Care: Protocol for a Systematic Review

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ABSTRACT

Introduction: Children and young people placed in out-of-home care (OoHC) are often affected by a history of trauma and adverse childhood experiences. Trauma in early childhood can impact on children's health and psychosocial development, whereas early interventions can improve children's development and placement stability. Although several interventions and practice models have been developed to improve health and psychosocial outcomes for children and young people in OoHC, there remains a lack of rigorous research examining the impact of these interventions in OoHC settings, as there are no systematic reviews examining the impact these interventions and practice models have on the children and young people they serve.

Objective: We aim to conduct a comprehensive systematic review to examine the effectiveness of interventions and practice models for improving health and psychosocial outcomes in children and young people living in OoHC and to identify relevant knowledge gaps.

Methods & Analysis: Major electronic databases including Medline, EMBASE, CINAHL, PsycInfo, Social Science and all EBM reviews will be systematically searched for any studies published between 2008 and 2018 of interventions and practice models developed to improve health and psychosocial outcomes for children and young people in OoHC. Two independent reviewers will assess titles and abstracts for eligibility according to pre-specified selection criteria, and will perform data extraction and quality appraisal. Meta-analyses and/or meta-regression will be conducted where appropriate.

Ethics and Dissemination: This study will not collect primary data and formal ethical approval is therefore not required. Findings from this systematic review will be disseminated in a peer-reviewed publication and conference presentations.

Registration: International Prospective Register for Systematic Reviews (PROSPERO) number CRD42019115082.

Article Summary

Strengths and Limitations of this Study:

- This research can guide the design and implementation of interventions in out-of-home care as well informing future research in this field;
- The current study employs rigorous international gold-standard methodology and a comprehensive search strategy;
- Limitations include the potential for publication bias since the systematic review will include only published data and further, studies may be too heterogeneous to obtain combined effect estimates.

1. Introduction:

Children and young people in Out-of-Home Care (OoHC) are some of the most vulnerable groups in society, often having experienced substantial harm, abuse, or neglect.[1, 2] OoHC refers to the short- or long-term care of children and young people up to 18 or 21 years of age (depending on country) who are unable to live with their families due to child protection orders and/or as a result of parents being unable to provide adequate care or protection.[3] In Australia, 47,915 children <18 years lived in OoHC in 2017, a rate of 8.7 per 1,000 children, reflecting an increase from 46,448 and 40,549 children in 2016 and 2013, respectively.[2, 4] These rising rates are concerning, since children and young people placed in OoHC are often characterised as having severe cognitive, emotional, behavioural and social problems,[1, 5] coupled with complex histories of maltreatment and neglect.[5, 6] This history of trauma is believed to have short- and long-term effects on brain development, from childhood through to adulthood, and often culminates into complex behavioural, psychological, and social challenges.[5, 6]

Children and young people in OoHC report poorer outcomes across a number of health and wellbeing indicators compared to those who remain with their biological family.[7] Since children and young people usually enter care having experienced trauma and neglect, deviant behaviour and mental health problems are particularly prevalent among children and young people in OoHC and this appears to be associated with both age at first placement and type of care.[8] A 2006 study found that up to 60% of children and young people in OoHC have a current mental health diagnosis including depression, attachment and conduct disorders, and attention deficit hyperactivity disorders,[9] and those placed in residential care tend to have higher rates compared to those in foster care, whereas individuals in kinship care report the fewest rate of mental health disorders.[8, 10] Children and young people in OoHC also report a significantly higher incidence of substance abuse, suicide ideation and suicide attempt,[11-13] as well as attachment difficulties, problematic sexual behaviour, eating disorders, delinquent behavior,

and reduced educational attainment compared with children and young people residing with their biological families.[8, 14] The poor outcomes that children and young people in OoHC face, some of which are mentioned above, play a significant role in the complexity of their overall health, making it more challenging to identify their health needs and develop appropriate health management plans. Evidently, children and young people in OoHC require more intensive intervention and support, as we are dealing with complex, multifaceted issues, that require a number of strategies that can effectively support their health and wellbeing.

In light of the poor health and psychosocial outcomes experienced by children and young people living in OoHC, effective and sustainable interventions for improving these outcomes are urgently needed. Over the last few years, a number of practice models and interventions have been developed with the aim of directly addressing the impact of trauma on health and psychosocial outcomes for children and young people in OoHC.[15] Some of these models, such as the Sanctuary Model, Therapeutic Residential Care and Treatment Foster Care are shifting towards needs-based care and incorporating a trauma-informed, therapeutic care approach within the OOHC placements.[16] In Australia, the UK, and the US, it is expected that children and young people entering OoHC have the appropriate health assessments (statutory) and that health care records and management plans are in place.[17-20] Unfortunately, this process is not always met, and even when a child is provided with a health management plan, their needs may not be incorporated and the plan may not be followed.[18] Collecting the necessary information can be difficult as health professionals must rely on parents to provide medical histories, explain health and behavioural concerns, and consent to the assessment and treatment of their child.[18] Despite carers' and case managers' best efforts to provide this information, the high percentage of placement breakdowns and constant change in caregivers and service providers create gaps in information pertaining to the individuals's social or family circumstances and medical and mental health, and there is risk of this information being lost.[6]

Most interventions have also not been properly evaluated and there remains a lack of rigorous research examining the impact of these interventions in improving health and/or psychosocial outcomes for children and young people in OoHC.[21] Indeed, a recent systematic review investigating the empirical evidence of trauma-informed, organisation-wide models implemented in residential OoHC settings identified three models including The Sanctuary Model, Children and Residential Experiences programme (CARE), and the Attachment Regulation and Competency framework (ARC), and concluded that the evidence base is limited, making it difficult to accurately evaluate outcomes of trauma-informed models.[22] Recent studies have outlined the health and psychosocial needs of children and young people in OoHC and the interventions and practice models that have been designed to meet these needs; however, to date, very little research has been focused on evaluating the effectiveness of these interventions.[15] To our knowledge, no previous systematic reviews have examined interventions or practice models designed to respond to the physical and psychosocial health needs of children or young people in residential, foster and kinship settings of OoHC.

To develop effective, evidence-based interventions in OoHC, we first need to understand which interventions and practice models work, and how their structures and processes can be implemented and sustained in practice. Otherwise, the cycle of disadvantage and poor health outcomes will not be broken, and children and young people in OoHC will remain at increased risk of adverse health and psychosocial outcomes. To this end, we aim to conduct a comprehensive systematic review which will: (1) assess the effectiveness of interventions and practice models for improving the health and psychosocial outcomes of children and young people living in OoHC (all types of placements); (2) examine whether a particular intervention or practice model is more effective than another; and (3) delineate which components of these interventions are associated with the greatest improvement in outcomes for these children and young people.

2. Systematic Review Questions:

- Are certain interventions or practice models effective in improving health and/or psychosocial outcomes for children and young people in OoHC compared with usual care?
- Are certain interventions or practice models more effective than others in improving health and/or psychosocial outcomes for children and young people in OoHC?
- Which elements are critical in determining the success of interventions, and for whom?

3. Methods and Analysis:

This systematic review utilises rigorous international gold standard methodology[23, 24] , and conforms to the reporting standards of the Preferred Reporting Items for Systematic Reviews and Meta-analyses[25] (PRISMA; Supplementary File). The protocol for the systematic review has been registered on the International Prospective Register for Systematic Reviews (PROSPERO) under the identification code: CRD42019115082.

3.1. Selection Criteria

As outlined in **Table 1**, a PICO (Population, Intervention, Comparison, Outcomes) framework was established *a priori* to screen studies and determine their eligibility for inclusion in the systematic review.

Table 1. PICO for study inclusion

	Participants (P)	Intervention (I)	Comparison (C)	Outcomes (O)	Study type	Limits
Inclusion criter	Children 0 - 21 years of age and living in OoHC • School aged • Youth • Adolescents • Children • Infants	Any intervention (e.g. Treatment foster care; therapeutic residential care, Sanctuary model, etc.) delivered in an out-of-home care setting (e.g. Foster care, kinship care, residential care, etc.)	No intervention/ usual care or other interventions in out-of-home care Children who remain with their biological/ foster families	All health and psychosocial outcomes including but not limited to: Intellectual; behavioural; psychosocial; mental; suicidal ideation; psychological functioning; social skills;	Randomized controlled trials: Non-randomized or uncontrolled trials; Systematic Reviews; Cohort studies; Cross-sectional; Longitudinal	English Language only Peer Reviewed Published in the last 10 years (2008 – 2018)

				emotional; educational attainment; relationships; illicit drug use; smoking; alcohol; eating disorders;		
Exclusion criteria	Adults >21 years of age	Adoption Rehabilitation			Editorial; commentary; narrative review; expert opinion	Literature published before 2008 Languages other than English.

3.2. Search Strategy

A systematic search, based on the selection criteria (Table 1) and combining MeSH terms and text words, was developed using the OVID platform and translated to other databases as appropriate. The search terms are outlined in **Table 2**.

Table 2. Sample of search terms used in electronic search

Concept 1: *Out of Home Care*   Foster care, foster, out of home, kinship, trauma informed, resident*, guardian care, family based care, family centered, home based, child protection, child welfare, non biological care, group home, group house, 'OoHC'
Concept 2: *Participants*   Looked after child, young person, young people, infan*, baby, babies, toddler, preschool*, adolescen*, teen*, minor, youth
Concept 3: *Intervention*   Model, outcome, evaluation, framework, theor*, intervention, program*, process*, prevention, treatment, strategy*, therap*, trauma informed, trauma focused, trauma service

Relevant articles will be sourced through electronic databases including: Medline, Medline in-process and other non-indexed citations, EMBASE, PsycINFO, CINAHL, Sociological Abstracts and All EBM Reviews incorporating: Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effects, Cochrane Central Register of

Controlled Trials, Cochrane Methodology Register, Health Technology Assessment, NHS Economic Evaluation Database. Bibliographies of relevant studies as well as systematic reviews identified by the search strategy will be screened for identification of additional studies. Where required data are not presented, the corresponding authors of included studies will be contacted to provide de-identified aggregate data for the purpose of meta-analyses if deemed necessary.

3.3. Screening of Search Results

Search results will be managed using the Endnote X.8.0 reference management software. Two reviewers will assess the titles, abstracts and keywords of every article retrieved by the search strategy according to the selection criteria described in Table 1. Full text of the articles will be retrieved for further assessment if the information provided suggests that the study meets the selection criteria or if there is any doubt regarding eligibility of the article based on the information given in the title and abstract. Where there is more than one article describing the same study and reporting different outcomes, these articles will be combined and considered a single unique study. Articles excluded after full text assessment will be tabulated with reasons for their exclusion, as per PRISMA guidelines.[26]

3.4. Data Extraction

Two independent reviewers will formally screen all included studies against the selection criteria and perform data extraction using a specifically designed data extraction form. Extracted data will include general study characteristics (author, year, country, setting, inclusion/ exclusion criteria), population characteristics (gender and age distribution and other relevant features), intervention and control characteristics (type/ model, duration, frequency etc), outcome assessments (physical and psychosocial outcomes and tools used to assess these), and results (point estimates and measures of variability for continuous outcomes, and frequency

counts or absolute numbers of episodes or relative measures of risk [risk ratio or odds ratio with confidence intervals] for dichotomous variables, numbers of participants, intention-to-treat analysis), and any other relevant validity results. Missing data will be obtained from corresponding authors wherever possible, and two reviewers will check all computed data entries for meta-analysis if applicable. Any disagreement will be resolved by discussion to reach a consensus.

3.5. Assessment of Risk of Bias and Quality of the Evidence

Methodological quality of included studies will be assessed at the study-level by two independent reviewers using a risk of bias assessment template according to study design. Individual quality items will be investigated using a descriptive component approach which will include assessment of key aspects such as methods of outcome assessment and reporting, statistical analysis components including study power and dealing with confounding, attrition rates, and conflicts of interest of authors. Using this process, a risk of bias rating (high, moderate, or low) will be assigned to each study.

Quality of the evidence for the effects of interventions in improving health and psychosocial outcomes for children and young people in OoHC will be assessed by two independent reviewers using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework.[27] This will be used to appraise quality at the outcome-level and, where appropriate, will incorporate aspects such as risk of bias, inconsistency, indirectness, imprecision, and publication bias. Based on this evaluation, a quality score (high, moderate, low, or very low) will be assigned to each outcome. Disagreement will be resolved by discussion to reach consensus.

[1]Patient and Public Involvement: This systematic review will not collect primary data and therefore patients and the public were not involved in the design, conduct or reporting of the research.

3.6. Data Analysis and Synthesis

Data will be presented in summary form and narratively as well as in tables (where possible) to describe the study designs, populations and findings and to address each research question. Data will be summarised statistically using meta-analysis of aggregate effect measures if available and if studies are deemed sufficiently homogenous to combine. Review Manager V.5 software will be used for meta-analysis, whereby data will be pooled and analysed using random-effects models to provide estimates of the effectiveness of the intervention for each outcome of interest. Results from meta-analyses will be expressed as relative risks (RR) or odds ratios (OR) with 95% confidence intervals (CI) for dichotomous outcomes and weighted mean differences (WMD) with 95% CI for continuous outcomes. Statistical homogeneity will be assessed using the I^2 test where I^2 values over 50% indicate moderate to high heterogeneity.[28] Statistical significance will be set at a two-tailed P <0.05. For studies with qualitative designs or that are heterogeneous or have insufficient data for pooling, a descriptive analysis will be presented.

3.7. Subgroup Analysis

Subgroup analysis, and where appropriate, meta-regression will be performed if possible based on study characteristics and results from the search. Where there is sufficient data, these analyses will be conducted based on pre-specified subgroups/covariates including age at placement, age at intervention, gender, ethnicity (indigenous vs non-indigenous), placement type (residential or group home vs foster family, and kinship vs non-kinship placement), types of abuse/reason for placement (maltreatment/abuse vs behavioural problems), types of intervention (psychological, social, behavioural), duration of intervention and length of follow-up. Other factors presumed to cause variations in the outcomes may be determined during the review process and these will be included in additional exploratory subgroup analyses.

3.8. Sensitivity Analysis

Sensitivity analysis will be conducted to explore the influence of heterogeneity (I^2 >50%) and risk of bias on effect size. Sensitivity analyses will be performed in which studies causing heterogeneity or studies with high risk of bias will be excluded from meta-analyses to examine their influence on the results. Where there are sufficient numbers of studies, visual inspection of funnel plots and Egger and Begg[29, 30] statistical tests will be used to assess publication bias and small study effects.

4. Discussion

Children and young people in OoHC have typically been exposed to a multitude of psychologically distressing and adverse experiences that manifests into childhood trauma.[31] Childhood trauma is an important public health concern as adverse childhood experiences can have substantial health, social, and economic implications which extend throughout the lifespan.[31]Therefore, there is a need for health and psychosocial interventions to be implemented to prevent further traumatic and adverse childhood experiences as early as possible, as these interventions may reduce the negative outcomes of adverse childhood experiences. Existing interventions and practice models aim to directly address the impact of trauma on a child's health or psychosocial outcomes, typically through trying to reduce symptoms or facilitate recovery.[31, 32] However, many of these interventions have not been properly evaluated, or have limited evidence of their effectiveness in improving the health and/or psychosocial outcomes for children and young people in OoHC. In order to develop effective interventions for those in OoHC, we need to understand which interventions work, and how their effects can be sustained and embedded (i.e., implemented) into practice.

The proposed systematic review aims to address these gaps by examining how interventions and practice models can be applied to organisations and carers to improve the

physical and psychosocial health of children and young people placed in OoHC. Using rigorous methodology, pre-specified criteria, and a pre-determined search strategy, this review will capture and synthesize existing quantitative and qualitative evidence on interventions in OoHC to establish their impact in improving health and psychosocial outcomes, and to disentangle the specific elements which contribute to their success. Findings from this review will provide much needed evidence to build the current knowledge base and to inform the implementation of effective interventions in OoHC, in an effort to alleviate the poor health and psychosocial outcomes of children and young people in OoHC.

5. Ethics and Dissemination:

This study does not require ethical approval as it does not involve primary data collection. We anticipate that findings from this review will contribute to an improved understanding of interventions which improve health and psychosocial outcomes for children and young people in OoHC and the key contributing factors within these interventions. These findings will be disseminated through peer reviewed publications and at conference meetings, to inform future research and to guide the development and real-world implementation of sustainable interventions in OoHC settings.

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5.1. Author Contributions:

EG developed the search strategy, wrote the first draft of the review protocol, and will lead the data collection and analysis. AM contributed to the design and scope of the search strategy, guiding the review process, and revising and editing the manuscript. RO and NH contributed to the revision and editing of the manuscript. HS determined the design and scope of the review, revised and edited the manuscript, will supervise the review process, and is the guarantor for ensuring the integrity and accuracy of the review data.

5.2. Funding Statement:

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5.3. Competing Interests Statement:

All authors declare no conflicts of interest.

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Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
	#2	If registered, provide the name of the registry (such as	2

		PROSPERO) and registration number	
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	14
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Sources	#5a	Indicate sources of financial or other support for the review	14
Sponsor	#5b	Provide name for the review funder and / or sponsor	N/A
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Rationale	#6	Describe the rationale for the review in the context of what is already known	4-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7-8
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-8

Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8-9
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	8
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9-10
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the	10

		outcome or study level, or both; state how this information will be used in data synthesis	
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	11
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	11
	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	11-12
	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	11
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	10
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

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Running Title: Improving Outcomes in Out-of-Home Care

Interventions and Practice Models for Improving Health and Psychosocial Outcomes of Children and Young People in Out-of-Home Care: Protocol for a Systematic Review

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ABSTRACT

Introduction: Children and young people placed in out-of-home care (OoHC) are often affected by a history of trauma and adverse childhood experiences. Trauma in early childhood can impact on children's health and psychosocial development, whereas early interventions can improve children's development and placement stability. Although several interventions and practice models have been developed to improve health and psychosocial outcomes for children and young people in OoHC, there remains a lack of rigorous research examining the impact of these interventions in OoHC settings, as there are no systematic reviews examining the impact these interventions and practice models have on the children and young people they serve. We aim to conduct a comprehensive systematic review to examine the effectiveness of interventions and practice models for improving health and psychosocial outcomes in children and young people living in OoHC and to identify relevant knowledge gaps.

Methods & Analysis: Major electronic databases including Medline, EMBASE, CINAHL, PsycInfo, Social Science and all EBM reviews will be systematically searched for any studies published between 2008 and 2018 of interventions and practice models developed to improve health and psychosocial outcomes for children and young people in OoHC. Two independent reviewers will assess titles and abstracts for eligibility according to pre-specified selection criteria, and will perform data extraction and quality appraisal. Meta-analyses and/or meta-regression will be conducted where appropriate.

Ethics and Dissemination: This study will not collect primary data and formal ethical approval is therefore not required. Findings from this systematic review will be disseminated in a peer-reviewed publication and conference presentations.

Registration: International Prospective Register for Systematic Reviews (PROSPERO) number CRD42019115082.

Article Summary

Strengths and Limitations of this Study:

- The current study employs rigorous international gold-standard methodology and a comprehensive search strategy;
- A limitation of this study includes the potential for publication bias since the systematic review will include only published data;
- Another limitation of this study includes the potential that studies may be too heterogeneous to obtain combined effect estimates.

1. Introduction:

Children and young people in Out-of-Home Care (OoHC) are some of the most vulnerable groups in society, often having experienced substantial harm, abuse, or neglect.[1, 2] OoHC refers to the short- or long-term care of children and young people up to 18 or 21 years of age (depending on country) who are unable to live with their families due to child protection orders and/or as a result of parents being unable to provide adequate care or protection.[3] In Australia, 47,915 children <18 years lived in OoHC in 2017, a rate of 8.7 per 1,000 children, reflecting an increase from 46,448 and 40,549 children in 2016 and 2013, respectively.[2, 4] These rising rates are concerning, since children and young people placed in OoHC are often characterised as having severe cognitive, emotional, behavioural and social problems,[1, 5] coupled with complex histories of maltreatment and neglect.[5, 6] This history of trauma is believed to have short- and long-term effects on brain development, from childhood through to adulthood, and often culminates into complex behavioural, psychological, and social challenges.[5, 6]

Children and young people in OoHC report poorer outcomes across a number of health and wellbeing indicators compared to those who remain with their biological family.[7] Since children and young people usually enter care having experienced trauma and neglect, deviant behaviour and mental health problems are particularly prevalent among children and young people in OoHC and this appears to be associated with both age at first placement and type of care.[8] A 2006 study found that up to 60% of children and young people in OoHC have a current mental health diagnosis including depression, attachment and conduct disorders, and attention deficit hyperactivity disorders,[9] and those placed in residential care tend to have higher rates compared to those in foster care, whereas individuals in kinship care report the fewest rate of mental health disorders.[8, 10] Children and young people in OoHC also report a significantly higher incidence of substance abuse, suicide ideation and suicide attempt,[11-13] as well as attachment difficulties, problematic sexual behaviour, eating disorders, delinquent behavior,

and reduced educational attainment compared with children and young people residing with their biological families.[8, 14] The poor outcomes that children and young people in OoHC face, some of which are mentioned above, play a significant role in the complexity of their overall health, making it more challenging to identify their health needs and develop appropriate health management plans. Evidently, children and young people in OoHC require more intensive intervention and support, as we are dealing with complex, multifaceted issues, that require a number of strategies that can effectively support their health and wellbeing.

In light of the poor health and psychosocial outcomes experienced by children and young people living in OoHC, effective and sustainable interventions for improving these outcomes are urgently needed. Over the last few years, a number of practice models and interventions have been developed with the aim of directly addressing the impact of trauma on health and psychosocial outcomes for children and young people in OoHC.[15] Some of these models, such as the Sanctuary Model, Therapeutic Residential Care and Treatment Foster Care are shifting towards needs-based care and incorporating a trauma-informed, therapeutic care approach within the OOHC placements.[16] In Australia, the UK, and the US, it is expected that children and young people entering OoHC have the appropriate health assessments (statutory) and that health care records and management plans are in place.[17-20] Unfortunately, this process is not always met, and even when a child is provided with a health management plan, their needs may not be incorporated and the plan may not be followed.[18] Collecting the necessary information can be difficult as health professionals must rely on parents to provide medical histories, explain health and behavioural concerns, and consent to the assessment and treatment of their child.[18] Despite carers' and case managers' best efforts to provide this information, the high percentage of placement breakdowns and constant change in caregivers and service providers create gaps in information pertaining to the individuals' social or family circumstances and medical and mental health, and there is risk of this information being lost.[6]

Most interventions have also not been properly evaluated and there remains a lack of rigorous research examining the impact of these interventions in improving health and/or psychosocial outcomes for children and young people in OoHC.[21] Indeed, a recent systematic review investigating the empirical evidence of trauma-informed, organisation-wide models implemented in residential OoHC settings identified three models including The Sanctuary Model, Children and Residential Experiences programme (CARE), and the Attachment Regulation and Competency framework (ARC), and concluded that the evidence base is limited, making it difficult to accurately evaluate outcomes of trauma-informed models.[22] Recent studies have outlined the health and psychosocial needs of children and young people in OoHC and the interventions and practice models that have been designed to meet these needs; however, to date, very little research has been focused on evaluating the effectiveness of these interventions.[15] To our knowledge, no previous systematic reviews have examined interventions or practice models designed to respond to the physical and psychosocial health needs of children or young people in residential, foster and kinship settings of OoHC.

To develop effective, evidence-based interventions in OoHC, we first need to understand which interventions and practice models work, and how their structures and processes can be implemented and sustained in practice. Otherwise, the cycle of disadvantage and poor health outcomes will not be broken, and children and young people in OoHC will remain at increased risk of adverse health and psychosocial outcomes. To this end, we aim to conduct a comprehensive systematic review which will: (1) assess the effectiveness of interventions and practice models for improving the health and psychosocial outcomes of children and young people living in OoHC (all types of placements); (2) examine whether a particular intervention or practice model is more effective than another; and (3) delineate which components of these interventions are associated with the greatest improvement in outcomes for these children and young people.

2. Systematic Review Questions:

- Are certain interventions or practice models effective in improving health and/or psychosocial outcomes for children and young people in OoHC compared with usual care?
- Are certain interventions or practice models more effective than others in improving health and/or psychosocial outcomes for children and young people in OoHC?
- Which elements are critical in determining the success of interventions, and for whom?

3. Methods and Analysis:

This systematic review utilises rigorous international gold standard methodology[23, 24] , and conforms to the reporting standards of the Preferred Reporting Items for Systematic Reviews and Meta-analyses[25] (PRISMA; Supplementary File). The protocol for the systematic review has been registered on the International Prospective Register for Systematic Reviews (PROSPERO) under the identification code: CRD42019115082.

3.1. Selection Criteria

As outlined in **Table 1**, a PICO (Population, Intervention, Comparison, Outcomes) framework was established *a priori* to screen studies and determine their eligibility for inclusion in the systematic review. Interventions and practice models developed for reunification have been excluded, however interventions and practice models that incorporate participants who transitioned into a different type of care setting are included.

Table 1. PICO for Study Inclusion

	Participants (P)	Intervention (I)	Comparison (C)	Outcomes (O)	Study type	Limits
Inclusion criteria	Children 0 - 21 years of age and living in OoHC • School aged • Youth • Adolescents • Children • Infants	Any intervention (e.g. Treatment foster care; therapeutic residential care, Sanctuary model, etc.) delivered in an out-of-home care setting (e.g. Foster care, kinship care, residential care)	No intervention/ usual care or other interventions in out-of-home care Children who remain with their biological/ foster families	All health and psychosocial outcomes including but not limited to: Intellectual; behavioural; psychosocial; mental; suicidal ideation; psychological functioning; social skills; emotional; educational attainment; relationships; illicit drug use; smoking; alcohol; eating disorders;	Randomized controlled trials: Non-randomized or uncontrolled trials; Systematic Reviews; Cohort studies; Cross-sectional; Longitudinal	English Language only Peer Reviewed Published in the last 10 years (2008 – 2018)
Exclusion criteria	Adults >21 years of age	Adoption Rehabilitation Orphanages			Editorial; commentary; narrative review; expert opinion	Literature published before 2008 Languages other than English.

3.2. Search Strategy

A systematic search, based on the selection criteria (Table 1) and combining MeSH terms and text words, was developed using the OVID platform and translated to other databases as appropriate. The search terms are outlined in **Table 2**.

Relevant articles will be sourced through electronic databases including: Medline, Medline in-process and other non-indexed citations, EMBASE, PsycINFO, CINAHL, Sociological Abstracts and All EBM Reviews incorporating: Cochrane Database of Systematic Reviews,

ACP Journal Club, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, Cochrane Methodology Register, Health Technology Assessment, NHS Economic Evaluation Database. Bibliographies of relevant studies as well as systematic reviews identified by the search strategy will be screened for identification of additional studies. Where required data are not presented, the corresponding authors of included studies will be contacted to provide de-identified aggregate data for the purpose of meta-analyses if deemed necessary.

Table 2. Sample of search terms used in electronic search

Concept 1: ***Out of Home Care***   Foster care, foster, out of home, kinship, trauma informed, resident*, guardian care, family based care, family centered, home based, child protection, child welfare, non biological care, group home, group house, 'OoHC'
Concept 2: ***Participants***   Looked after child, young person, young people, infan*, baby, babies, toddler, preschool*, adolescen*, teen*, minor, youth
Concept 3: ***Intervention***   Model, outcome, evaluation, framework, theor*, intervention, program*, process*, prevention, treatment, strategy*, therap*, trauma informed, trauma focused, trauma service

3.3. Screening of Search Results

Search results will be managed using the Endnote X.8.0 reference management software. Two reviewers will assess the titles, abstracts and keywords of every article retrieved by the search strategy according to the selection criteria described in Table 1. Full text of the articles will be retrieved for further assessment if the information provided suggests that the study meets the selection criteria or if there is any doubt regarding eligibility of the article based on the information given in the title and abstract. Where there is more than one article describing the same study and reporting different outcomes, these articles will be combined and

considered a single unique study. Articles excluded after full text assessment will be tabulated with reasons for their exclusion, as per PRISMA guidelines.[26]

3.4. Data Extraction

Two independent reviewers will formally screen all included studies against the selection criteria and perform data extraction using a specifically designed data extraction form. Extracted data will include general study characteristics (author, year, country, setting, inclusion/ exclusion criteria), population characteristics (gender and age distribution and other relevant features), intervention and control characteristics (type/ model, duration, frequency etc), outcome assessments (physical and psychosocial outcomes and tools used to assess these), and results (point estimates and measures of variability for continuous outcomes, and frequency counts or absolute numbers of episodes or relative measures of risk [risk ratio or odds ratio with confidence intervals] for dichotomous variables, numbers of participants, intention-to-treat analysis), and any other relevant validity results. Missing data will be obtained from corresponding authors wherever possible, and two reviewers will check all computed data entries for meta-analysis if applicable. Any disagreement will be resolved by discussion to reach a consensus.

3.5. Assessment of Risk of Bias and Quality of the Evidence

Methodological quality of included studies will be assessed at the study-level by two independent reviewers using a risk of bias assessment template according to study design. Individual quality items will be investigated using a descriptive component approach which will include assessment of key aspects such as methods of outcome assessment and reporting, statistical analysis components including study power and dealing with confounding, attrition rates, and conflicts of interest of authors. Using this process, a risk of bias rating (high, moderate, or low) will be assigned to each study.

Quality of the evidence for the effects of interventions in improving health and psychosocial outcomes for children and young people in OoHC will be assessed by two independent reviewers using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework.[27] This will be used to appraise quality at the outcome-level and, where appropriate, will incorporate aspects such as risk of bias, inconsistency, indirectness, imprecision, and publication bias. Based on this evaluation, a quality score (high, moderate, low, or very low) will be assigned to each outcome. Disagreement will be resolved by discussion to reach consensus.

3.6. Data Analysis and Synthesis

Data will be presented in summary form and narratively as well as in tables (where possible) to describe the study designs, populations and findings and to address each research question. Data will be summarised statistically using meta-analysis of aggregate effect measures if available and if studies are deemed sufficiently homogenous to combine. The meta-analysis will be performed on studies in which a baseline and follow up effect is available (i.e., RCT and quasi-experimental) and wherein the same outcome of interest has been reported (i.e., anxiety, depression, self-harming behaviour, delinquent behaviour, obesity) along with a change in effect. As the outcomes of interest will likely be assessed using a diverse range of instruments, a random effects model will be estimated accounting for the heterogeneity between the studies. Review Manager V.5 software will be used for meta-analysis and results will be expressed as relative risks (RR) or odds ratios (OR) with 95% confidence intervals (CI) for dichotomous outcomes, and weighted mean differences (WMD) with 95% CI for continuous outcomes. Statistical homogeneity will be assessed using the I^2 test where I^2 values over 50% indicate moderate to high heterogeneity.[28] Statistical significance will be set at a two-tailed P <0.05. For studies with qualitative designs or have insufficient data for pooling, a descriptive analysis will be presented.

3.7. Subgroup Analysis

Subgroup analysis, and where appropriate, meta-regression will be performed if possible based on study characteristics and results from the search. Where there is sufficient data, these analyses will be conducted based on pre-specified subgroups/covariates including age at placement, age at intervention, gender, ethnicity (indigenous vs non-indigenous), placement type (residential or group home vs foster family, and kinship vs non-kinship placement), types of abuse/reason for placement (maltreatment/abuse vs behavioural problems), types of intervention (psychological, social, behavioural), duration of intervention and length of follow-up. Other factors presumed to cause variations in the outcomes may be determined during the review process and these will be included in additional exploratory subgroup analyses.

3.8. Sensitivity Analysis

Sensitivity analysis will be performed to explore the influence of heterogeneity (I2 >50%) and determine the robustness of the observed effect size. Specifically, the primary analysis will be repeated by altering the dataset to only include medium and high quality studies to examine their influence on the results. If the findings are robust, then the studies of all quality will be retained, if there are changes in the findings then further examination of this will be performed. Where there are sufficient numbers of studies, visual inspection of funnel plots and Egger and Begg[29, 30] statistical tests will be used to assess publication bias and small study effects.

3.9. Patient and Public Involvement

This systematic review will not collect primary data and therefore patients and the public were not involved in the design, conduct or reporting of the research.

4. Discussion

Children and young people in OoHC have typically been exposed to a multitude of psychologically distressing and adverse experiences that manifests into childhood trauma.[31]

Childhood trauma is an important public health concern as adverse childhood experiences can have substantial health, social, and economic implications which extend throughout the lifespan.[31]Therefore, there is a need for health and psychosocial interventions to be implemented to prevent further traumatic and adverse childhood experiences as early as possible, as these interventions may reduce the negative outcomes of adverse childhood experiences. Existing interventions and practice models aim to directly address the impact of trauma on a child's health or psychosocial outcomes, typically through trying to reduce symptoms or facilitate recovery.[31, 32] However, many of these interventions have not been properly evaluated, or have limited evidence of their effectiveness in improving the health and/or psychosocial outcomes for children and young people in OoHC. In order to develop effective interventions for those in OoHC, we need to understand which interventions work, and how their effects can be sustained and embedded (i.e., implemented) into practice.

The proposed systematic review aims to address these gaps by examining how interventions and practice models can be applied to organisations and carers to improve the physical and psychosocial health of children and young people placed in OoHC. Using rigorous methodology, pre-specified criteria, and a pre-determined search strategy, this review will capture and synthesize existing quantitative and qualitative evidence on interventions in OoHC to establish their impact in improving health and psychosocial outcomes, and to disentangle the specific elements which contribute to their success. Findings from this review will provide much needed evidence to build the current knowledge base and to inform the implementation of effective interventions in OoHC, in an effort to alleviate the poor health and psychosocial outcomes of children and young people in OoHC.

5. Ethics and Dissemination

This study does not require ethical approval as it does not involve primary data collection. We anticipate that findings from this review will contribute to an improved understanding of

interventions which improve health and psychosocial outcomes for children and young people in OoHC and the key contributing factors within these interventions. These findings will be disseminated through peer reviewed publications and at conference meetings, to inform future research and to guide the development and real-world implementation of sustainable interventions in OoHC settings.

5.1. Data Availability Statement

Data will be made available upon reasonable request. The data will be available from the corresponding author HS.

6. Acknowledgements

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6.1. Author Contributions

EG developed the search strategy, wrote the first draft of the review protocol, and will lead the data collection and analysis. AM contributed to the design and scope of the search strategy, guiding the review process, and revising and editing the manuscript. RO and NH contributed to the revision and editing of the manuscript. HS determined the design and scope of the review, revised and edited the manuscript, will supervise the review process, and is the guarantor for ensuring the integrity and accuracy of the review data.

6.2. Funding Statement

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

6.3. Competing Interests Statement

All authors declare no conflicts of interest.

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Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	14
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important	N/A

		protocol amendments	
Sources	#5a	Indicate sources of financial or other support for the review	14
Sponsor	#5b	Provide name for the review funder and / or sponsor	N/A
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Rationale	#6	Describe the rationale for the review in the context of what is already known	4-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7-8
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-8
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8-9
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	8
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9-10
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8

Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	10
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	11
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	11
	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	11-12
	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	11
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	10
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

BMJ Open

Interventions and Practice Models for Improving Health and Psychosocial Outcomes of Children and Young People in Out-of-Home Care: Protocol for a Systematic Review

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Running Title: Improving Outcomes in Out-of-Home Care

Interventions and Practice Models for Improving Health and Psychosocial Outcomes of Children and Young People in Out-of-Home Care: Protocol for a Systematic Review

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Keywords: Out of home care, psychosocial health, behavioural outcomes, health outcomes, interventions, implementation.

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ABSTRACT

Introduction: Children and young people placed in out-of-home care (OoHC) are often affected by a history of trauma and adverse childhood experiences. Trauma in early childhood can impact on children's health and psychosocial development, whereas early interventions can improve children's development and placement stability. Although several interventions and practice models have been developed to improve health and psychosocial outcomes for children and young people in OoHC, there remains a lack of rigorous research examining the impact of these interventions in OoHC settings, as there are no systematic reviews examining the impact these interventions and practice models have on the children and young people they serve. We aim to conduct a comprehensive systematic review to examine the effectiveness of interventions and practice models for improving health and psychosocial outcomes in children and young people living in OoHC and to identify relevant knowledge gaps.

Methods & Analysis: Major electronic databases including Medline, EMBASE, CINAHL, PsycInfo, Social Science and all EBM reviews will be systematically searched for any studies published between 2008 and 2018 of interventions and practice models developed to improve health and psychosocial outcomes for children and young people in OoHC. Two independent reviewers will assess titles and abstracts for eligibility according to pre-specified selection criteria, and will perform data extraction and quality appraisal. Meta-analyses and/or meta-regression will be conducted where appropriate.

Ethics and Dissemination: This study will not collect primary data and formal ethical approval is therefore not required. Findings from this systematic review will be disseminated in a peer-reviewed publication and conference presentations.

Registration: International Prospective Register for Systematic Reviews (PROSPERO) number CRD42019115082.

Article Summary

Strengths and Limitations of this Study:

- The current study employs rigorous international gold-standard methodology and a comprehensive search strategy;
- A limitation of this study includes the potential for publication bias since the systematic review will include only published data;
- Another limitation of this study includes the potential that studies may be too heterogeneous to obtain combined effect estimates.

1. Introduction:

Children and young people in Out-of-Home Care (OoHC) are some of the most vulnerable groups in society, often having experienced substantial harm, abuse, or neglect.[1, 2] OoHC refers to the short- or long-term care of children and young people up to 18 or 21 years of age (depending on country) who are unable to live with their families due to child protection orders and/or as a result of parents being unable to provide adequate care or protection.[3] In Australia, 47,915 children <18 years lived in OoHC in 2017, a rate of 8.7 per 1,000 children, reflecting an increase from 46,448 and 40,549 children in 2016 and 2013, respectively.[2, 4] These rising rates are concerning, since children and young people placed in OoHC are often characterised as having severe cognitive, emotional, behavioural and social problems,[1, 5] coupled with complex histories of maltreatment and neglect.[5, 6] This history of trauma is believed to have short- and long-term effects on brain development, from childhood through to adulthood, and often culminates into complex behavioural, psychological, and social challenges.[5, 6]

Children and young people in OoHC report poorer outcomes across a number of health and wellbeing indicators compared to those who remain with their biological family.[7] Since children and young people usually enter care having experienced trauma and neglect, deviant behaviour and mental health problems are particularly prevalent among children and young people in OoHC and this appears to be associated with both age at first placement and type of care.[8] A 2006 study found that up to 60% of children and young people in OoHC have a current mental health diagnosis including depression, attachment and conduct disorders, and attention deficit hyperactivity disorders,[9] and those placed in residential care tend to have higher rates compared to those in foster care, whereas individuals in kinship care report the fewest rate of mental health disorders.[8, 10] Children and young people in OoHC also report a significantly higher incidence of substance abuse, suicide ideation and suicide attempt,[11-13] as well as attachment difficulties, problematic sexual behaviour, eating disorders, delinquent behavior,

and reduced educational attainment compared with children and young people residing with their biological families.[8, 14] The poor outcomes that children and young people in OoHC face, some of which are mentioned above, play a significant role in the complexity of their overall health, making it more challenging to identify their health needs and develop appropriate health management plans. Evidently, children and young people in OoHC require more intensive intervention and support, as we are dealing with complex, multifaceted issues, that require a number of strategies that can effectively support their health and wellbeing.

In light of the poor health and psychosocial outcomes experienced by children and young people living in OoHC, effective and sustainable interventions for improving these outcomes are urgently needed. Over the last few years, a number of practice models and interventions have been developed with the aim of directly addressing the impact of trauma on health and psychosocial outcomes for children and young people in OoHC.[15] Some of these models, such as the Sanctuary Model, Therapeutic Residential Care and Treatment Foster Care are shifting towards needs-based care and incorporating a trauma-informed, therapeutic care approach within the OOHC placements.[16] In Australia, the UK, and the US, it is expected that children and young people entering OoHC have the appropriate health assessments (statutory) and that health care records and management plans are in place.[17-20] Unfortunately, this process is not always met, and even when a child is provided with a health management plan, their needs may not be incorporated and the plan may not be followed.[18] Collecting the necessary information can be difficult as health professionals must rely on parents to provide medical histories, explain health and behavioural concerns, and consent to the assessment and treatment of their child.[18] Despite carers' and case managers' best efforts to provide this information, the high percentage of placement breakdowns and constant change in caregivers and service providers create gaps in information pertaining to the individuals' social or family circumstances and medical and mental health, and there is risk of this information being lost.[6]

Most interventions have also not been properly evaluated and there remains a lack of rigorous research examining the impact of these interventions in improving health and/or psychosocial outcomes for children and young people in OoHC.[21] Indeed, a recent systematic review investigating the empirical evidence of trauma-informed, organisation-wide models implemented in residential OoHC settings identified three models including The Sanctuary Model, Children and Residential Experiences programme (CARE), and the Attachment Regulation and Competency framework (ARC), and concluded that the evidence base is limited, making it difficult to accurately evaluate outcomes of trauma-informed models.[22] Recent studies have outlined the health and psychosocial needs of children and young people in OoHC and the interventions and practice models that have been designed to meet these needs; however, to date, very little research has been focused on evaluating the effectiveness of these interventions.[15] To our knowledge, no previous systematic reviews have examined interventions or practice models designed to respond to the physical and psychosocial health needs of children or young people in residential, foster and kinship settings of OoHC.

To develop effective, evidence-based interventions in OoHC, we first need to understand which interventions and practice models work, and how their structures and processes can be implemented and sustained in practice. Otherwise, the cycle of disadvantage and poor health outcomes will not be broken, and children and young people in OoHC will remain at increased risk of adverse health and psychosocial outcomes. To this end, we aim to conduct a comprehensive systematic review which will: (1) assess the effectiveness of interventions and practice models for improving the health and psychosocial outcomes of children and young people living in OoHC (all types of placements); (2) examine whether a particular intervention or practice model is more effective than another; and (3) delineate which components of these interventions are associated with the greatest improvement in outcomes for these children and young people.

2. Systematic Review Questions:

- Are certain interventions or practice models effective in improving health and/or psychosocial outcomes for children and young people in OoHC compared with usual care?
- Are certain interventions or practice models more effective than others in improving health and/or psychosocial outcomes for children and young people in OoHC?
- Which elements are critical in determining the success of interventions, and for whom?

3. Methods and Analysis:

This systematic review utilises rigorous international gold standard methodology[23, 24] , and conforms to the reporting standards of the Preferred Reporting Items for Systematic Reviews and Meta-analyses[25] (PRISMA; Supplementary File). The protocol for the systematic review has been registered on the International Prospective Register for Systematic Reviews (PROSPERO) under the identification code: CRD42019115082.

3.1. Selection Criteria

As outlined in **Table 1**, a PICO (Population, Intervention, Comparison, Outcomes) framework was established *a priori* to screen studies and determine their eligibility for inclusion in the systematic review. Interventions and practice models developed for reunification have been excluded, however interventions and practice models that incorporate participants who transitioned into a different type of care setting are included.

Table 1. PICO for Study Inclusion

	Participants (P)	Intervention (I)	Comparison (C)	Outcomes (O)	Study type	Limits
Inclusion criteria	Children 0 - 21 years of age and living in OoHC • School aged • Youth • Adolescents • Children • Infants	Any intervention (e.g. Treatment foster care; therapeutic residential care, Sanctuary model, etc.) delivered in an out-of-home care setting (e.g. Foster care, kinship care, residential care)	No intervention/ usual care or other interventions in out-of-home care Children who remain with their biological/ foster families	All health and psychosocial outcomes including but not limited to: Intellectual; behavioural; psychosocial; mental; suicidal ideation; psychological functioning; social skills; emotional; educational attainment; relationships; illicit drug use; smoking; alcohol; eating disorders;	Randomized controlled trials: Non-randomized or uncontrolled trials; Systematic Reviews; Cohort studies; Cross-sectional; Longitudinal	English Language only Peer Reviewed Published in the last 10 years (2008 – 2018)
Exclusion criteria	Adults >21 years of age	Adoption Rehabilitation Orphanages			Editorial; commentary; narrative review; expert opinion	Literature published before 2008 Languages other than English.

3.2. Search Strategy

A systematic search, based on the selection criteria (Table 1) and combining MeSH terms and text words, was developed using the OVID platform and translated to other databases as appropriate (Supplementary File). The search terms are outlined in **Table 2**.

Relevant articles will be sourced through electronic databases including: Medline, Medline in-process and other non-indexed citations, EMBASE, PsycINFO, CINAHL, Sociological Abstracts and All EBM Reviews incorporating: Cochrane Database of Systematic Reviews,

ACP Journal Club, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, Cochrane Methodology Register, Health Technology Assessment, NHS Economic Evaluation Database. Bibliographies of relevant studies as well as systematic reviews identified by the search strategy will be screened for identification of additional studies. Where required data are not presented, the corresponding authors of included studies will be contacted to provide de-identified aggregate data for the purpose of meta-analyses if deemed necessary.

Table 2. Sample of search terms used in electronic search

Concept 1: ***Out of Home Care***   Foster care, foster, out of home, kinship, trauma informed, resident*, guardian care, family based care, family centered, home based, child protection, child welfare, non biological care, group home, group house, 'OoHC'
Concept 2: ***Participants***   Looked after child, young person, young people, infan*, baby, babies, toddler, preschool*, adolescen*, teen*, minor, youth
Concept 3: ***Intervention***   Model, outcome, evaluation, framework, theor*, intervention, program*, process*, prevention, treatment, strategy*, therap*, trauma informed, trauma focused, trauma service

3.3. Screening of Search Results

Search results will be managed using the Endnote X.8.0 reference management software. Two reviewers will assess the titles, abstracts and keywords of every article retrieved by the search strategy according to the selection criteria described in Table 1. Full text of the articles will be retrieved for further assessment if the information provided suggests that the study meets the selection criteria or if there is any doubt regarding eligibility of the article based on the information given in the title and abstract. Where there is more than one article describing the same study and reporting different outcomes, these articles will be combined and

considered a single unique study. Articles excluded after full text assessment will be tabulated with reasons for their exclusion, as per PRISMA guidelines.[26]

3.4. Data Extraction

Two independent reviewers will formally screen all included studies against the selection criteria and perform data extraction using a specifically designed data extraction form. Extracted data will include general study characteristics (author, year, country, setting, inclusion/ exclusion criteria), population characteristics (gender and age distribution and other relevant features), intervention and control characteristics (type/ model, duration, frequency etc), outcome assessments (physical and psychosocial outcomes and tools used to assess these), and results (point estimates and measures of variability for continuous outcomes, and frequency counts or absolute numbers of episodes or relative measures of risk [risk ratio or odds ratio with confidence intervals] for dichotomous variables, numbers of participants, intention-to-treat analysis), and any other relevant validity results. Missing data will be obtained from corresponding authors wherever possible, and two reviewers will check all computed data entries for meta-analysis if applicable. Any disagreement will be resolved by discussion to reach a consensus.

3.5. Assessment of Risk of Bias and Quality of the Evidence

Methodological quality of included studies will be assessed at the study-level by two independent reviewers using a risk of bias assessment template according to study design. Individual quality items will be investigated using a descriptive component approach which will include assessment of key aspects such as methods of outcome assessment and reporting, statistical analysis components including study power and dealing with confounding, attrition rates, and conflicts of interest of authors. Using this process, a risk of bias rating (high, moderate, or low) will be assigned to each study.

Quality of the evidence for the effects of interventions in improving health and psychosocial outcomes for children and young people in OoHC will be assessed by two independent reviewers using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework.[27] This will be used to appraise quality at the outcome-level and, where appropriate, will incorporate aspects such as risk of bias, inconsistency, indirectness, imprecision, and publication bias. Based on this evaluation, a quality score (high, moderate, low, or very low) will be assigned to each outcome. Disagreement will be resolved by discussion to reach consensus.

3.6. Data Analysis and Synthesis

Data will be presented in summary form and narratively as well as in tables (where possible) to describe the study designs, populations and findings and to address each research question. Data will be summarised statistically using meta-analysis of aggregate effect measures if available and if studies are deemed sufficiently homogenous to combine. The meta-analysis will be performed on studies in which a baseline and follow up effect is available (i.e., RCT and quasi-experimental) and wherein the same outcome of interest has been reported (i.e., anxiety, depression, self-harming behaviour, delinquent behaviour, obesity) along with a change in effect. As the outcomes of interest will likely be assessed using a diverse range of instruments, a random effects model will be estimated accounting for the heterogeneity between the studies. Review Manager V.5 software will be used for meta-analysis and results will be expressed as relative risks (RR) or odds ratios (OR) with 95% confidence intervals (CI) for dichotomous outcomes, and weighted mean differences (WMD) with 95% CI for continuous outcomes. Statistical homogeneity will be assessed using the I^2 test where I^2 values over 50% indicate moderate to high heterogeneity.[28] Statistical significance will be set at a two-tailed P <0.05. For studies with qualitative designs or have insufficient data for pooling, a descriptive analysis will be presented.

3.7. Subgroup Analysis

Subgroup analysis, and where appropriate, meta-regression will be performed if possible based on study characteristics and results from the search. Where there is sufficient data, these analyses will be conducted based on pre-specified subgroups/covariates including age at placement, age at intervention, gender, ethnicity (indigenous vs non-indigenous), placement type (residential or group home vs foster family, and kinship vs non-kinship placement), types of abuse/reason for placement (maltreatment/abuse vs behavioural problems), types of intervention (psychological, social, behavioural), duration of intervention and length of follow-up. Other factors presumed to cause variations in the outcomes may be determined during the review process and these will be included in additional exploratory subgroup analyses.

3.8. Sensitivity Analysis

Sensitivity analysis will be performed to explore the influence of heterogeneity (I2 >50%) and determine the robustness of the observed effect size. Specifically, the primary analysis will be repeated by altering the dataset to only include medium and high quality studies to examine their influence on the results. If the findings are robust, then the studies of all quality will be retained, if there are changes in the findings then further examination of this will be performed. Where there are sufficient numbers of studies, visual inspection of funnel plots and Egger and Begg[29, 30] statistical tests will be used to assess publication bias and small study effects.

3.9. Patient and Public Involvement

This systematic review will not collect primary data and therefore patients and the public were not involved in the design, conduct or reporting of the research.

4. Discussion

Children and young people in OoHC have typically been exposed to a multitude of psychologically distressing and adverse experiences that manifests into childhood trauma.[31]

Childhood trauma is an important public health concern as adverse childhood experiences can have substantial health, social, and economic implications which extend throughout the lifespan.[31]Therefore, there is a need for health and psychosocial interventions to be implemented to prevent further traumatic and adverse childhood experiences as early as possible, as these interventions may reduce the negative outcomes of adverse childhood experiences. Existing interventions and practice models aim to directly address the impact of trauma on a child's health or psychosocial outcomes, typically through trying to reduce symptoms or facilitate recovery.[31, 32] However, many of these interventions have not been properly evaluated, or have limited evidence of their effectiveness in improving the health and/or psychosocial outcomes for children and young people in OoHC. In order to develop effective interventions for those in OoHC, we need to understand which interventions work, and how their effects can be sustained and embedded (i.e., implemented) into practice.

The proposed systematic review aims to address these gaps by examining how interventions and practice models can be applied to organisations and carers to improve the physical and psychosocial health of children and young people placed in OoHC. Using rigorous methodology, pre-specified criteria, and a pre-determined search strategy, this review will capture and synthesize existing quantitative and qualitative evidence on interventions in OoHC to establish their impact in improving health and psychosocial outcomes, and to disentangle the specific elements which contribute to their success. Findings from this review will provide much needed evidence to build the current knowledge base and to inform the implementation of effective interventions in OoHC, in an effort to alleviate the poor health and psychosocial outcomes of children and young people in OoHC.

5. Ethics and Dissemination

This study does not require ethical approval as it does not involve primary data collection. We anticipate that findings from this review will contribute to an improved understanding of

interventions which improve health and psychosocial outcomes for children and young people in OoHC and the key contributing factors within these interventions. These findings will be disseminated through peer reviewed publications and at conference meetings, to inform future research and to guide the development and real-world implementation of sustainable interventions in OoHC settings.

5.1. Data Availability Statement

Data will be made available upon reasonable request. The data will be available from the corresponding author HS.

6. Acknowledgements

EG is supported by a PhD scholarship provided by MacKillop Family Services. AM is supported by an Early Career Fellowship provided by the National Health and Medical Research Council (NHMRC) of Australia. HS is supported by a NHMRC senior research fellowship. We thank Dr. Marie Misso for her input and expertise in developing the search strategy and helping to run the initial database searches.

6.1. Author Contributions

EG developed the search strategy, wrote the first draft of the review protocol, and will lead the data collection and analysis. AM contributed to the design and scope of the search strategy, guiding the review process, and revising and editing the manuscript. RO and NH contributed to the revision and editing of the manuscript. HS determined the design and scope of the review, revised and edited the manuscript, will supervise the review process, and is the guarantor for ensuring the integrity and accuracy of the review data.

6.2. Funding Statement

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

6.3. Competing Interests Statement

All authors declare no conflicts of interest.

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Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	14
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important	N/A

		protocol amendments	
Sources	#5a	Indicate sources of financial or other support for the review	14
Sponsor	#5b	Provide name for the review funder and / or sponsor	N/A
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Rationale	#6	Describe the rationale for the review in the context of what is already known	4-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7-8
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-8
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8-9
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	8
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9-10
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8

Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	10
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	11
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	11
	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	11-12
	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	11
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	10
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

Search Strategy

This supplementary file contains a search strategy developed using the OVID platform combining MeSH terms and text words, and two search strategies that have been translated to other databases as appropriate.

Supplementary File 1.0. Search Strategy for Medline, Embase, EBM, and PsychInfo

#	Search Terms
1	foster care/
2	(foster adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
3	(out adj2 home adj2 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
4	(kinship adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
5	(trauma informed adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
6	(resident* adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
7	(guardian adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
8	(family based adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
9	(family centred adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
10	(home based adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
11	(child adj3 (protection or welfare or placement*)).tw.
12	(non biological adj3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*)).tw.
13	(group adj2 (home or house or care or home care or placement)).tw.
14	Oohc.tw.
15	or/2-14
16	1 or 15
17	looked after child*.tw.
18	(young adj3 (person or people)).tw.
19	infan*.tw.
20	baby.tw.
21	babies.tw.
22	toddler.tw.
23	preschool*.tw.
24	adolescen*.tw.
25	teen*.tw.
26	minor.tw.
27	youth.tw.
28	or/17-27
29	model.tw.
30	outcome.tw.
31	evaluation.tw.
32	framework.tw.
33	theor*.tw.
34	intervention.tw.
35	program*.tw.
36	process*.tw.
37	prevention.tw.
38	treatment.tw.
39	strateg*.tw.
40	therap*.tw.
41	trauma informed.tw.
42	trauma focused.tw.
43	trauma services.tw.
44	or/29-43
45	16 and 28 and 44
46	limit 45 to (english language and humans and yr="2008 -Current")

Supplementary File 1.1. Search Strategy for CINAHL

#	Search Terms
S1	(MH "Foster Home Care")
S2	(foster N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S3	(out N2 home N2 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S4	(kinship N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S5	(trauma informed N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S6	(resident* N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S7	(guardian N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S8	(family based N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S9	(family centred N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S10	(home based N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S11	(child N3 (protection or welfare or placement*))
S12	(non biological N3 (care or home* or home care or welfare or organisation or famil* or child* or parent* or placement*))
S13	(group N2 (home or house or care or home care or placement))
S14	OOHC
S15	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S16	looked after child*
S17	(young N3 (person or people))
S18	infan*
S19	baby
S20	babies
S21	toddlers
S22	preschool*
S23	adolescen*
S24	teen*
S25	minors
S26	youth
S27	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26
S28	(health or psychoisocial) N3 (issue* or outcome* or need* or concern*)
S29	illness OR disease OR sickness OR condition
S30	health*
S31	S28 OR S29 OR S30
S32	S15 AND S27 AND S30
S33	S15 AND S27 AND S30
S34	model OR outcome OR evaluation OR framework OR theor* OR intervention OR program* OR process* OR prevention OR treatment OR strateg* OR therap* OR trauma informed OR trauma focused OR trauma services
S35	S32 AND S34

Supplementary File 1.2. Search Strategy for Sociological Abstracts

	Search Terms
Concept 1	Foster care OR foster* OR out **of** home OR kinship OR trauma informed OR resident* OR guardian care OR family based care OR family centred OR home based OR child protection OR child welfare OR non biological care OR group home OR group house OR 'OoHC'
Concept 2 (AND)	Looked after child OR young person OR young people OR infan* OR baby OR babies OR toddler OR preschool* OR adolescen* OR teen* OR minor OR youth
Concept 3 (AND)	Model OR outcome OR evaluation OR framework OR theor* OR intervention OR program* OR process* OR prevention OR treatment OR strategy* OR therap* OR trauma informed OR trauma focused OR trauma service
	Limit to: peer reviewed
	Language: English
	Date: From 2008 to 2018