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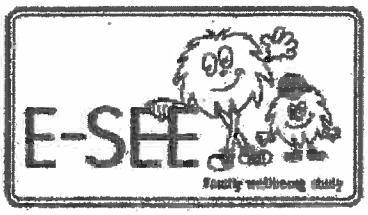

Study title: E-SEE

Enhancing Social-Emotional Health and Wellbeing in the Early Years (E-SEE): A Community-based Randomised Controlled Trial and Economic Evaluation of the Incredible Years Infant and Toddler (0-2) Parenting Programmes: External Pilot PhaseNIHR 13/93/10

Statistical Analysis Plan

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Contents

List of abbreviations used

AE	Adverse Event
ASQ:SE-2	Ages and stages questionnaire: social and emotional, 2nd edition
CC	Children's Centre
CI	Confidence Interval
CRF	Case Report Form
CSRI	Client Service Receipt Inventory
CTRU	Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
ECBI	Eyberg Child Behaviour Inventory
E-SEE	Enhancing Social and Emotional health in the Early years
FU	Follow-up
GCP	Good Clinical Practice
HRQoL	Health Related Quality of Life
ICC	Intraclass Correlation Coefficient
IQR	Inter Quartile Range
IY	The Incredible Years programme
IY-I	Incredible Years Infant programme
IY-T	Incredible Years Toddler programme
LA	Local Authority
MI	Multiple Imputation
MPAS	Maternal Postnatal Attachment Scale
NIHR	National Institute for Health Research
PAC	Parent Advisory Committee
PedsQL	Pediatric Quality of Life Inventory
PHQ-9	Patient Health Questionnaire
PPAS	Paternal Postnatal Attachment Scale
PSOC	Parent Sense of Competence
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAU	Services as usual
SD	Standard Deviation
SDQ	Strengths and Difficulties Questionnaire
SE	Standard Error
SOP	Standard Operating Procedure
TMG	Trial management group
TSC	Trial steering committee
UK	United Kingdom
UoS	University of Sheffield
UoY	University of York

1 Introduction

This statistical analysis plan (SAP) is written in conjunction with the International Conference on Harmonisation topic E9 [1], applicable Standard Operating Procedures (SOPs) from the University of Sheffield Clinical Trials Research Unit (CTRU) and trial documents (Protocol, case report form (CRF) and Data Validation Specifications). The SAP will guide the Trial Statistician during the statistical analysis in order to answer the objectives of the study. It excludes the health economics and process evaluation (which will be described elsewhere). This SAP is written for the external pilot phase of the E-SEE trial; details of the analysis for the full trial is presented in a separate SAP.

1.1 Study Background

E-SEE is a community based programme involving an 18 month external pilot randomised controlled trial (RCT) leading to a definitive 30 month RCT. The aim of the study is to compare the Incredible Years (IY) group-based parent programme, delivered using a proportionate universal approach, to service as usual (SAU).

IY parent programmes are parent education and training interventions which are informed by social learning theory designed to enhance the social and emotional wellbeing of children aged 0-12 years. The intervention being tested is comprised of three levels:

1. **The Incredible Babies (IY-B) book:** A Guide and Journal of Your Baby's First Year: This book provides information to parents on how to promote and understand a baby's physical, social, emotional and language development. It includes safety alerts, developmental principles, and a journal section to record progress.

2. **Incredible Years-Infant (IY-I):** In the parents and babies programme, parents learn how to help their babies feel loved, safe, and secure. They learn how to encourage their babies' physical and language development. The programme involves parents attending a two-hour session with their babies, once a week, for 10 weeks. The IY-I parent programmes are delivered to groups of up to 10 parents. The programme is delivered by two trained facilitators who use video clips of real-life situations to support the training and there are lots of opportunities for group discussions and practice exercises for parents to do with their babies.

3. **Incredible Years Toddler (IY-T):** In the parents and toddlers basic program, parents learn how to help their toddlers feel loved and secure and how to encourage their toddler's language, social, and emotional development. They learn how to establish clear and predictable routines, handle separations and reunions, and use positive discipline to manage misbehaviour. The programme involves parents attending a two-hour session, once a week, for 12 weeks. The IY-T parent programmes are delivered to groups of up to 14 parents. The programme is delivered by two trained facilitators and a crèche may be provided.

The intervention dose (or level received) is based on the mother's depression levels and child's social and emotional wellbeing at different stages in the trial. Intervention group participants may or may not receive levels 2 or 3, but all receive level 1. Parent-child dyads are the participants in the E-SEE study and outcome variables are measured at 3 follow up times after baseline (FU0). Follow up measurements are taken at 2 months post baseline

(FU1), 9 months post baseline (FU2) and 18 months post baseline (FU3). This is described further in section 6.2

This study is funded by the National Institute for Health Research (NIHR), PHR.

The study was originally designed as a two-phase randomised trial comprising an internal pilot followed by a pragmatic full RCT. In May 2017 the protocol was amended and parents and co-parents who were part of the pilot phase were no longer to be included in the main phase of the trial and analysis. The pilot-phase is to be analysed and reported as an external pilot trial, following discussions with TSC and DMEC and with agreement from NIHR. This SAP relates only to the external pilot. The sample size recalculation for the pragmatic full RCT has been conducted and details are given in Appendix 13.3 which was taken from the document approved/agreed by the TSC and sent to the funder on 3/5/2017 and included in protocol v6.

All statistical analyses will be performed in a validated statistical software package such as R [2].

1.2 Primary Objectives

The primary objective of the external pilot study is to assess the feasibility of trial recruitment plans, the proposed intervention and outcome measures.

a) **Recruitment:** Establish referral and recruitment pathways as assessed by achieving required sample size of 288 primary care givers at FU0.
b) **Retention and adherence:** Based on previous IY research, we expect retention from randomisation to the data collection points to be approximately 68% regardless of condition allocation, with 70% of intervention participants attending a minimum of 50% of the sessions in each programme.
c) **Establishing fidelity:** Implementation fidelity rates for; i) IY-B) will be assessed regarding receipt and use of book at first follow-up (FU1), ii) IY-I and IY-T will be assessed via facilitator attendance and contact logs, self-report, independent quality assurance checks, IY accreditation, and levels of supervision, at the end of programme delivery.
d) **Outcome Measures:** The battery of outcome measures include the PHQ-9 (the depression screener) and ASQ-SE (child wellbeing screener) will be explored as appropriate and acceptable to the target population.

Methods for objective (c) are described as part of the Process Evaluation components of the trial in the study Protocol. .

1.3 Secondary Objectives

The secondary objectives of the pilot phase are to provide reliable estimates of the critical design parameters used in the original sample size calculation, and use the values of these parameters to recalculate the sample size. [For operational reasons the sample size re-calculation was undertaken in April 2017 from the available pilot data at that time. Appendix 13.3.]

2 Study Outcome Measures

2.1.1 Primary Endpoint

The primary endpoints for the pilot study are:

a) Recruitment: assessed by whether the required sample size of 288 primary care-givers at FU0 is achieved;
b) Retention and Adherence: assessed by whether retention to the data collection points is approximately 68% regardless of condition allocation, with 70% of intervention participants attending a minimum of 50% of the sessions in each programme;
c) Fidelity of intervention: assessed by i) receipt of the book in the IY-B stage and ii) facilitator self-report, independent quality assurance checks, IY accreditation, and levels of supervision in the IY-I and IY-T stages;
d) Appropriateness of the FU0 and outcome measures to assess impact: assessed by the number and percentage of participants who complete each outcome measure at FU0, FU1, FU2 and FU3 and the variability of each outcome measure at FU0, FU1, FU2 and FU3.

2.1.2 Secondary Endpoints

The secondary numerical endpoints of the pilot study are:

a) To estimate the variability in the primary outcome (ASQ-SE) of each group at FU1, FU2 (IY-I) and FU3 (IY-T);
b) To estimate the correlation between measures of the primary clinical outcome at different times;
c) To estimate the pooled SD of the primary outcome at FU1, FU2 and FU3;
d) To estimate the average group size attending IY-I and IY-T;
e) To estimate the prevalence of mild to severe depression at FU0, FU1, FU2 and FU3;
f) To estimate the prevalence of ASQ-SE monitoring levels at FU0, FU1, FU2 and FU3

2.2 Clinical outcomes

Child primary outcome:

The following will be measured at all time-points (FU0, FU1, FU2 and FU3), unless otherwise stated:

a) *Social and emotional wellbeing* –using parent report *Ages & Stages Questionnaire – Social Emotional* (ASQ:SE-2). The co-parent will not be asked to complete this questionnaire.

Child secondary outcomes:

The following measures will be completed independently by parent and co-parent unless otherwise stated.

b) *Behaviour* – measured at FU3 using parent/co-parent report *Strengths and Difficulties Questionnaire* (SDQ).

c) *Attachment* – using *The CARE Index*, observational report, solely conducted with the parent-child dyad.
d) *Cognitive development* – measured at FU3 using parent/co-parent report *PedsQL Infant Scale.*
e) *Health (quality of life)* – measured at FU3 using parent/co-parent report *PedsQL Infant Scale.*
f) *Service use* –using parent report: *Client Service Receipt Inventory* (CSRI).

Parent and co-parent primary outcome:

The following measures will be completed independently at all time-points (FU0, FU1, FU2 and FU3) unless otherwise stated:

a) *Depression* –using the parent/co-parent report *Patient Health Questionnaire (PHQ-9).*

Parent and co-parent secondary outcomes:

b) *Carer-child attachment/interaction* – measured at FU3 using parent/co-parent report *Maternal Postnatal Attachment Scale (MPAS) and/or Paternal Postnatal Attachment Scale (PPAS).*
c) *Parenting skill* – using parent/co-parent report *Parent Sense of Competence (PSoC).*
d) *Health Related Quality of Life (HRQoL)* –using parent/co-parent report *EQ5D-5L.*
e) *Service use* – using parent report CSRI.
f) *Breastfeeding rates at FU0, FU1 and FU2.*

3 Sample Size Estimation

A sample size of 288 randomised was planned for the pilot phase of the study, justification for this can be found in the protocol. Sample size re-estimation for the main study has been conducted and is detailed in Appendix 13.3

4 Randomisation & Blinding

Randomisation is at the individual level using a web-based randomisation system developed by Sheffield CTRU in collaboration with a University of Sheffield spin-off company (epiGenesys) and using a randomisation sequence prepared by the trial statistician. E-SEE participants were randomised in a 3:1 ratio[1], intervention to control arms. Please see protocol for the full list of stratification factors.

Randomisation occurs after eligibility has been established, informed consent obtained, and FU0 measures collected from primary-caregivers to reduce initial attrition. The allocation schedule is concealed and allocation will only be confirmed to the participants once eligibility and consent is confirmed by researchers. A member of the UoY research team inputs participant information to the online system to enable randomisation, and allocation results are returned immediately. The UoY trial coordinator informs families and services of allocation.

The statistician will remain blind until data freeze and analysis will be completed unblind. A full description of the level of blinding of all study team member can be found in protocol.

[1] The allocation of 2.9:1 was rounded so block randomisation could be implemented.

5 Interim Analysis & Study Monitoring

Three committees have been set up to govern the conduct of the study:

- TSC
- DMEC
- TMG

The TSC consists of an independent chair with clinical and research expertise in the topic area, and three other topic experts, as the sponsor sees fit and as agreed by the grant awarding body.

The DMEC consists of an independent chair with clinical and research expertise in the topic area, a topic expert, plus an independent medical statistician, as the sponsor sees fit and as agreed by the grant awarding body. The role of the DMEC is to review serious adverse events (SAEs) thought to be treatment-related and look at outcome data regularly during data collection.

Decision to stop the trial early on grounds of safety will be made by the TSC on the basis of advice from the DMEC.

5.1 Stopping Rules

The research team will assess whether progression to full trial is appropriate. A report will be submitted to funders and the TSC for consideration. The TSC will assess the feasibility of the trial in month 24, with recruitment, retention and intervention fidelity being considered (building on regular monitoring and report writing throughout the trial). The TSC will also look at preliminary data at 12 months after recruitment commences, as we will be able to assess the success of recruitment and retention to IY-I at this stage.

Criteria to continue to definitive trial

a) Ability to recruit 144 participants in each LA at baseline
b) Ability for LAs to successfully deliver required number of groups
c) Intervention groups consist of a viable group (minimum 8 primary-caregivers)
d) IY group retention levels reach 70% at IY-I and IY-T programme end
e) Maximum 12% loss at each data collection time point (equivalent to 32% overall loss)
f) Intervention delivery fidelity assessment of 80% (using the standard, weekly-completed, IY checklists that correspond with the components set out in the respective programme manuals) in each LA across co-facilitators.

Primary outcomes, costs and processes will be assessed at FU3 (18 months post randomisation).

6 Data Sources, Evaluability & Study Populations

6.1 Data Sources

The data used in this pilot study will come from data entered onto the CRFs and questionnaires completed and entered onto the CTRU's web-based data management system for the capture and storage of participant data.

6.2 Data Collection

Data will be collected from participants at the following points in both the pilot and main study:

- Eligibility assessment upon receipt of the 'referral' form;
- Baseline (FU0);
- 2 months post baseline (FU1);
- 9 months post baseline (FU2);
- 18 months post baseline (FU3).

For the purpose of the trial, data that is collected within the period 4 weeks before or after the 2 month and 9 month time points and 8 weeks before or after the 18 month time point will be accepted. A summary of forms and outcome measures and when they will be used can be seen in Appendix 13.4. Detailed scoring methods can be found in protocol.

6.3 Study Population

6.3.1 Participants

Parents (primary caregivers who have the main parenting responsibility for the index child, including biological parents, step parents, foster parents and legal guardians) and co-parents, of children aged 8 weeks and under will be identified by family and child service staff, self-referral and Health Visitors. The Parent Advisory Committee (PAC) members will have an important role in promoting the research in the local community using a variety of methods (e.g. attending community groups and forums), and will be able to signpost interested parents to researchers with responsibility for recruitment. Family contact details will be passed, with consent, to the research team for researchers to assess eligibility status and obtain written, informed, consent.

A full list of inclusion and exclusion criteria can be found in the study protocol.

This trial will be conducted in compliance with the protocol, Good Clinical Practice (GCP) and regulatory requirements.

6.3.2 Inclusion on the Intervention (for Intervention arm)

Primary-caregivers are randomly allocated to either treatment or control in a 3:1 ratio stratified according to level of need at FU0 based on the depression scores of the parent, with main parenting responsibility and gender of the child and primary parent and site.

A full description of inclusion criteria for IY-I and IY-T components of the intervention can be found in the protocol.

6.4 Analysis Population

6.4.1 Intention to Treat

The ITT population includes all participants for whom consent is obtained and who are randomised to treatment, regardless of whether they received the intervention or not. This is the primary analysis set and endpoints will be summarised for the ITT population unless otherwise stated.

6.4.2 Per protocol

The per-protocol population will include all participants who completed data collection within the specified windows (section 6.2) and those participants who were eligible for and accepted invitation to IY-I and/or IY-T components of the intervention and attended at least one therapy session. If a participant received IY-I and subsequently received IY-T, they must attend at least one of each IY-I and IY-T sessions to be included in the per-protocol analysis. Data will not be summarised for the per-protocol set for the external pilot, however the number and percentage of participants meeting the per-protocol threshold will be presented.

7 Statistical Analysis for Pilot Study

7.1 General Considerations

Data will be reported and presented according to the proposed modifications for reporting pilot trials as well as the CONSORT statement [4], [5]. The analyses will be performed on the ITT population. The final analysis will be performed after data lock by a CTRU statistician under the supervision of the Senior Trial Statistician. Any analyses carried out during the trial by treatment group will be done by an independent CTRU statistician.

7.2 Recruitment and Attrition Rates

Levels of recruitment, consent and participant throughput will be reported and presented in the CONSORT flow diagram. An example of the CONSORT flow diagram can be seen in section 13.1.

The following figures will be reported either in the CONSORT flow diagram or in a separate summary table:

The number of potential participants who:

- Are potentially eligible as identified by self-referral, children's centre staff, health visitors and PPI engagement activities;
- Were approached for the study;
- Were recruited per site, per month;
- Completed each assessment at FU0, FU1, FU2 and FU3;
- Were randomised to treatment or control;
- Withdrew consent and were lost to follow up by treatment group and overall;
- Eligible for IY-I and IY-T
- Discontinued IY intervention and the reasons for discontinuation where given;
- Had mild to severe depression (PHQ-9 ≥5) by treatment group and overall at FU0, FU1, FU2 and FU3;
- Had ASQ:SE-2 monitoring level or above at each FU
- Were included and excluded from analysis and the reasons for exclusion by treatment group and overall;
- Had missing outcome measures at FU0, FU1, FU2 and/or FU3 by treatment group and overall;
- Deviated from protocol by treatment group and overall (using data collected on the 'Protocol non-compliance form).

7.2.1 Reasons for Refused Consent

Reasons for refused consent, where given, will be recorded on the CRF. Statements on refusal of consent categorised as 'other' with details will be classified into categories where possible. The number and percentage of participants refusing consent for each category will be reported (as a proportion of all participants that refused consent) by centre.

7.2.2 Eligibility

Eligibility to participate will be assessed at referral and the first home visit by data collectors.

The numbers and reasons for exclusion will be reported at each of these stages and overall. The number and % of the intervention group eligible for IY-I and IY-T groups will be presented split by the threshold used (PHQ-9>=5 or >=4 depending on protocol version in place at the time).

7.2.3 Attrition

The rate of attrition will be reported (defined as the proportion not completing the primary outcome questionnaire, ASQ:SE-2). The reasons for attrition, where provided, will be reported as number and percentage in category.

7.3 Number of Missing Values/Complete Cases

We will report the number of participants who had complete data for each of the key parameters (each outcome measure) for each time-point by treatment group and overall. Missing data will not be imputed for clinical outcomes for the pilot RCT.

For participant questionnaires, the item response rate at each visit will be reported. Response rate will be measured as a fraction of the total number of items. An example of this table can be seen in section 13.2.

7.3.1 Missing items within a questionnaire

Some of the outcome measures that are used are questionnaires and may be susceptible to missing items. Following the pilot study, any questionnaires that are susceptible to missing items will be identified and the extent of missing item data will be presented. Methods based on the relevant guidance for each measure will be used to score questionnaires in the presence of missing data. Details on the scoring of each questionnaire can be found in the protocol (section 9).

7.4 Baseline Characteristics (FU0)

The baseline demographics and clinical characteristics of the primary-caregivers and child will be reported. For the continuous variables (e.g. age) either mean and SD will be presented or median and inter quartile range (IQR) depending on the distribution of the data. The number of observations used in each calculation will be presented alongside the summaries. For the categorical variables, (e.g. ethnicity), the number and percentage of participants in each of the categories and the total number of observations will be presented.

All baseline summaries will be presented and reported for each treatment arm and in total. An example of the table is given in section 13.2. No statistical significance testing will be done to test baseline imbalances between the intervention arms but any noteworthy differences will be descriptively reported.

The following summaries will be presented:

Demographics:	Child: Sex. Ethnicity, Religion Primary care-giver: Age, Sex, Ethnicity, Religion, Income, Marital Status, Primary-caregiver education, breastfeeding rate
Clinical outcomes	Child:ASQ:SE-2, CARE Index, CSRI Primary caregiver: PHQ-9, PSOC, EQ5D-5L, CSRI

7.5 Intervention Attendance

For the IY-I and IY-T stages, the following intervention attendance summaries:

- Number offered/eligible for IY-I or IY-T at each site
- Number of groups at each site
- Session size (median, IQR, minimum, maximum)
- Number of sessions attended per participant (median, IQR, minimum, maximum)
- Reason for session non-attendance
- The proportion of participants attending at least 1/2/3/5/10/12 sessions (denominator to be all those who attended at least 1 session)

Dot plots of session attendance per-participant will also be presented.

7.6 Intervention Fidelity & Assessment of Study Design

Methods for the assessment of fidelity will be part of the Process Evaluation component of the study which is described in further detail in the study protocol.

Ancillary Sub-study C will assess the study design. Methods and results of this sub-study will be presented elsewhere but may inform the methods for the analysis of the main trial once the external pilot study is completed

7.7 Summary of Usual Care

To examine the features of usual care, the information from the CSRI will be summarised. The number of participants who received each type of treatment available, as part of usual care, will be presented.

7.8 Clinical Outcomes

Descriptive statistics will be presented for the clinical outcomes. For continuous outcomes at FU1, mean differences between groups along with 95% confidence intervals (CIs) will be presented. The 95% confidence interval will be calculated using a multiple linear regression model and adjusting for site, stratifying factors (sex of parent and child and initial level of parent depression and the baseline value of the outcome by including as covariates. All clinical outcomes will be presented on the ITT population only. There will be no formal hypothesis testing in the analysis of the external pilot study data.

Clinical outcomes (listed in section 2.2) at FU2 and FU3 will be presented graphically using dotplots and overlaid box plot at each timepoint, dots will be colour coded depending on whether the participant received the intervention or not (based on attending at least one session).

The following outcomes were only collected at FU3:

- SDQ (child)
- PedsQL (child)
- MPAS/PPAS (parent and/or co-parent)

The effect of IY-B over time will also be presented graphically using dotplots and overlaid box plot excluding those that attended any IY-I or IY-T group sessions.

The following numerical/ continuous outcomes measured at FU1 will be presented:

- ASQ:SE-2
- PHQ-9
- EQ5D-5L
- CARE Index (7 scales)
- PSOC (2 subscales)

The means in ASQ:SE-2 above outcomes will also be presented by the following subgroups of the intervention group:

- Received IY-B only
- Received IY-B and attended IY-I
- Received IY-B and attended IY-T
- Received IY-B and attended both IY-I and IY-T

7.8.1 Breastfeeding

At FU0, FU1 and FU2 the following information on breastfeeding will be presented by treatment group and overall

- The proportion exclusively breast feeding, both breast and bottle feeding, breast and bottle feeding (includes breast milk) and not breastfeeding

We will also present the median (IQR) age of child when they stopped breastfeeding over the denominator of all those that had ever breastfed (by treatment group and overall).

7.8.2 Safety

Safety will be assessed by recording adverse events (AEs). All those working on the trial will notify the Sheffield CTRU about any AEs during home visits, entering data, interventions etc. Those judged to be serious will have an expedited reporting procedure. The E-SEE AE reporting procedure is outlined in a specific SOP. In relation to the questionnaire responses that indicate suicidal thoughts or domestic violence, specific SOPs are followed. These are expected SAEs, and as such will not be reported directly to the Research Ethics Committee. Scores on questionnaires that indicate depression are expected adverse events.

The following figures will be presented by child, primary care-giver and co-parent:

- The number and percentage of participants reporting an AE;
- The number and percentage of participants reporting a SAE;
- The number and percentage of participants reporting a treatment related AE;
- A list of all AEs and their details.

Where possible, AEs will be categorised and the number and percentage of events in each category will also be presented.

7.9 Summary data used for sample size recalculation

A summary of the sample size recalculation that was conducted in April 2017 can be found in Appendix 13.3.

8 Detailed calculations

8.1 ASQ:SE-2

The ASQ:SE-2 is a parent-report based tool for screening children's social and emotional development during the first five years of life. The master set comprises 9 questionnaires, ranging from 1-72 months covering 9 specific developmental ages; 2, 6, 12, 18, 24, 30, 36, 48, and 60 months. In this study we are using only the first four of these questionnaires. The version will be selected by the researcher to match the child's chronological age. The scoring will be standardised across time points by putting scores onto a zero to 100 scale.

9 Ancillary Sub-studies

The E-SEE trial will include a number of ancillary sub-studies which are described in more detail in the trial protocol. The detailed methods of these studies will be reported in a separate document.

Some results from Ancillary sub-study C (Statistical design and analysis of trials evaluating complex interventions) will inform the methods for the analysis and multiple imputation methods of Phase 2 once the external pilot study is completed.

10 Implementation of the Analysis Plan

This SAP will be used as a work description for the statistician involved in the trial. All analyses will be performed by a statistician based within CTRU (under the supervision of Senior Trial Statistician, Dr Dawn Teare).

Initially, the data manager will provide blinded data for preliminary checks by the statistician. Following database freeze, unblinded data will be delivered to the statistician to define analysis sets and test statistical programs. Any queries will be communicated to the study and data manager. The database will be re-frozen following any queries and amendments after agreement between the statistician, data manager and study manager. No changes will be made once the data has been re-frozen, Database freeze will be conducted in accordance with SOP DM012.

11 Modifications to the Original Protocol Analysis Statement

The E-SEE SAP v1 was written for both internal pilot phase and full trial phase of the E-SEE trial. After the protocol was amended to make the pilot study external, this SAP was written to outline the analysis for the external pilot only. Any modifications to the original protocol statement are detailed in the protocol 'Protocol amendments since version 1'.

12 References

Trial Documents

Title	Version	Date	Location
Study Protocol	8	07/11/2017	N:\projects\E-SEE\PROJECT DOCUMENTATION

CTRU Standard Operating Procedures

Title	Version	Date	Location
ST007 Randomisation	1	Effective 15th October 2014	N:\projects\CTRU\Quality Assurance\SOPs
DM012 Study database lock and retention	3	24th March 2014	N:\projects\CTRU\Quality Assurance\SOPs\Current SOPs

[1] I. Conference, O. N. Harmonisation, O. F. Technical, R. For, R. Of, P. For, and H. Use, "E2F," no. August, 2010.

[2] R. C. Team, "R: A language and environment for statistical computing," 2012.

[3] T. Bywater, J. Hutchings, C. Whitaker, C. Evans, and L. Parry, "The Incredible Years Therapeutic Dinosaur Programme to build social and emotional competence in Welsh primary schools: Study protocol for a randomised controlled trial," *Trials*, vol. 12, no. 1, p. 39, 2011.

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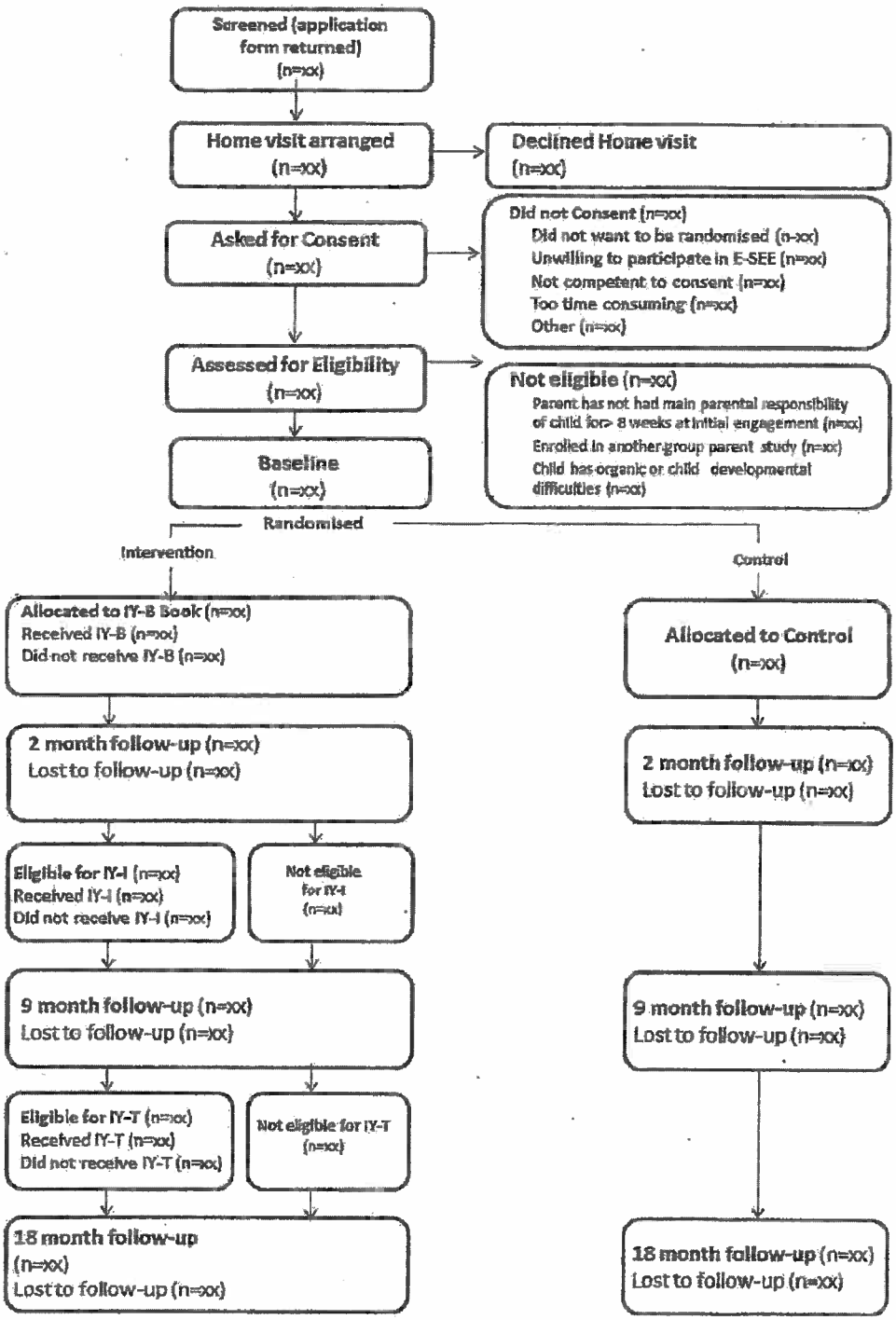
[5] L. Thabane, J. Ma, R. Chu, J. Cheng, A. Ismaila, L. P. Rios, R. Robson, M. Thabane, L. Giangregorio, and C. H. Goldsmith, "A tutorial on pilot studies: the what, why and how," *BMC Med. Res. Methodol.*, vol. 10, no. 1, p. 1, 2010.

13 Appendix

13.1 CONSORT Flow Diagram

Figure 1: An example of participants' progress through the phases of the trial



The CONSORT diagram can be extended to include reasons for withdrawal in each group.

13.2 Example Tables

The following tables show 'dummy' examples for some column headings and row names.

Table 1: Summary of baseline characteristics of primary caregiver by treatment group and overall.

Variable		Control	Intervention	All
Total		n (%)	n (%)	n (%)
Gender	Male	n (%)	n (%)	n (%)
	Female	n (%)	n (%)	n (%)
Ethnicity	White	n (%)	n (%)	n (%)
	Mixed race	n (%)	n (%)	n (%)
	Black/black British	n (%)	n (%)	n (%)
	Asian/ Asian British	n (%)	n (%)	n (%)
	Other	n (%)	n (%)	n (%)
Religion	None	n (%)	n (%)	n (%)
	Muslim	n (%)	n (%)	n (%)
	Christian	n (%)	n (%)	n (%)
	Other	n (%)	n (%)	n (%)
Relationship status	Married living together	n (%)	n (%)	n (%)
	Living together	n (%)	n (%)	n (%)
	Living together part of the time	n (%)	n (%)	n (%)
	Separated	n (%)	n (%)	n (%)
Education	AS or S levels	n (%)	n (%)	n (%)
	O levels or GCSE: 5 or more	n (%)	n (%)	n (%)
	O levels or GCSE: 4 or less	n (%)	n (%)	n (%)
	None	n (%)	n (%)	n (%)

Age (years)	Mean (SD)	x (xx)	x (xx)	x (xx)
	N	n	N	n
Income (£)	Mean (SD)	x (xx)	x (xx)	x (xx)
	N	n	N	n

This table will be repeated for Co-parents and children (sex, ethnicity, religion, premature).

Table 2: Summary of baseline child clinical outcomes by intervention arm

		Treatment group		
		Treatment	Control	Overall
Outcome				
ASQ:SE-2	N	xx	xx	
	Mean (SD)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
	Median (IQR)	xx.x(xx.x-xx.x)	xx.x(xx.x-xx.x)	xx.x(xx.x-xx.x)
	Min-Max	xx-xx	xx-xx	xx-xx
CARE Index (7 scales)	N	xx	xx	
	Mean (SD)	xx.x(xx.x)	xx.x(xx.x)	xx.x(xx.x)
	Median (IQR)	xx.x(xx.x-xx.x)	xx.x(xx.x-xx.x)	xx.x(xx.x-xx.x)
	Min-Max	xx-xx	xx-xx	xx-xx

This table will be repeated for Primary caregivers (PHQ-9, PSOC, EQ5D-5L) and co-parents (Primary caregiver: PHQ-9, PSOC, EQ5D-5L)

Table 3: Summary of primary clinical outcomes at FU1: control vs intervention

	Treatment group						
	Treatment			Control			
Outcome	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**Mean diff**
ASQ:SE-2	x	xx	xx	x	xx	x	xx (xx,xx)
PHQ-9	x	xx	xx	x	xx	x	xx (xx,xx)

Table 4: Summary of secondary clinical outcomes at FU1: control vs intervention

	Treatment group						
	Treatment			Control			
Outcome	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**Mean diff**
Child							
CARE Index (7	x	xx	xx	x	xx	x	xx (xx,xx)

scales)							
Primary care-giver							
PSOC (2 subscales)	x	xx	xx	x	xx	x	xx (xx,xx)
EQ5D-5L	x	xx	xx	x	xx	x	xx (xx,xx)
Co-parent							
PSOC (2 subscales)	x	xx	xx	x	xx	x	xx (xx,xx)
EQ5D-5L	x	xx	xx	x	xx	x	xx (xx,xx)

Table 5: Summary of recruitment by recruitment site and month.

Month	Site A	Site B
Weeks 1-4	n	n
Weeks 5-8	n	n
Extension period	n	n

This table will be extended to show the full recruitment of the trial.

Table 6: Questionnaire item response rates for available questionnaires

Questionnaire	Follow up	Total items n	Median (min-max) response rate		
			Treatment	Control	Response Rate
ASQ:SE-2	FU0	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU1	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU2	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
PHQ-9	FU0	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU1	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU2	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
PSOC	FU0	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU1	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU2	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
EQ5D-5L	FU0	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU1	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU2	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
PEDSQL	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
SDQ	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)

MPAS	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)
PPAS	FU3	n	xx (xx to xx)	xx (xx to xx)	xx (xx to xx)

Table 7: Summary of Service as Usual at baseline

	Intervention		Control	
Type of care	**No of participants**	**Average time spent**	**No of participants**	**Average time spent**
Child				
...	n	xx	n	xx
...	n	xx	n	xx
...	n	xx	n	xx
Primary care-giver				
...	n	xx	n	xx
...	n	xx	n	xx
...	n	xx	n	xx

Row names in this table will be determined by reports of SAU based on the CSRI. This table will be repeated for FU1, FU2 and FU3

Table 8: Summary of intervention received

Intervention		
Number (%) who received the book*	xx(xx.x%)	
	IY-I	IY-T
Number of intervention groups	n	n
Site A	n	n
Site B	n	n
Session size (based on primary care-givers)		
N	N	N
Mean (SD)	xx (xx)	xx (xx)
Median (IQR)	xx (xx, xx)	xx (xx, xx)
Min., Max.	xx, xx	xx, xx
Number of sessions attended (per participant)		
N	N	N
Mean (SD)	xx (xx)	xx (xx)
Median (IQR)	xx (xx, xx)	xx (xx, xx)
Min., Max.	xx, xx	xx, xx
Proportion of participants attending at least 1	nn/nnn (n%)n	nn/nnn (n%)
Proportion of participants attending at least 2 sessions	nn/nnn (n%)	nn/nnn (n%)
Proportion of participants attending at least 3 sessions	nn/nnn (n%)	nn/nnn (n%)
Proportion of participants attending at least 5 sessions	nn/nnn (n%)	nn/nnn (n%)
Number of sessions declined (per participant)		
N	N	N
Mean (SD)	xx (xx)	xx (xx)
Median (IQR)	xx (xx, xx)	xx (xx, xx)
Min., Max.	xx, xx	xx, xx
Reason for intervention withdrawal, n(%)		
Time consuming/ too much effort	n (%)	n (%)
Too far to travel	n (%)	n (%)
Didn't like being in a group	n (%)	n (%)
Didn't find it useful	n (%)	n (%)
Other	n (%)	n (%)

*Information in relation to receipt of book is collected at FU1

Table 9: Summary of Adverse Events and Serious Adverse events in primary caregivers

	Intervention	Control	Overall
AEs n	nn	nn	nn
Primary care-givers with at least 1 AE (%)	nn(%)	nn(%)	nn(%)
AE related to treatment	nn(%)	nn(%)	nn(%)
Type of AE			
Self-harming or suicidal thoughts	nn(%)	nn(%)	nn(%)
Severe depression (PHQ-9>20)	nn(%)	nn(%)	nn(%)
Severely or extremely anxious (EQ5D-5L)	nn(%)	nn(%)	nn(%)
Serious Adverse Events n	nn	Nn	nn
Primary care-givers with at least 1 SAE	nn(%)	nn(%)	nn(%)
Seriousness			
...			

This table will be repeated for children (without 'Type of AE') and co-parents

Table 10: Summary of reasons for discontinuation following randomisation

	Site 1	Site 2
Participant withdrew consent	nn (xx%)	nn(xx%)
Participant died	nn(xx%)	nn(xx%)
Participant lost to follow up	nn(xx%)	nn(xx%)
...	nn(xx%)	nn(xx%)

Table 11: Summary of ASQ:SE-2 at FU3 by intervention subgroup

	Treatment group						
	Treatment			Control			
Outcome	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**Mean diff**
IY-B only	x	xx	xx	x	xx	x	xx (xx,xx)
Received IY-B and attended IY-I	x	xx	xx				
Received IY-B and attended IY-T	x	xx	xx				

Received IY-B and attended both IY-I and IY-T	x	xx	xx

This table will be repeated for FU1 *(first row IY-B only) and FU2 (first 2 rows).

13.3 E-SEE revised sample size April 2017

Data from the pilot phase of the E-SEE trial is to be used to refine the sample size requirements for the full trial. Originally the pilot was to be internal, but two key issues arising in the pilot have led us to recommend that it should now be external. The eligibility criteria to be offered IY-I and IY-T has changed to include ASQ:SE2 and the very low uptake of IY-I and IY-T in both BwD and Devon (a total of 10 attending spread over 4 groups) led to concerns that those attending the groups were not necessarily experiencing a generalisable form of the intervention. Two hundred and five dyads were recruited to the pilot and these dyads have reached FU2 with data at FU3 available from July 2017. Hence we now have precise and context relevant estimates of most of the key design parameters which are needed for the sample size calculation. The sample size calculations presented here assume the pilot study will be treated as an external pilot and hence these total numbers need to be recruited in the main trial.

We show two separate justifications for the revised main trial sample size. The first retains the same original design with four research questions and the second presents an alternative single research question design. ***The first justification will require a total sample size of 750. The second justification uses the same key design parameter values but by proposing a repeated measures design will require a total sample size of 606.*** We recommend the adoption of the second design, which will require each site to recruit and randomize 152 dyads.

1. Retaining the original E-SEE design with four primary research analyses.

E-SEE was designed to deliver four primary analyses which are summarized in Table 1 below. The main research question is "To what extent does the proportionate delivery model of IY (and each dose level) enhance child social emotional wellbeing at age 20 months of age, and adult wellbeing, compared to services as usual (SAU)?" The four analyses examine the evidence for the overall effect of the intervention at FU3, and the effect of the individual components of the intervention (i.e. the IY book, IY-I and IY-T).

Table 1: A summary of the primary analyses for the E-SEE trial

	Child Outcome	Time point	Description
Primary Analysis A	ASQ:SE2	FU3	Comparison of Intervention (IY) and Services as Usual (SAU) group
Primary Analysis B	ASQ:SE2	FU1	Comparison of IY and SAU group
Primary	ASQ:SE2	FU2	Comparison of those eligible to

Analysis C			receive treatment of IY-I in Intervention and SAU
Primary Analysis D	ASQ:SE2	FU3	Comparison of those eligible to receive treatment of IY-T in Intervention and SAU

All four questions/analyses were equally important so Bonferroni adjustment was applied resulting in 1.25% two sided significance level for each question. The original sample size ensured at least 80% power to answer each question.

Table 2 below summarises the key design parameter values that were used in the original calculations and how these have changed as data has become available through the pilot.

Table 2: Design parameters necessary for sample size calculations:

	Value assumed in proposal	**Observed value in pilot** (by March 2017)	**Value used in sample size re-calculation**
Standard Deviation (SD) of ASQ:SE2	FU0 25 FU1 25 FU2 25 FU3 25	at FU0 12.6 at FU1 15.6 at FU2 17.5 at FU3 no data [this is the SD of those measured at each FU ignoring treatment group]	At FU0 12.6 at FU1 15.6 at FU2 17.5 ***at FU3 18** [these numbers will be an overestimate of the within treatment group SD if there is an effect of IY]
ASQ:SE2 pairwise correlation	0.6	FU0 vs FU1 = 0.40 FU0 vs FU2 = 0.26 FU1 vs FU2 = 0.40	FU0 vs FU1 = 0.40 FU0 vs FU2 = 0.26 FU1 vs FU2 = 0.40 ***FU0 vs FU3 = 0.26**** ***FU2 vs FU3 = 0.40****
Proportion eligible for IY-I IY-T	 40% 30% (but 40% in SAU)	The eligibility criteria changed during the pilot. However, retrospectively we know how many would have been eligible using our final criteria. 64 out of 197: 32% 61 out of 189: 32%	 ***32%*** ***32%***
Proportion accepting and attending IY-I IY-T		 BwD 4 out of 12 33% Devon 6 out of 15 40% BwD 10 out of 31 32% Devon no data	 ***34%*** ***34%***

Attrition at each stage	12% Overall 32%	FU1 193 of 205 5.9% FU2 189 of 193 2.1% FU3 no data	FU1 5.9% FU2 2.1% *FU3 4%** *Overall 12%**
Group intervention size	10	6 (developer agreed)	6
ICC	0.05	ICC not calculated from pilot data as very low numbers attended groups and concerns that correlation may not be representative of when groups are the recommended size.	0.05
Design effect	1.45		1.25

= A conservative estimate based on data accrued so far in the pilot

The design effect has changed as we retain the original estimate of the ICC=0.05 but reduce the intervention group size to 6 as is now recommended by the IY developer. As in the original proposal, though not everyone in the treatment arm will be offered the group based treatment we apply the design effect to inflate the numbers in the treatment arm. The sample size calculations presented below assume the same minimum clinically important effect sizes in ASQ:SE2 units as in the original proposal.

The unbalanced allocation ratio was originally set to ensure that sufficient parents would be eligible and able to attend the group based interventions. We now know that around 1 third of parents eligible for IY-I and IY-T will ultimately attend. We will have four recruitment sites and these each need to run a minimum of 2 IY groups of at least size 6. So our recruitment needs to ensure that 48 (2 x 6 x 4) parents receive the intervention and remain in the trial until FU3. Assuming 32% are eligible for IY and 34% of these attend, this translates to a total of 441 parents required to be in the IY arm at FU3. (Our design effect of 1.25 means this is equivalent to 353 independent observations.)

Sample size required for primary analysis A:

The original proposal justified a minimum clinically important difference of 5 ASQ:SE2 units at FU3 for children in the IY arm compared to children in the SAU arm (after adjusting for baseline). Assuming the SD at FU3 is 18, correlation with baseline is 0.26 and significance level is 1.25%, 441 in IY and 219 in SAU would give us 80% power to detect this difference. Hence allowing for overall attrition of 12% we would **require 750 to be randomised with the allocation ratio 2:1** to ensure 80% power for analysis A. The next three sections present the power for each of the remaining primary analyses assuming 750 are randomized in total.

Power for primary analysis B: At FU1 where all in IY have received a book but no group based treatment, allowing for 5.9% attrition and correlation with baseline of 0.4, **471 in the IY arm compared with 234 in the SAU arm will give in excess of 90% power, with 1.25% two-sided significance** to detect a difference in the change in overall scores of 5.5 units, where SD= 15.6.

Power for primary analysis C: At FU1 we expect 151 dyads to be eligible to be offered IY-I in the IY arm and 75 in SAU. Allowing for 2.1% attrition these numbers reduce to 148 and 73 reaching FU2. Assuming the correlation between FU1 and FU2 is 0.4 and the SD at FU2 is 17.5 these numbers will result **in excess of 90% power, with 1.25% two-sided significance** to detect a difference in the mean scores of 11 units.

Power for primary analysis D: At FU2, we expect 147 dyads to be eligible to be offered IY-T compared to 73 dyads in the SAU arm. Allowing for 4% attrition these numbers will drop to 141 and 70 at FU3. Assuming the SD=18 and correlation between FU3 and FU2 is 0.4, these numbers will result in **excess of 90% power, with 1.25% two-sided significance** to detect a difference between the group means of 11 units.

So while we have power over 90% to address questions B to D, the primary question A achieves only 80% power. If 750 need to be recruited this would mean each site would need to recruit 188, five sites would mean 150 would be recruited by each site which looks more feasible but a further site would need to be adopted by the trial.

Table 3: The expected numbers reaching each follow-up stage when 750 are randomized.

	IY arm	Eligible for IY-I	Attends IY-I	Eligible for IY-T	Attends IY-T	SAU
FU0	501					249
FU1	471	151	51			234
FU2	461		50	147	50	229
FU3	441		NA		48	219

Internal pilot vs external pilot.

If we remain with the original design we could include the internal pilot and the total numbers required to be recruited in the main trial possibly decreased, however changes to the eligibility

criteria will make the analysis (primarily questions C and D) difficult and the very low numbers receiving the IY-I means that the true effect size will be further diluted when conducting the ITT analysis. The changes to eligibility incurred at the IY-I stage of the pilot may make results difficult to interpret.

2. Designing the main E-SEE trial with a single research question.

We propose an alternative to the original trial design consisting of replacing the four research questions with the single research question "Do the scores of children in the IY arm, on average, stay below those scores for children in SAU over the three follow-up measures?" The benefit of asking a single research question is that power is increased and there is no need for Bonferroni adjustment. The disadvantage is that we lose the capacity to ask the four individual research questions, but the previous section shows that we need a very large sample to achieve 80% power to address primary analysis question A. We propose to add the 3 analyses (B, C and D) as secondary analyses to the protocol.

Overall this is similar to original ***research question A*** except now we will use all the follow-up measurements in a single mixed effects model repeated measures analysis. Rather than simply expecting scores to be lower at FU3 adjusted for baseline, we now expect the average scores to be lower at each follow-up in IY compared to SAU. We assume that correlation with FU0 and FU3 will be the same as observed in the pilot for FU0 and FU2 (0.26). As was justified in the original design we set the clinically important difference at FU3 to be 5 units of the ASQ:SE2. We expect this effect to be consistently seen over the three follow-up points (primary analysis B assumed 5.5 points difference at FU1, so we are allowing for a slightly lower average effect overall). Assuming an average effect of 5 units below SAU, the SD at FU3 is 18 and the same design effect of 1.25 for the IY arm with a two sided 5% significance level and 90% power we would require to have retained at FU3 441 in SAU and 92 in IY. **Allowing for overall attrition of 12% this would require 606 to be randomized with an allocation ratio of 4.8:1.**

Table 4: The expected numbers reaching each FU stage when 606 are randomized.

	IY arm	Eligible for IY-I	Attends IY-I	Eligible for IY-T	Attends IY-T	SAU
FU0	501					105
FU1	471	151	51			99
FU2	461		50	147	50	97
FU3	441		NA		48	92

The requirement of 48 dyads receiving IY-T means the same number of dyads need to be randomized to the IY arm (501) as in the original design. However, because of the repeated

measures design we can achieve 90% power with fewer controls (105 rather than 249). This results in the randomization allocation ratio of 4.8:1.

The major reason the repeated measures analysis is so much more powerful here is because the correlation between follow-up measures observed in the pilot is low (0.4).

Statistical analysis for new design: The single primary question will be assessed by analyzing the full set of repeated measures in an intention to treat framework. A multilevel mixed model will be used to allow for a treatment and time effect whilst allowing for the clustering by participant and group treatments and confounding and stratifying variables. This approach means that provided participants have at least 1 follow-up measure they can be included in the analysis.

13.4 Outcome Measures

Complete list out outcome measures and the time points they were completed (taken from the protocol)

Outcomes & timepoints	Measures	Description	Copies for Parent	Copies for Co-Parent	Previous research time to complete	Developer Guidelines Time to complete
		Baseline(6-8 weeks postpartum)				
Social & emotional well-being	ASQ:SE-2	Parent self-report	√		5-10 mins	10-15
Parent or co-parent depression	PHQ-9	Parent/co-parent self-report	√	√	3 mins	5
Attachment	CARE Index***	Observation	√		3-5 mins	3-5
Service use	CSRI**	Data collector administered	√	√	5 mins	10
Parenting skill	PSOC	Parent/co-parent self-report	√	√	5 mins	10
Parent or co-parent health	EQ5D-5L	Parent/co-parent self-report	√	√	1 min	*10*
Demographics	Bespoke form	Data collector administered	√	√	4 mins	*none*
Relationship questions****	Bespoke form	Parent self-report	√		1 min	*none*
					Approximate time for parent to complete battery of measures based on previous research =	26-33 minutes

2-months (post-baseline) follow-up						
Social & emotional well-being	ASQ:SE-2	Parent self-report	√		5-10 mins	10-15
Parent or co-parent depression	PHQ-9	Parent/co-parent self-report	√	√	3 mins	5
Attachment	CARE Index***	Observation	√		3-5 mins	3-5
Service use	CSRI**	Data collector administered	√	√	5 mins	10
Parenting skill	PSOC	Parent/co-parent self-report	√	√	5 mins	10
Parent or co-parent health	EQ5D-5L	Parent/co-parent self-report	√	√	1 min	10
Short demographics	Bespoke form	Data collector administered	√	√	1 min	*none*
Relationship questions****	Bespoke form	Parent self-report	√		1 min	*none*
Approximate time for parent to complete battery of measures based on previous research = 23-30 minutes						
9-month follow-up						
Social & emotional well-being	ASQ:SE-2	Parent self-report	√		5-10 mins	10-15
Parent or co-parent depression	PHQ-9	Parent/co-parent self-report	√	√	3 mins	5
Attachment	CARE Index***	Observation	√		3-5 mins	3-5
Service use	CSRI**	Data collector administered	√	√	5 mins	10
Parenting skill	PSOC	Parent/co-parent self-report	√	√	5 mins	10
Parent or co-parent health	EQ5D-5L	Parent/co-parent self-report	√	√	1 min	10

Short demographics	Bespoke form	Data collector administered	√	√	1 min	*none*
Relationship questions****	Bespoke form	Parent self-report	√		1 min	*none*
		Approximate time for parent to complete battery of measures based on previous research = 23-30 minutes				
		18-month follow-up				
Social & emotional well-being	ASQ:SE-2	Parent self-report	√		5-10 mins	10-15
Parent or co-parent depression	PHQ-9	Parent/co-parent self-report	√	√	3 mins	5
Attachment	CARE Index***	Observation	√		3-5 mins	3-5
Service use	CSRI**	Data collector administered	√	√	5 mins	10
Parenting skill	PSOC	Parent/co-parent self-report	√	√	5 mins	10
Parent or co-parent health	EQ5D-5L	Parent/co-parent self-report	√	√	1 min	10
Child health (& quality of life)	PEDSQL	Parent/co-parent self-report	√	√	5 mins	10
Attachment	MPAS/PPAS*	Parent/co-parent self-report	√	√	5 mins	10
Child behaviour	SDQ	Parent/co-parent self-report	√	√	5 mins	10
Short demographics	Bespoke form	Data collector administered	√	√	1 min	*none*
Relationship questions****	Bespoke form	Parent/co-parent self-report	√		1 min	*none*
		Approximate time for parent to complete battery of measures based on previous research = 38-45 minutes				