Care-experienced cHildren and young people's Interventions to improve Mental health and wEllbeing outcomes: Systematic review

CHIMES

Study Identifiers

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Contents

1. Background and Scientific Rationale

1.1. What is the problem being addressed?

Recent data report that 78,999 of children and young people are registered as residing in local authority care in England and Wales (1, 2), continuing a steady increase in numbers over the past two decades (3). The mental health and wellbeing of this population are a growing public health and social care concern, with an over-representation of mental and physical co-morbidities (4). Almost 50% of individuals involved in the child welfare system have a diagnosable mental health condition (5), and are nearly five times as likely to have at least one psychiatric diagnosis compared to the general population (6). Care-experienced individuals are at an elevated risk of poor subjective wellbeing (7), and more than four times as likely to attempt suicide (7). Emotional and behavioural disorders potentiate the risk of a range of other outcomes, including limited physical health, increased criminality and lower levels of employment (8). Adverse mental health outcomes incur significant health and social care costs, often due to the associated risk of placement instability and breakdown (9). Frequent placement changes are shown to increase mental health costs (10), with evidence from the UK reporting that insecure and unstable care placements cost £22,415 more per child per annum (across health, social care and criminal justice) than stable care pathways (11).

1.2. Why is this research important in improving the health of the public?

There is a clearly expressed need to improve provision for care-experienced children and young people, with NICE guidance stating that the UK evidence base does not adequately serve this population (12). Recognition and prioritisation of this unmet need is reflected in two recent NIHR commissioned briefs on interventions for looked-after children and young people (18/05) and health and social care services for the transition of looked-after young people leaving care (17/108). The policy context also demonstrates a strong commitment to this area, with the Department for Education and Department of Health and Social Care's joint statutory guidance on the promotion of health and wellbeing for looked-after children mandating that local authorities ensure the provision of timely and adequate care (13). This is imperative given the variability in existing provision, where there are reported incidents of failure to identify need, too stringent eligibility thresholds, and withholding of care where there is not a stable placement (14). There are also concerns about the lack of support for carers, arising from the stress and poor psychological wellbeing from parenting children with complex mental health and behavioural needs (15). A comprehensive synthesis is required to identify evidence-based approaches addressing the mental health and wellbeing of care-experienced children and young people to develop recommendations for policy and practice. Given that evidence in the UK remains emergent, this review aims to understand the potential relevance and transportability of international approaches to this context. To this end, there needs to be a specific focus on integrating recent advances in the use of complexity science within systematic reviews (16, 17), to understand how systems interact with intervention characteristics and implementation to generate outcomes.

1.3. What interventions aim to improve the mental health and wellbeing of care-experienced children and young people?

Mental health and wellbeing interventions for care-experienced children and young people can broadly be categorised as preventative or treatment. Prevention approaches operate across a range of socio-ecological domains, and have included a focus on community level change (e.g. Flying Start) (18), functioning within the care placement (19, 20), the theoretical orientation of social care teams (e.g. adoption of trauma informed model) (21), and the social and emotional competencies of the individual child or young person (22). Treatment of diagnosable mental health conditions have tended to draw more upon intra-personal and inter-personal theories of

change, focusing on both the type and availability of therapeutic approaches (23). There are a diverse range of delivery settings and delivery agents in use, which has important implications for the contextual contingency of effects.

The evidence base for these interventions remains equivocal (24), although there is some indication that interventions might effectively address a cluster of proposed review outcomes (e.g. long term impacts of Multidimensional Treatment Foster Care on suicidal ideation and depressive symptoms (25)). This suggests that the development of an overarching theory of change, or compatible theories of change across socio-ecological domains, that addresses multiple outcomes might be feasible. The interventions to be included in the review are presented in Appendix A.

1.4. What will be the added value of the proposed review?

We conducted a scoping search of extant systematic reviews and structured literature synthesising relevant research evidence. Searches identified twelve directly relevant or related syntheses (2011-2018) (24, 26-36).

While these reviews progress the evidence base, they are subject to the following four limitations:

1) The most comprehensive and inclusive reviews lack a rigorous systematic methodology. For example, the most recent, encompassing and relevant review to the UK context was not systematic, and explicitly states that the literature included is not exhaustive (24). Through the use of a robust methodology, and sensitive search strategy, the present review will provide a more comprehensive analysis of the extant literature.

2) Existing reviews tend to focus on restricted intervention packages (e.g. Treatment Foster Care) (26), theories (e.g. professional knowledge and education) (27) or outcomes (e.g. externalising behaviours) (32, 33). As such we do not know the extent to which an over-arching theory (or theories) or set of components could effectively address multiple mental health and wellbeing outcomes. The proposed review will compare between intervention theories and types to understand what might be most effective and cost-effective. It will further consider if these different approaches can impact upon a range of outcomes, which may reduce the number of interventions that need to operate and hence be resourced within a system.

3) Reviews are often restricted to specific populations, notably foster care (22, 23, 26, 28, 32). There is minimal consideration of other key sub-groups (e.g. kinship care, residential care). Given that risk profiles for mental health conditions may vary across sub-groups, it is necessary to understand what interventions work for which ones. Equally, as individuals in care often transition through multiple placement types (e.g. move into residential care following breakdown of multiple foster care placements), it is imperative to understand whether there might be continuity in intervention approaches, or if a particular theory or activities are no longer effective within a new placement type. This review will examine which interventions and theories are evidenced for different outcomes across different placement types, and where evidence is still lacking.

4) Reviews are largely focused on synthesising outcome data, with only rudimentary treatment of context or process data (e.g. neglect of process evaluations reporting contextual characteristics impacting on implementation and outcome). It is imperative to address this context and complexity as international variations in systems may constrain the transportability of evidence and the extent to which we can 'borrow strength' from the original evaluation (37). Multi-dimensional Treatment Foster Care (MTFC) and Multi-systematic therapy (MST) provide key examples of the difficulties in replicating the positive effects of USA originated interventions in Sweden (38). MST was not effective when replicated in the new context as it was essentially equal to treatment as usual (TAU), whilst MTFC indicated an effect as it combined components that are common in TAU in Sweden but are rarely delivered as an integrated suite of provision. The proposed review, in taking a complex systems perspective,

will focus on understanding why interventions have or have not demonstrated effects, primarily by synthesising data on how an intervention interacts with and is shaped by the context.

2. Review Aims

The primary aim of this study is to systematically review and synthesise extant international evidence on interventions addressing the mental health and wellbeing of care-experienced children and young people.

3. Research Questions

This research aim will be addressed through the following research questions:

RQ1: What are the types, theories and outcomes tested in mental health and wellbeing interventions for care-experienced children and young people?

RQ2: What are the effects (including inequities and harms) and economic effects of interventions?

RQ3: How do contextual characteristics shape implementation factors, and what are key enablers and inhibitors of implementation?

RQ4: What is the acceptability of interventions to target populations?

RQ5: Can and how might intervention types, theories, components, and outcomes be related in an overarching system-based programme theory?

RQ6: Drawing on the findings from RQ1-5, what do stakeholders think is the most feasible and acceptable intervention in the UK that could progress to further outcome or implementation evaluation?

4. Workpackages

In order to address the six research questions, we will undertake five work packages, which will support project management and the allocation of resources. The work packages, and the research questions they will address, are as follows:

WP0: *Study Coordination and Dissemination* (RQ1-6)

WP1: *Searches, Extraction and Appraisal* (RQ1-6)

WP2: *Mapping Intervention Theories, Context, Implementation and Acceptability* (RQ1; RQ3; RQ4)

WP3: *Synthesising Intervention Effects* (RQ2)

WP4: *Modelling of Intervention Theory* (RQ5)

WP5*: Stakeholder Consultation* (RQ6)

5. Study Design

5.1. WP0: Study Coordination and Dissemination (RQ1-6)

This work package will coordinate work undertaken within the other work packages, ensure accordance with the protocol, monitor risk, oversee governance and resource expenditure, and manage outputs, dissemination and impact activities. As this is a complex, mixed method systematic review, a particular focus here will be to ensure that that the syntheses of the subsequent work packages are coherently integrated (39).

5.2. WP1: Searches, Extraction and Appraisal (RQ1-6)

5.2.1. Protocol Registration

The study is registered with PROSPERO and awaiting confirmation.

5.2.2. Size of Available Literature

We conducted a search of PubMed to identify studies (21/07/2019) and had 1941 retrievals published between 1994 and 2019. Screening studies against our inclusion criteria, 184 potentially eligible records remained, including 15 theory of change papers, 146 outcome evaluations, 23 process evaluations and qualitative studies, and 10 economic evaluations. From these retrievals, combined with the additional primary studies we know to be included in previous reviews, it is evident that there is substantial body of evidence that warrant synthesis.

5.2.3. Inclusion Criteria

The inclusion parameters are reported in accordance with the PICO framework (Appendix B).

Population: The target population for intervention participation can be care-experienced children and young people, or their proximal relationships, organisations and communities. Children and Young People: Children and young people aged ≤25 year olds. Currently placed in care, transitioning out of care, or previous care experience. Period of time in care is not restricted. Care can include in-home care (voluntary transfer of parental responsibility to statutory services) and out-of-home care (foster care; residential care; formal kinship care; unaccompanied asylum seekers). Care must specify statutory involvement. The following populations are excluded: general population; children in need; individuals at the edge of care; care without statutory involvement (e.g. informal kinship care); adoption, orphages and unaccompanied asylum seekers. Families, Groups and Organisations: Any individual(s)/groups/organisations where their participation in an intervention will lead to child-level outcome changes. May include but not limited to: carer, birth family, teacher or social worker (e.g. Fostering Changes (20), Head Start (40)).

Intervention: We conceive of interventions as any attempt to disrupt existing system practices. They may be mono-component or multi-component and operate across any of the following ecological domains: individual; inter-personal; organisational; community; and policy/legal. Interventions may focus on prevention and/or management/reduction of symptomatology. Interventions do not necessarily have to be termed 'mental health' interventions, and could be interventions based on education, social care, criminal justice or housing provided that they include a relevant outcome. There are no a-priori criteria for implementation (i.e. delivery setting, delivery mode, delivery agent). Pharmacological interventions are excluded. The parameters of interventions are presented in Appendix A.

***Comparator*:** Treatment as usual; other active treatment; no specified treatment.

Outcomes: Three domains of primary outcomes: 1) Mental, behavioural or neurodevelopmental disorders as specified by ICD 11; 2) Subjective wellbeing (Eudaimonia and Hedonia) (including quality of life and life satisfaction); 3) Self-harm; suicidal ideation; suicide. Outcomes may be prevention and/or management/reduction of symptomatology. Outcome measures may use dichotomous, categorical or continuous variables. Outcomes must be reported at the level of the

child or young person. Domains of outcomes may be ascertained through clinical assessment, self-report or report by another informant (e.g. teacher). Bio-medical markers of potential mental health problems (e.g. cortisol as a measurement of stress) are excluded.

Study Design:

Theories of change: Describe intended theory, logic model or mechanisms of effect. May include mediation analysis (RQ1).

Outcome evaluation: (Individual/cluster) randomised controlled trials and quasi-experimental study designs (difference in difference; non-equivalent control groups). We exclude post measurement only or pre-post measurement in intervention group only (RQ1; RQ2).

Process evaluation: All qualitative and quantitative study designs (RQ1; RQ3; RQ4). Included studies must empirically report on implementation, relevant contextual influences and acceptability.

Economic evaluation: Economic evaluations must relate costs to benefits. They can report: cost-minimisation, cost-effectiveness, cost utility or cost-benefit analysis. They can be model-based or trial-based. Decision-analytic models capturing intervention impacts on mental health and wellbeing will be eligible (RQ2).

Relationship Between Study Designs: To be included in the review theory of change papers must have a associated empirical outcome evaluation. Process evaluations and economic evaluations do not necessarily have to be linked to an empirical outcome evaluation, as they provide wider contextual insight into how interventions interact with complex system characteristics.

5.2.4. Search Strategy and Study Retrieval

We will conduct comprehensive searches for published and unpublished studies. A provisional search strategy has been developed in Ovid MEDLINE (Appendix C). The search strategy has been designed by a single information specialist (RT) to support the integration of different syntheses. A more sensitive and specific strategy will be tested on study commencement and will be further refined in consultation with stakeholders at study commencement.

The following electronic bibliographic databases will be searched: ASSIA, British Education Index, Child Development & Adolescent Studies, CINAHL, Embase, ERIC, Cochrane Database of Clinical Controlled Trials (CENTRAL), HMIC, IBSS, Medline (Medline in Process and Medline ePub), PsycINFO, Scopus, Social Policy & Practice, Social Services Abstracts, Sociological Abstracts and Web of Science (Social Sciences Citation Index, Conference Proceedings Citation Index- Social Science & Humanities, Emerging Sources Citation Index).

Supplementary searching techniques will include citation tracking of included studies, contacting international experts, searching trial registers and consulting websites of key social and health care organisations (grey literature). We will also conduct searches for 'clusters' of related study reports to help construct context and descriptions of theories of change (41, 42). There will be no language limitations. We recognise that the linguistic capabilities of the team are limited to English and Spanish. We will seek to obtain translation support for studies not published in these languages. Inclusion will be restricted from 1990, where ratification of the UN Convention on the Rights of the Child (43), which prescribed comprehensive social and health care provision for children internationally and started the proliferation of intervention in this area. To maximise applicability of evidence to the UK, studies from lower-middle income countries will be excluded.

5.2.5. Data Storage and Study Selection

Data will be exported to EPPI Reviewer 4 for de-duplication and screening. Storage of all data together will permit the sharing of relevant literature across workpackages. The inclusion criteria pro-forma (Appendix B) will be piloted and calibrated by two reviewers screening the same 50 references, with disagreement being resolved through consensus or recourse to a third

reviewer. In the first instance reference titles will be screened on the basis of title to identity clearly irrelevant retrievals (e.g. pharmacological treatments), with these exclusions being verified by a second reviewer. Titles and abstracts of remaining studies will be screened independently and in duplicate. Where there is disagreement or if there is insufficient detail, studies will automatically progress to full text screening. Full texts will be retrieved and appraised for study inclusion. Conflicts will be resolved through discussion or recourse to a third reviewer. A record of the selection process will be retained in adherence with the PRISMA flow diagram.

5.2.6. Mapping the Data

Once the final number of included studies is confirmed, we will chart the clustering of studies, constructing a visual knowledge map similar to that recommended within scoping reviews (44, 45). Study characteristics will be extracted into a table according to intervention characteristics (e.g. location across ecological domains of individual, inter-personal, organisational, community and policy), outcome, and study design. This process will provide a useful study output by identifying evidence clusters and gaps where further research is required. Study charting will support decision-making about the extent of data extraction and synthesis to be undertaken at the next stage, in order to manage workload. We will label studies where they may be included in the review but do not provide deep / relevant data for further synthesis (e.g. only one study providing data on suicide and cannot be included in meta-analysis). We will consult with the Study Advisory Group on the appropriateness of the extent of extraction and synthesis to be undertaken with different groups of studies at this stage. Decision making about the review's remit moving forward will be confirmed with the NIHR at the six month reporting stage.

5.2.7. Data Extraction

Standardised data extraction forms will be developed and calibrated with a subset of studies for input to EPPI Reviewer 4. Two versions of extraction forms will be developed based on the decision making from the mapping of the data (Section 5.2.6.). The first will be for studies included in the review but not included in more in-depth synthesis (e.g. not included in meta-analysis). The second will be for studies included in more in-depth synthesis. As part of a framework synthesis approach (46-48), primary qualitative text will be coded in vivo to develop a preliminary coding tree that includes a set of a priori codes but will be amended to incorporate emergent codes. On confirmation of the form and coding tree, two reviewers will independently extract and code data from 10% of studies, with the remainder being extracted by one reviewer and verified by a second.

For all studies data will be extracted on: study characteristics (i.e. country, year, research aim), participant demographics; setting; study design and methods; and intervention characteristics (i.e. theory of change, intervention components/activities, implementation theory; implementation strategy; implementation agents (49)).

For outcome evaluations we will also abstract data on: measurements, sequence generation, allocation concealment, blinding, data completeness, baseline differences and adjustment for difference, control of confounding, outcomes at follow-up at both population and sub-group level.

Process evaluations will focus on how contextual characteristics impact upon implementation and activation of the theory of change. Implementation will be extracted according to the empirical processes of activating the implementation theory; achieving the implementation strategy and using proposed implementation agents. Quantifiable assessments of implementation including reach, receipt and fidelity will be extracted. Contextual characteristics will be classified according to the CICI framework geographical; epidemiological; legal; socio-economic; socio-cultural; ethical; and political (49). We will discriminate between contextual factors specific to the intervention and those which characterise TAU. Acceptability data will be abstracted.

For economic evaluations, we will extract data on direct and indirect costs, perspective, structural and empirical inputs, time horizon, and cost-effectiveness.

Studies may be characterised by incomplete data or information (e.g. outcome measurements or primary data to calculate effect size), and in this instance we will contact the author where feasible to request additional information. If we cannot locate this data we will record that study information is missing, and this will be included in the risk of bias assessment.

5.2.8. Quality Appraisal and Risk of Bias

Study data will be appraised with a methodologically appropriate tool. Theories of change will be appraised using a tailored appraisal tool developed by one of the co-applicants (50). Domains of assessment will be: clarity of constructs; clarity of relationships between constructs; testability; parsimony and generalisability.

Outcome evaluations will be assessed with the methodologically relevant tool (e.g. interrupted time series, RCTs) prescribed by the Cochrane Handbook for Systematic Reviews of Interventions (51). In the case of randomised controlled trials, risk of bias will be identified across seven domains: sequence generation; allocation concealment; blinding of participants, personnel and outcome assessments; completeness of outcome data; selective reporting of outcomes; other sources of bias. Each domain will be rated as high risk, low risk or unclear risk.

Qualitative data within process evaluations will be appraised using a tool developed in previous systematic reviews (52, 53). It will address two key domains: reliability and trustworthiness (sampling rigour; data collection rigour; analysis rigour; data supporting analysis); and usefulness (breadth/depth of findings; privileges participant perspectives). Two global assessments of overall reliability/trustworthiness and overall usefulness will then be made. Domains are rated as high, medium or low.

Economic data will be appraised with a dedicated checklist for economic evaluations (54). It will assess if there are appropriate descriptions of comparators; identification and valuation of costs and consequences; discounting; and analysis of uncertainty.

We will also consider the governance and ethical conduct of studies, and assess data on the sufficiency of ethical reporting and compliance with basic ethical tenets (e.g. informed consent, anonymity, and confidentiality) (55). All quality appraisal will be undertaken independently and in duplicate, with disagreement being resolved through discussion or recourse to a third reviewer.

5.2.9. Data Analysis

5.2.9.1. WP2: Intervention Theories, Context, Implementation and Acceptability (RQ1; RQ4; RQ5).

We will construct a single taxonomy describing intervention types, theories of change and outcomes. It will be used to understand if there are different or dominant theories according to different types of interventions and/or outcomes (50). Data will be drawn from all included study types (i.e. theory papers, process evaluations and outcomes) in recognition of the fact that theories may be presented in background/ discussion sections. We will rely upon authors' narratives of the underpinning theories of change, and in the event that there are inconsistences in the presentation of theory across sibling papers of the same interventions, we will not aim to adjudicate between description but present these variations and nuances.

Process data (including both quantitative and qualitative data) will serve to understand context, implementation and acceptability. Context will be classified according to the CICI framework: geographical; epidemiological; legal; socio-economic; socio-cultural; ethical; and political (49). There will be a focus on contextual factors that interact with the intervention and determine implementation and acceptability, and also the context of TAU as this will likely help explain the transferability of intervention effects to the UK context. Implementation will be classified

according to the CICI framework: implementation theory; implementation strategy and implementation agents (49). It will also consider quantifiable assessments of implementation, including: reach; receipt; and fidelity. Acceptability will be considered as the experiences of all stakeholders, including participants, delivery agents and service funders, and their interactions with the interventions. Data will be primarily drawn from process papers. We will synthesise both presented primary data from the results sections of studies, but also authors' narratives and reflections. For both theory of change and process studies, quality will not be used as a criterion for inclusion, but studies with clearer and more comprehensive theory or process description will be given more interpretive weight.

The process of analysis will adhere to the five phases of framework synthesis (46-48, 56), and include the following stages: 1) Familiarisation: Reviewers will read the included studies in order to achieve immersion in the data and become sensitised to within study and between study differences; 2) Develop a thematic framework: An a priori thematic framework will be developed, and then refined and calibrated a subset of data. A code book will be produced, with codes capturing the essence of the themes. The a priori framework will be derived from the appending logic model which prescribes the parameters of the review. Themes will also be related to key domains of concepts of interest (e.g. key context and implementation domains from the CICI framework (49)). The a priori framework will be confirmed by the research team before progressing to the next phase. 3) Indexing: The remaining corpus of data will be indexed with the framework. New themes, and associated codes, may be generated in vivo through the process of constant comparison across studies and against the framework. Proposed new themes will require confirmation by a second reviewers before being integrated into the framework. Indexing of 10% of papers will be conducted independently and in duplicate, with the remainder being conducted by one reviewer and verified by a second. Memos will be recorded to inform the subsequent phases. 4) Charting the data into a framework matrix: We will extract data into a matrix, summarizing data by category from each transcript.; 5) Mapping and interpretation: Drawing on the matrix we will create a typology of interventions, define new concepts or progress existing concepts, and find associations between themes to help understand how and why interventions may or may not be effective. The synthesis may be presented graphically and narratively, with a summary table providing key data on study quality and intervention characteristics and outcomes measured.

5.2.9.2. WP3: Synthesising Intervention Outcome Effects, Equities and Economic Effects (RQ2).

Depending on the heterogeneity of interventions, as assessed through the classification undertaken in WP2, we will consider meta-analysing effect estimates from included outcome evaluations. In preparation for meta-analysis, effect estimates extracted from studies will be classified into outcome domains: 1) Subjective wellbeing (e.g. Short Warwick-Edinburgh Mental Wellbeing Scale); 2) Prevalence, incidence or symptomatology of mental, behavioural or neurodevelopmental disorders as specified by ICD 11 (e.g. prevalence of depression; incident diagnoses of depression; score on Beck Depression Inventory); and 3) Self-harm; suicidal ideation; suicide.

Where appropriate outcomes will be converted to odds ratios using logistic transformation for pooling. Estimates from cluster randomised trials will be checked for unit of analysis issues, and where necessary, an inflation factor will be applied to the standard error of effect estimates. Where intra-cluster correlation coefficients are not available and effect estimates have not been adjusted for clustering, we will impute an ICC using the average of estimates for specific outcomes from 'most similar' intervention evaluations.

We will then undertake robust variance estimation meta-analyses according to intervention type, outcome and timepoint, considering up to six months from baseline as short-term, six months to two years and mid-term, and beyond two years as long-term. Robust variance estimation meta-analysis is a method that permits the inclusion of more than one effect

estimate per study in a meta-analysis; this is in contrast to standard meta-analysis models that assume independence between individual effect estimates. It is common in meta-analysis of psychosocial interventions for outcome evaluations to present multiple relevant effect estimates per outcome (e.g. multiple estimates of child behavioural problems). This method will permit use of all relevant information from included studies. Within each meta-analysis, we will examine heterogeneity using a combination of Cochran's Q, tau-squared and I^2. Where heterogeneity is substantial (I^2 >50%), we will scrutinise included studies to hypothesise and explore the reasons for this.

Equity effects will be categorized according to PROGRESS-Plus (57). The domains are: place; race/ethnicity; occupation; gender/sex; religion; education; socioeconomic status; social capital; discriminated characteristics; relationship features; and time-dependent relationships. Data will be reported in adherence to the PRISMA E-2012 extension (58). Analysis of equity effects will be conducted with studies where moderation and interaction effects are presented. We will use harvest plots to assess equity effects and meta-regression to test whether characteristics of study populations are associated with effectiveness. Intervention harms will be treated in accordance with the PRISMA harms extension (59).

Economic evaluations will be summarized. Summarized data will include measures of costs, cost -effectiveness, indirect resource use, and whether a trial-based or model-based analysis was conducted. If there is sufficient homogeneity in measures across studies, these will be synthesised via meta-analysis. Measures of costs, cost-effectiveness and indirect resource use will be adjusted in line with inflation and currency to provide a contextually relevant estimate of costs in the current UK context. Data will be further presented in a narrative summary of intervention costs, which can be used to inform stakeholder consultation and intervention prioritisation (WP5).

5.2.9.3. Integration of WP2 and WP3 and Interpretation of Findings for WP4 and WP5

The review will adhere to a convergent synthesis design (60, 61), which means that qualitative and quantitative research is collected and analysed at the same time in a complementary manner. Key opportunities have been noted throughout the review process to ensure the complementation of the qualitative and quantitative synthesis (60):

1) Review-team level: We will ensure the close coordination of work packages synthesising the qualitative and quantitative data (WP2 and WP3 respectively) through the overarching WP0. Further, the two Research Associates who have mixed methods experience will work across all syntheses;

2) Question formulation: Research questions are designed to be complementary and contingent, where achieving a rich answer for one question is dependent on the findings of other questions. Primarily, to explain the effects and economic effects of interventions (RQ2) we require data synthesised in response to the two questions exploring contextual determinants of implementation factors (RQ3) and stakeholder acceptability (RQ4);

3) Study searching, screening and selection: Screening will be undertaken for all study types simultaneously and by the same members of the research team. Storage and analysis of studies will be undertaken centrally (in EPPI Reviewer) to ensure study data can be easily shared across work packages;

4) Assessment of methodological limitations in primary studies and reviews: We propose to utilise method specific appraisal tools that have been combined in previous reviews as they provide epistemological flexibility or consonance. We will consider appraising the certainty of evidence generated through the different reviews with the compatible tools of GRADE (62) and GRADE CERQual (63);

5) Synthesis and Integration: We will use a results-based convergent synthesis design (60, 61). (Figure 1). As presented, this will initially entail the separate synthesis of qualitative and

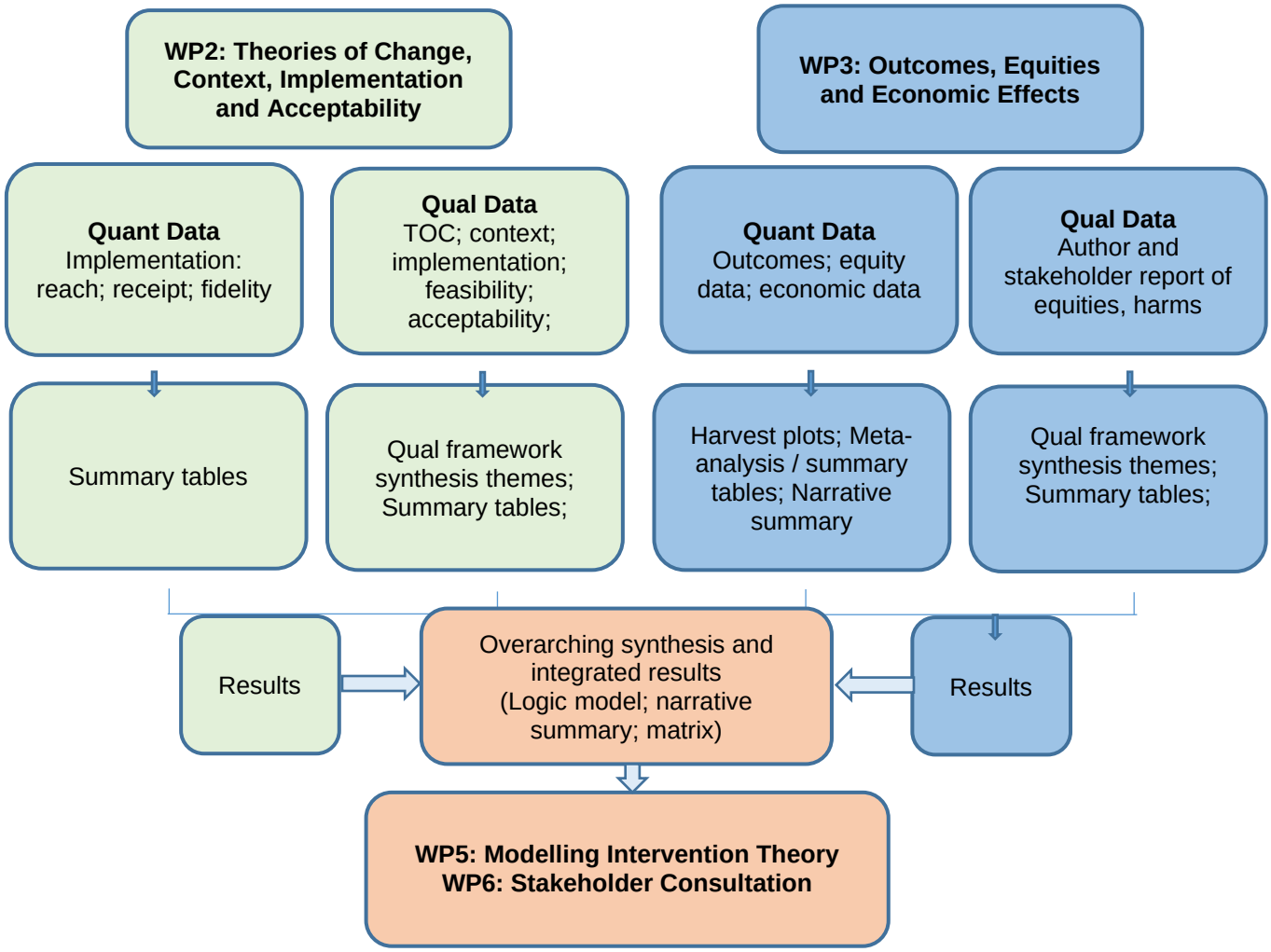
quantitative data within WP2 and WP3 and the methodologically appropriate reporting of these specific findings. These syntheses will be integrated in the following ways:

The taxonomy describing intervention types, theories and outcomes from the qualitative synthesis (WP2) will inform and structure the analyses undertaken as part of the quantitative synthesis (WP3), with the meta-analyses of effects being conducted according to the intervention types, theories and outcomes that will have been a priori classified in the taxonomy.

The synthesis of context, implementation and acceptability (WP2) will be integrated with the outcome data (WP3) to explain intervention effectiveness and potential variations in effects. To this end we will use a narrative summary in addition to a matrix approach adapted from one utilised in several recent Cochrane reviews (64).The 2x2matrix will map context, implementation, acceptability, participant values and costs against the included interventions types/theories. This will demonstrate if these factors have been fully addressed by the interventions. Together with the accompanying narrative summary, the matrix will help to explain (in) effectiveness (or even harm), and give direction as to what factors need to be better accommodated moving forward and how. For example, qualitative data on acceptability may indicate that the intervention does not align with participant values, and future interventions (or progressions of the included interventions) may need to be responsive to a different or wider set of values.

The synthesis from WP2 and WP3 will inform the development of a logic model (s), which will inform the basis of the stakeholder consultation in the subsequent work packages (WP4; WP5). We will modify the review logic model through the integration of data, to clarify and expand upon key intervention domains: theory (theories of change); setting; population; context; implementation; and outcomes. The logic model then will illustrate the relationship between the underpinning theories of change, intervention effectiveness and important modifying factors that impact upon implementation and acceptability. The final version will aim to be the best fit with the diverse evidence and PPI perspectives, notably the preferences of care-experienced children and young people, and carers.

Figure 1. Results based convergent synthesis design



Reviewers will reflect upon their background, position, prior beliefs and any other relevant factors that influence the interpretation and reporting of data. Memos will be retained throughout the review process and reflections will be discussed within the research team.

5.3. WP4: Modelling of Intervention Theory (RQ5)

Drawing upon the integrated data from WP2 and WP3 we will aim to identify if there is one overarching theory of change or number of compatible theories, including theories at different ecological levels, which can address multiple outcomes of interest. We will consider if there are existing interventions that have embodied these theories. From the process data, we will consider key contextual and implementation factors associated with the interventions that use these theories of change, in order to develop a preliminary understanding of how theories might operate in practice, particularly within a UK context.

We will diagrammatically depict the overarching theory or theories of change with the use of logic models. Depending on the nature of the data included in the review, we will seek to construct system-based logic models that privilege contextual contingencies (65). These logic models will be accompanied by narrative summaries of the identified interventions that activate the theory or theories of change. Together these logic models and summaries of interventions will serve as preliminary discussion points for stakeholder consultation (WP5).

5.4. WP5: Stakeholder Consultation and Intervention Prioritisation (RQ6)

We will host four key stakeholder consultations to understand the applicability of the identified evidence-base in the UK context by exploring the candidate theory/ theories of change and prioritising intervention(s) moving forward. They will also provide key dissemination opportunities to share the findings of the review.

Two of the stakeholder events will be hosted by The Fostering Network, a UK wide organisation. They will be held in North Wales and South Wales, but will have reach into England. The intended audience will be carers and the children and young people they care for. One consultation will be held with CASCADE Voices, which is an advisory organisation of care-experienced children and young people. The final consultation will be held with CASCADE ExChange, which is a national network of social care practitioners in Wales. We will also seek consultation with key policy stakeholders.

There are then three key phases of assessment that will be undertaken in prioritising particular theories and accompanying interventions to take forward to further evaluation in the UK context (Figure 2).

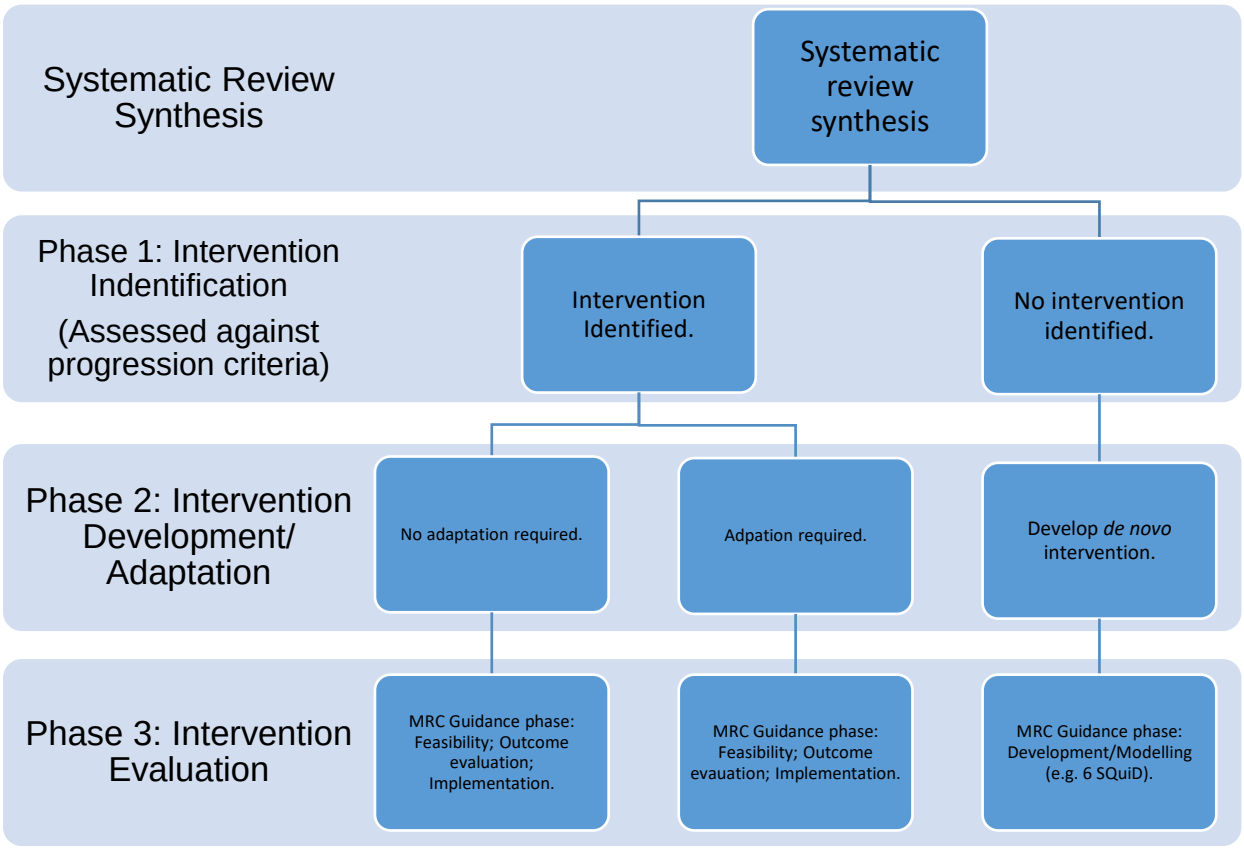
Phase 1 Intervention Identification: We will ask stakeholders to assess the candidate theories of change, and associated interventions, against the following progression criteria: 1) Acceptability; and 2) Feasibility (particularly feasibility of implementing an intervention in the UK context). If there are multiple interventions that embody the overarching theory / theories of change, we will ask stakeholders to assess which of these interventions best meet the progression criteria. At the end of this phase we should have established a potentially acceptable and feasible theory of change (single theory or interacting theories across socio-ecological domains), and intervention components. Where no candidate theories meet the progression criteria, or an overarching theory is identified but there are no clear interventions (e.g. no intervention embodies all of the interacting aspects of the theory), we will consider that a de novo intervention is required for the UK context.

Phase 2 Intervention Development and Adaptation: If a theory of change is identified, and has an associated intervention, we will assess if adaptation is required (e.g. the intervention is to be transported from the USA). We will ask stakeholders to consider the similarities of the original and UK context using a simplified version of the CICI framework (49). If the contexts are considered dissimilar, stakeholders will consider the types of adaptations that may be required. The in progress Medical Research Council funded study on the adaptation of complex interventions to new contexts (of which Dr Rhiannon Evans is co-PI) (66), will inform this process. If a de novo intervention has been deemed necessary, we will ask stakeholders to undertake preliminary consultation on developing an intervention, and consider what might be acceptable and feasible.

Phase 3 Intervention Evaluation: This phase will consider the appropriate research design that might be proposed to evaluate the intervention. To support decision making in the case where we are evaluating an existing intervention (adapted or non-adapted), we will use the 'borrowing strength' framework to assess if the outcome data from the original context is applicable within the UK context (37). The framework dictates that if contexts are largely congruent or adaptations are minimal, then an implementation study may be warranted. Where contexts are significantly dissimilar or substantial adaptation has been undertaken, more extensive feasibility and outcome evaluation will be required. We will use the Medical Research Council's guidance on developing and evaluating complex interventions to define the evaluation design to be undertaken (67). In the event that a de novo intervention is required, we will plan development and evaluation in accordance with key frameworks, notably the *Six steps in intervention development* (6SQuID) model (68) and guidance from the *Identifying and critiquing different approaches to developing complex interventions* (INDEX) study (69). We anticipate that decision-making at this phase will be predominantly conducted by the research team.

On completion of this final phase, we anticipate having a clearly identified research agenda to progress beyond the review. Depending on the requirement to develop a de novo intervention or to replicate/adapt an intervention for use in the UK context, we will make a subsequent funding application to the Medical Research Council PHIND panel or the NIHR PHR panel.

Figure 2. Intervention Prioritisation for Evaluation in UK Context



6. Dissemination, Outputs and Anticipated Impacts

6.1. Anticipated Outputs

We will generate four written outputs from the review: 1) the NIHR PHR monograph; 2) an evidence map from the data charting (WP1); 3) academic publications (WP2; WP3); and 4) a briefing report for policy and practitioners. We will feed this report to the What Works Centre for Children's Social Care, who provide a depository of evidence summaries on their website for social care professionals. On completion of the grant we aim to develop a research proposal to the MRC PHIND panel or NIHR PHR to optimise and test a priority intervention.

Dissemination: We will integrate dissemination activities within the stakeholder consultations as part of WP5. We will undertake a range of presentations at academic, policy and practice workshops and conferences. We have requested resource to attend an international social care and methodological conference. We will host a CASCADE ExChange podcast. We will use DECIPHer's dedicated communication team, who will ensure social media dissemination via Twitter and blog posts. We will also work with the extensive TRIUMPH infrastructure and community to share our findings. Further dissemination activities will be identified in collaboration with our PPI stakeholders and collaborators throughout the course of the study..

6.2. Anticipated Impacts

There are four primary impacts that we anticipate being achieved from this study: 1) Due to its methodological robustness and comprehensive remit we anticipate that no further synthesis will be required in the short to medium term. This will ensure that resource can be invested into intervention development and evaluation phases; 2) In identifying key theories of change, and their potential contextual contingencies, we can support the development of more effective interventions in future; 3) The review will provide vital knowledge to policymakers, practitioners and other related stakeholders as to which interventions are effective, which should be pursued within the UK context, and which ineffective approaches necessitate disinvestment. It will further support understanding of how we might best implement interventions to ensure they are effective, and provide key insights into contextual inhibitors of implementation; and 4) In developing knowledge of which interventions are working, finite public resources can hopefully be expended on approaches that can best improve and ensure the mental health and wellbeing of care-experienced children and young people.

7. Project Management and Governance

7.1. Project Advisory Group (PAG)

The Project Advisory Group will include academics, a policy-maker, practitioner and PPI representatives. The PAG will meet at two key study milestones. First, to support refinement of the inclusion criteria. Second, to contribute to the interpretation of findings and consider dissemination opportunities that have arisen.

The membership of the PAG has been confirmed to include:

Professor Nicky Stanley, Professor of Social Work, University of Central Lancashire (Chair)

Dr Kelly Dickson, Research Officer, EPPI-Centre / UCL Institute of Education

Henry Vaile, Improving Outcomes Senior Policy Manager, Social Services, Welsh Government

Dr Aideen Naughton, Designated Doctor / Service Lead, National Safeguarding Team, Public Health Wales

Chris Dunn, Programmes Manager Voices from Care Cymru (Representing children and young peoples voices from care)

Two carers (x2): TBC (Currently being recruited by The Fostering Network)

7.2. Project Workpackage Groups

To address each of the study research questions, work package groups will be established to oversee delivery and ensure adherence to the proposed timeline. Each work package will be led by a member of the research team and comprise relevant methodological experts and the two Research Associates who will undertake the day to day activity:

WP0: *Study Coordination and Dissemination* (Lead RE)

WP1: *Searches, Extraction and Appraisal* (Lead HM/RE)

WP2: *Intervention Theories, Context and Implementation, and Acceptability* (Lead RE)

WP3: *Synthesising Intervention Effects* (Lead GMT)

WP4: *Modelling of Intervention Theory* (Lead MR/RE)

WP5: Stakeholder Consultation (Lead MB/CW)

Each workpackage group will meet on a monthly basis for the duration of its operation, and will report to the bi-monthly Project Management Group (PMG). The PI will meet with the two Research Associates on a weekly basis.

7.3. Data Management and Curation

Data and study outputs will be centrally stored on Cardiff University's network server. Where review processes are conducted in EPPI Reviewer, outputs will be exported to Cardiff University's network server at each stage. The Principal Investigator will have responsibility for the appropriate storage of data and study outputs to ensure future replicability of the review.

7.4. Intellectual Property

Cardiff University's Technology Transfer Officer will be consulted as outputs are generated to ensure that any arising Intellectual Property is appropriately captured and protected. Cardiff University will be responsible for protecting arising Intellectual Property. A collaboration agreement will be put in place clarifying and outlining ownership of foreground and background Intellectual Property. Anticipated outputs that will require consideration for Intellectual Property include: specialist 'knowhow' and study outputs. Research outputs will be constantly reviewed during the bi-monthly Project Management Group meetings, where arising Intellectual Property will be included in the agenda.

7.5. Ethical and Regulatory Approvals

Cardiff University's School of Social Sciences Research Ethics Committee have confirmed that ethical approval is not required for the review activity. They have requested a submission to the ethics panel at a later stage to confirm if WP5: Stakeholder Consultation requires ethical approval. In recognition of the increased importance of considering the ethical dimension of systematic reviews (55), we will monitor the ethical approval procedures reported in primary studies included in the review alongside the quality appraisal.

7.6. Patient and Public Involvement

The study includes a comprehensive PPI plan that involves engagement with the Fostering Network, CASCADE Voices, the TRIUMPH Network, and CASCADE ExChange.

Stakeholder Consultation (CASCADE Voices): CASCADE Voices is a collaboration between Voices from Care Cymru and CASCADE, Cardiff University. It is a group of care-experienced young people who provide advice on research studies, from the inception to dissemination. The group regularly undertakes training with the University. We will engage with the group at two key study milestones: 1) Refining and confirming the scope of the review, notably the search strategy and inclusion criteria; and 2) Consultation on identified interventions that might be most feasible and acceptable within the UK context and which may progress to further evaluation. Throughout we will explore joint opportunities for additional dissemination activity.

Stakeholder Consultation (The Fostering Network): The Network will host two stakeholder engagement events towards the end of the study. We have experience of coordinating such events with the Network in a previous study (https://gov.wales/sites/default/files/publications/2018-03/strategy-raising-the-ambitions-and-educational-attainment-of-children-who-are-looked-after-in-wales.pdf), which were highly successful. The events will draw together a diverse range of foster carers and children and young people, with one event being undertaken in South Wales and one in North Wales. Based on the previous events, we will offer a range of engagement activities (e.g. indoor climbing), which will be interspersed with discussions about what types of interventions, identified through the review, might be feasible and acceptable moving forward.

Stakeholder Consultation (ExChange): This is an all Wales network that brings together social care stakeholders to share experiences and expertise. We will host a practitioners' workshop concurrent with the Fostering Network's stakeholder events to ensure we are achieving the social care professional's perspective on the feasibility and acceptability of an intervention that might progress to future evaluation. We will also explore the opportunity of producing an ExChange podcast.

TRIUMPH Network: The process and outputs of the study will be coordinated with the activity of the TRIUMPH network, specifically its key groups theme. Leveraging the network resource, we will: 1) Maximise use of all engagement activities (e.g. workshops, residentials) to integrate opportunities to consult on the process and findings of the review; 2) Seek opportunities to identify and develop policy and practitioner relationships that might support any future intervention development and evaluation. For example, the review may identify a potentially effective theory of change, which may already be implemented as part of locally innovative practice by an organisation engaged with TRIUMPH. Criteria around use of Network funding is still under negotiation, but there is currently consideration that resource may be spent on intervention costs.

7.7. Success Criteria and Barriers to Proposed Work

Success Criteria: There are three key success criteria that we will use to appraise the study: 1) study completion within the proposed timeframe, with the provided resource model, and in

accordance with governance procedures. 2) meaningful engagement with stakeholders and stakeholder satisfaction with study processes and outputs. Across all stakeholder consultation and engagement activities we will ask for reflection on the methods through which engagement has been undertaken and the nature of outputs produced. We will iteratively refine PPI and dissemination activities in order to respond to feedback. 3) realisation of a comprehensive dissemination strategy that will lead to research, policy and practice impact.

These are provisional success criteria and will be refined and expanded in consultation with CASCADE Voices.

7.8. Monitoring Risk

A risk register will be maintained for the study to ensure progress in accordance with the flow chart of activity. The principal investigator will oversee the risk register (WP0). The register will be a standing agenda at bi-monthly project management meetings. An agreement will be made if the risk needs monitoring or immediate resolution, and if the risk needs to be reported to the funder in cases where a contractual variation or virement may be required.

The key risks that will be monitored (and which map onto the success criteria) are: 1) reputational risk and ethical conduct; 2) study completion (risk to compliance with the timeline; and risk to study resource); 3) engagement of stakeholders and stakeholder satisfaction with study processes and outputs; and 4) dissemination and impact.

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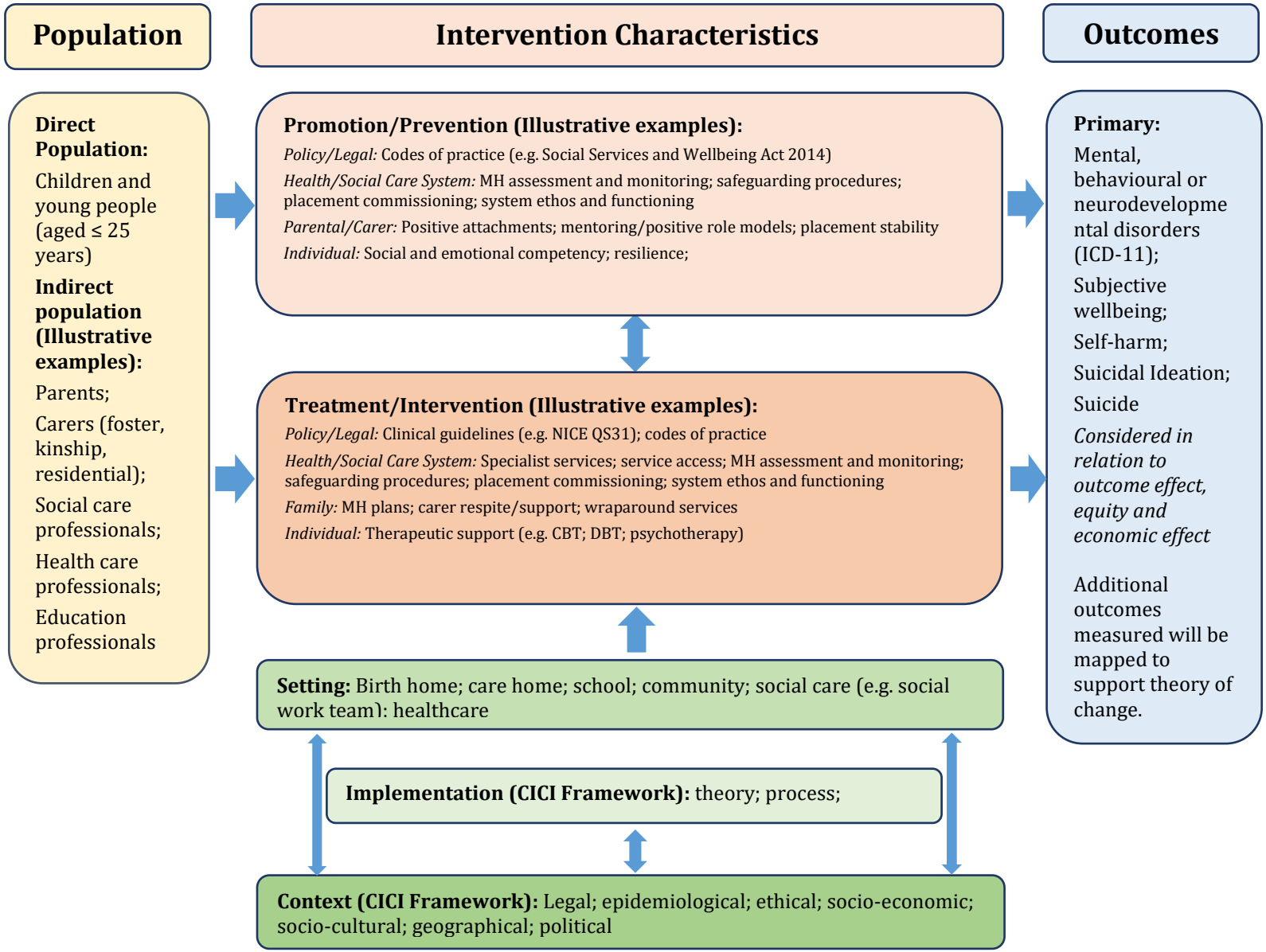
Appendix A: Systematic Review Logic Model



Appendix B. Inclusion Criteria

Each publication must meet the following inclusion criteria to progress to the subsequent assessment phase.
Year**:* Published since 1990. ***Language**:* All languages included. ***Country**:* Higher income countries (34 countries as defined by Work Bank OECD classification). ***Publication type*:** Empirical research. Non-empirical publications reporting intervention theory linked to empirical evaluation. Systematic reviews to be included and labelled at screening stage for forensic searching of empirical studies. EXCLUDE: Commentaries, letters, scale validation. ***Study Design*:** *Theory of change:* Description theory of change; logic model; testing mechanism of effect (e.g. mediation analysis). *Outcome evaluation:* (Individual/cluster) randomised controlled trials; quasi-experimental (difference in difference; non-equivalent control groups). *Process evaluation*: All study designs. *Economic evaluation*: Model-based; trial-based. NOTE: All theory of change articles must have a sibling eligible outcome evaluation to meet the inclusion criteria. EXCLUDE: Post-test measurement only; post measurement in intervention group only. ***Primary Outcomes: (Subjective) wellbeing; quality of life, life satisfaction; mental health, behavioural or neurodevelopmental disorders (neurodevelopmental; schizophrenia/primary psychotic; catatonia; mood; anxiety/fear-related; OCD; stress; dissociation; feeding/eating; elimination; impulse control; disruptive/dissocial; personality; paraphilic; factitious; neurocognitive; mental/behavioural associated with pregnancy/childbirth); self-harm /self-injury (with or without suicidal intent); suicidal ideation; suicide. EXCLUDE: Substance misuse; euthanasia or assisted suicide; accidental death (e.g. accidental overdose). Bio-medical markers of potential mental health problems (e.g. cortisol as a measurement of stress). ***Primary Outcome Population*** (i.e. primary outcome must be measured in this population)*:* Children and young people (aged up to and including 25). Currently with statutory care or previous experience of care. Care defined as: foster care; residential care; children's home; care order/permanence order; kinship care; residential schools / residential boarding schools; respite care. EXCLUDE: Adoption; Children in Need (CiN); edge of care; residential treatment centres; adult prisons (without care history); Youth Offending Institutions (without care history); Custody (without care history); homeless; unaccompanied asylum seeking children; orphanages. ***Comparator:*** Treatment as usual; other active treatment; no specified treatment. ***Intervention Type:*** Interventions are defined as an attempt to disrupt the system. Any "intervention type". Interventions can focus on prevention or treatment. ***Intervention Setting:*** Any intervention setting. ***Intervention Implementation**:* Any intervention implementation theory, strategy or agents. ***Target Intervention Population:*** Any target intervention population.

Appendix C: Provisional Search Strategy (Developed in Ovid MEDLINE)

Key: / = MeSH subject Heading; ti,ab = searches for keywords in title and abstract; * = truncation; adj*n* = adjacency operator that finds words within *n* words or each other

1. mental health/ or mental disorders/ or anxiety disorders/ or "bipolar and related disorders"/ or "disruptive, impulse control, and conduct disorders"/ or dissociative disorders/ or elimination disorders/ or "feeding and eating disorders"/ or mood disorders/ or motor disorders/ or neurocognitive disorders/ or neurodevelopmental disorders/ or neurotic disorders/ or paraphilic disorders/ or personality disorders/ or "schizophrenia spectrum and other psychotic disorders"/ or sexual dysfunctions, psychological/ or sleep wake disorders/ or somatoform disorders/ or substance-related disorders/ or "trauma and stressor related disorders"/
2. Personal Satisfaction/
3. "Quality of Life"/
4. (wellbeing or selfcare or "self care" or "ill-being" or "ill being" or illbeing or happiness or flourishing or eudaimonic or eudaimonia or eudaemonia or eudemonia or hedonic or hedonia or "life satisfaction" or "satisfaction with life").ti,ab.
5. ("positive and negative affect schedule" or panas or "Warwick-Edinburgh Mental Wellbeing" or wemwbs or "state trait anxiety inventory" or "perceived stress scale").ti,ab.
6. ((behaviour* or neurodevelopmental or mood or personality or fear or disruptive or dissocial or impulse or factitious or neurocognitive or feeding or eating or elimination or disruptive or dissocial or anxiety or stress or depressive) adj3 (disorder* or condition* or problem*)).ti,ab
7. ("bodily distress" or paraphilic or paraphilia or catatonia or catatonic or dissociation or "impulse control").ti,ab.
8. ((Emotional or psychological or mental) adj3 (stress or distress)).ti,ab.
9. ("mental health" or schizophrenia or psychotic or psychosis or OCD or "obsessive compulsive disorder").ti,ab.
10. (suicid* adj2 (intent or ideation)).ti,ab.
11. self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/
12. (self adj2 (harm or injur* or cutting or multiation or poison* or burn*)).ti,ab.
13. (suicid* adj2 (intent or ideation)).ti,ab.
14. or/1-13 [Outcomes]
15. (substitute care or "local authority care" or state care or public care or "children* home" or support* living or supported lodging* or care leaver* or "children in care" or "young people in care").ti,ab.
16. ((Refugee* or asylum) adj5 (kid* or child* or youngster or young person or young people or youth or adolescent* or teen* or girl* or boy* or juvenile*)).tw.
17. (child* adj3 (state care or statutory care)).tw.
18. ((residential or foster or kinship) adj3 (care or home*) adj5 (kid* or child* or youngster or young person or young people or youth or adolescent* or teen* or girl* or boy* or juvenile*)).tw.
19. (("in care" adj3 (kid* or child* or youngster or young person or young people or youth or adolescent* or teen* or girl* or boy* or juvenile*)) and (welfare or state or statutory or social)).ti,ab.
20. (custody adj5 (kid* or child* or youngster or young person or young people or youth or adolescent* or teen* or girl* or boy* or juvenile*)).tw.
21. (looked after adj3 (kid* or child* or youngster or young person or young people or youth or adolescent* or teen* or girl* or boy* or juvenile*)).tw.
22. (orphan* adj3 (kid* or child* or youngster or young person or young people or youth or adolescent* or teen* or girl* or boy* or juvenile*)).tw.

23. ((incarcerat* or jail*) adj3 (kid* or child* or youngster or young person or young people or youth or adolescent* or teen* or girl* or boy* or juvenile*)).tw.
24. (nonparent adj3 (care or custody)).tw.
25. Foster Home Care/ or Child, Institutionalized/ or Child, Orphaned/
26. (leaving adj2 care).ti,ab.
27. **or/15-26 [Population]**
28. (("pre?test" or pretest or posttest or "post-test" or "pre-intervention" or "post-intervention" or "controlled before" or "before and after" or "follow-up assessment") and (controlled or control or "comparison participants" or "comparison group" or "usual care" or placebo)).ti,ab.
29. ("quasi-experiment*" or quasiexperiment* or "quasi-randomi*" or "quasirandomi*" or "natural* experiment" or "time series" or "interrupted time").ti,ab.
30. ((controlled or control or intervention or comparison) adj3 (group or groups or study or trial or evaluation or cohort or cohorts or longitudinal or matched or matching or experiment or experimental)).ti,ab.
31. ("difference in difference" or "instrumental variable*" or "propensity score matching" or "process evaluation").ti,ab.
32. ((cost or costs or costing or economic) adj1 (analysis or effectiveness or benefit or evaluation or utility or savings or measure or measures)).ti,ab.
33. (trial or "randomi?ed controlled trial" or rct or "cross-over design" or " cross over design" or "crossover design" or "cross-over study" or "cross over study" or "crossover study" or "factorial design" or "controlled study" or "controlled design" or "single-blind" or "single blind" or "double-blind" or "double blind" or "triple-blind" or "triple blind").ti,ab.
34. Controlled Clinical Trial/ or Randomized Controlled Trial/
35. "costs and cost analysis"/ or "cost allocation"/ or cost-benefit analysis/ or "cost control"/ or "cost of illness"/ or "cost sharing"/ or health care costs/ or health expenditures/
36. (effectiveness or effect or effects).ti,ab.
37. or/28-36 [Study Designs]
40. 14 and 27 and 37 [Population AND Outcomes AND Study Design

Appendix D: CHIMES Gantt Chart

The project gantt chart is presented in the project management plan (V3 28.02.2022).