

## **BAP-EFL Trial**

A feasibility randomised controlled trial of Being a Parent-Enjoying Family Life

Statistical Analysis Plan

Qualitative Analysis Plan

Version 2

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This document contains up to date statistical analysis plans (with version numbers and dates).

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## **A) QUANTITATIVE ANALYSIS PLAN**

**Investigators: Ellie Baker (research coordinator), Jordan Troup (randomiser), Crispin Day (Chief Investigator), Patrick Smith (Co-Investigator).**

### **1. Description of the trial**

A two-arm parallel-group feasibility RCT with nested process evaluation to assess whether a full scale RCT is feasible and acceptable to participants. 72 parent/caregiver participants will be recruited via community pathways and randomised using a minimisation approach to either (i) Being a Parent-Enjoying Family Life (BAP-EFL) or (ii) standard Empowering Parents Empowering Communities- Being a Parent (EPEC-BAP), an active control group. A mixed-methods process evaluation incorporating quantitative data collected on attendance and fidelity and qualitative data from written feedback and semi-structured interviews with a subgroup of participants (n=24) will be carried out. No health economic evaluation will be undertaken at this feasibility stage.

This analysis plan should be read as a supplement to trial protocol, as such only a summary description of the trial design (See figure 1), research objectives, measures and sample size will be repeated here. For a detailed description of trial design and methods, see Being a Parent-Enjoying Family Life study protocol v5. 279116.

#### **1.1 Principal research objectives to be addressed**

The aim of this study is to examine the feasibility of trial methods and treatment acceptability to inform the planning and conduct of a definitive randomised controlled trial of BaP-Enjoying Family Life. The specific objectives are:

1. To assess (a) the primary feasibility parameters for participant recruitment and retention and (b) secondary parameters for BaP-Enjoying Family Life acceptability and fidelity.
2. To examine the acceptability of proposed trial methods, including randomisation.
3. To investigate the influence of participant and service factors on trial methods, intervention acceptability and fidelity, including in-depth qualitative analysis of interviews from a sub-group of participants to develop a fine grain understanding of parents/caregivers' subjective experience of trial and intervention procedures.
4. To obtain variance estimates for parents/caregiver and child outcomes for future sample size calculations.

#### **1.2 Progression to a full trial**

Progression from feasibility to a future definitive RCT is based on the criteria in Table 1. A traffic light system will be used with thresholds for each feasibility criteria of green, amber and red. Rating (a) is green and indicates progression to full trial is feasible; rating (b) is amber and indicates progress should be considered if improvements derived from feasibility findings are possible, and rating (c) do not progress before further testing.

**Figure 1. Trial design flow diagram**

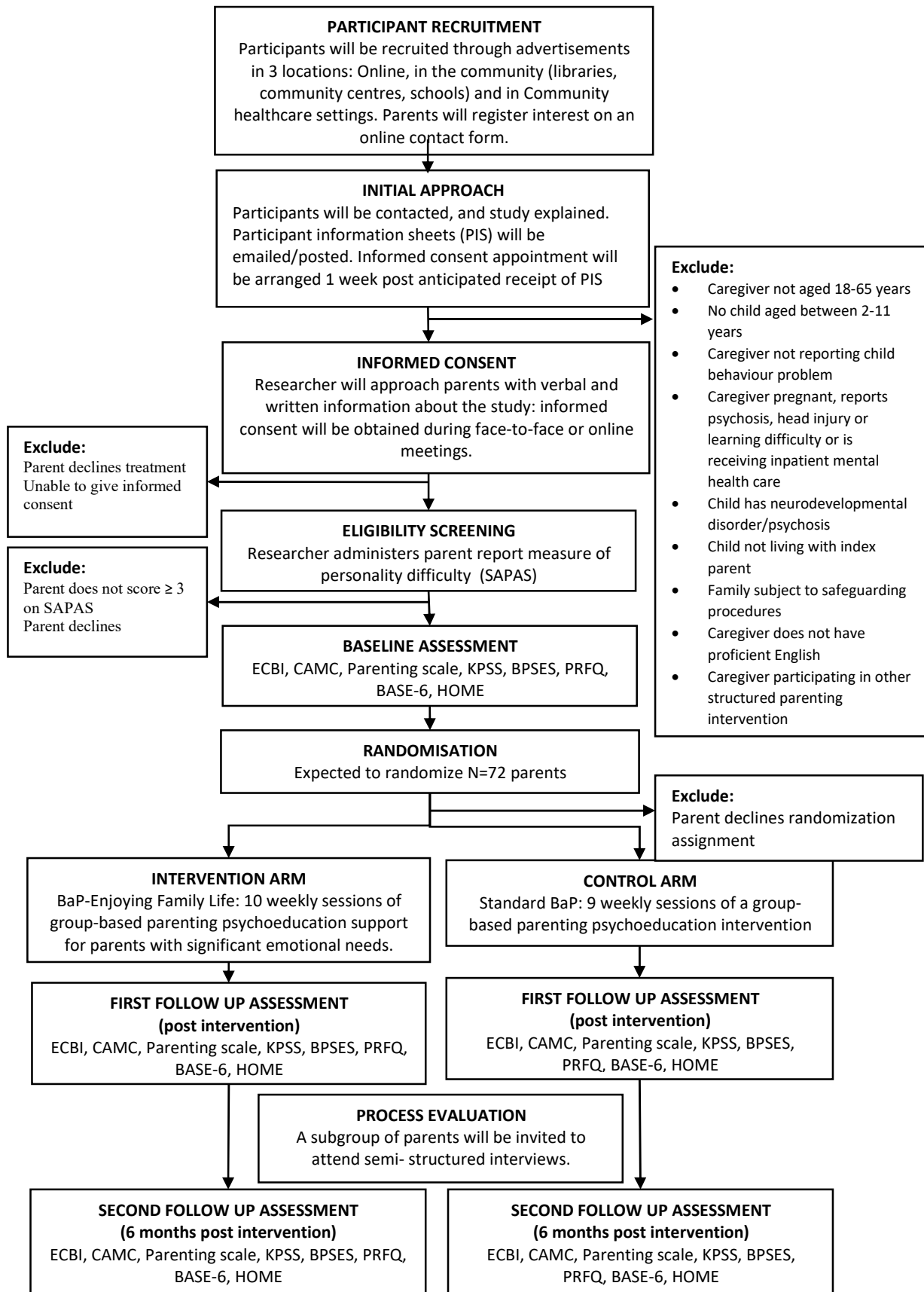


Table 1. Primary and secondary feasibility progression parameters to pre-define whether the trial should progress to a definitive clinical trial.

| <b>Parameter</b>                |  |   |
|---------------------------------|--|---|
| Primary Progression Parameter   | Time 2 participant retention rate is sufficient for a fully powered definitive RCT                   | <ul style="list-style-type: none"> <li>a. Time 2 retention at &gt;65%</li> <li>b. Time 2 retention at 45-65%</li> <li>c. Time 2 retention rate at &lt;45%</li> </ul>  |
| Primary progression parameter   | Trial participants who meet SAPAS criteria are identified at a sufficient rate for a definitive RCT. | <ul style="list-style-type: none"> <li>a. &gt; 60% of participants who complete informed consent will meet SAPAS criteria</li> <li>b. 33%-60% of participants who complete informed consent will meet SAPAS criteria</li> <li>c. &lt; 33% of participants who complete informed consent will meet SAPAS criteria.</li> </ul>  |
| Secondary progression parameter | Trial participants are recruited at a sufficient rate required for a definitive RCT                  | <ul style="list-style-type: none"> <li>a. 50-72 participants are randomised as planned</li> <li>b. Between 25-50 participants are randomised</li> <li>c. Less than 24 participants are randomised</li> </ul>  |
| Secondary progression parameter | BaP-Enjoying Family Life intervention is acceptable to parents/caregivers                            | <ul style="list-style-type: none"> <li>a. At least 75% of parents rate BaP-Enjoying Family Life with a total TARs score of <math>\geq 27</math></li> <li>b. 55-74% of parents rate BaP-Enjoying Family Life with a total TARS score of <math>\geq 27</math></li> <li>c. &lt;55% of parents rate BaP-Enjoying Family Life with a total TARs score of <math>\geq 27</math></li> </ul> |
| Secondary progression parameter | BaP-Enjoying Family Life & EPEC-Being a Parent Fidelity will be reached                              | <ul style="list-style-type: none"> <li>a. 80% or more – Good Fidelity</li> <li>b. 60-80% - Fair fidelity, deviation from the manual that may require further training and/or supervisory support</li> <li>c. &gt;60% - Significant deviation from manual, fidelity not reached</li> </ul>   |

### 1.3 Measures

#### Eligibility:

Interest form- where heard about the groups, borough.

Standardised assessment of Personality- Abbreviated scale (SAPAS)

#### Baseline Demographics.

We will collect parent & child age, sex, and ethnicity; family household composition and family socioeconomic status (including household income and previous education of both parents). We will also collect information about current mental health treatment and previous attendance to a parenting intervention.

#### Feasibility outcomes:

##### Recruitment and retention outcomes:

- (i) Proportion of participant identification (Number and percentage parents/caregivers who self-identify as interested in receiving BaP-Enjoying Family Life and participating in clinical trial)
- (ii) Proportion of trial participation:
  - a. Number and percentage of parents screened out of numbers interested,
  - b. Number and percentage of parents eligible from those consenting,
  - c. Number and percent of parents providing informed written consent from those interested
  - d. Number and percentage of parents randomisation from those eligible and consenting

and reasons for non-participation

- (iii) Number and proportion (percentage of total invited) of complete, partial complete and no response to questionnaire and observational assessments for data collection at baseline, Time 2 and 3 follow up in both arms of the trial and reasons for missing data. Retention for the feasibility progression parameter will be assessed based on proportion of completed primary outcome measure (i.e. child behaviour).

- (iv) Rates of intervention use:

- a. Uptake (Percentage of parents attending 1 session)
- b. Session attendance- mean and standard deviation number of sessions attended per arm
- c. Retention – number of treatment completers (attending 5 or more sessions), low attenders (number of parents attending 1-4 sessions), non-attenders.

from participants in both arms of trial and reasons for missed sessions and drop out

##### Intervention and trial acceptability outcomes

- (v) Treatment acceptability and group experience: Treatment Acceptability Rating Scale (TARS), Group Cohesiveness Scale (GCS; Wongpakaran et al., 2013), only collected at T2.
- (vi) Treatment Fidelity: a specially designed weekly fidelity measure containing 4 items and completed by parent group leaders together after each session.

- (vii) Nested process evaluation: Key informant semi-structured interviews will be conducted with parent/caregiver participants in order to explore treatment acceptability, implementation of trial procedures and intervention delivery.

### **Clinical outcomes:**

#### Primary outcome:

- (i) Child behaviour: Eyberg Child Behaviours Inventory (Eyberg et al., 1978); Concerns About My Child (CAMC; Scott et al., 2001; Day et al., 2017)

#### Secondary outcomes:

- (ii) Parenting behaviour: Arnold O’Leary Parenting Scale (Arnold et al., 1993)
- (iii) Parent-child observational assessment: Home Observation Measurement of the Environment (Department of Health, Cox and Bentovim., 2000)
- (iv) Parenting satisfaction and self-efficacy: Kansas Parental Satisfaction Scale (KPSS; James et al., 1985), Brief Parent Self Efficacy Scale (National academy of Parenting Research)
- (v) Parent wellbeing: Brief adjustment Scale- 6 (BASE-6; Cruz et al., 2019)
- (vi) Parent reflective function: Parent reflective function questionnaire (Luyten et al., 2017)

### **Adverse events & Serious adverse events:**

Adverse events and Serious adverse events (for definition, see Being a Parent-Enjoying Family Life study protocol v5. 279116) will be collected and reported as frequency and proportions from total sample.

## **1.4 Sample size estimation (including clinical significance)**

A total sample of n=72 is sufficient for precise feasibility parameter estimates: primary feasibility criterion is trial retention rate of at least 65%, based on median completion rates for PD diagnosis. A total sample of 72 allows 95% confidence that an anticipated 6-month follow up rate of 70% or larger will be estimated within  $\pm 10.7\%$  percentage point (Browne, 1995).

Process evaluation: A subgroup sample of 24 parents/caregiver participants for the process evaluation was decided based on both pragmatic reasons and to ensure saturation is reached. It is estimated that between 10-12 participants are needed to reach saturation in homogenous groups (Boddy, 2016). As we have two treatment groups, a sample of 24 should allow for sufficient saturation of themes regarding trial and intervention experience and acceptability. Purposive sampling will consider the effects of attendance on treatment experience, however as this is a feasibility study and there is no clear data on retention rates for the intervention, it is challenging to estimate the proportion of participants in each “attendance” group to sample from.

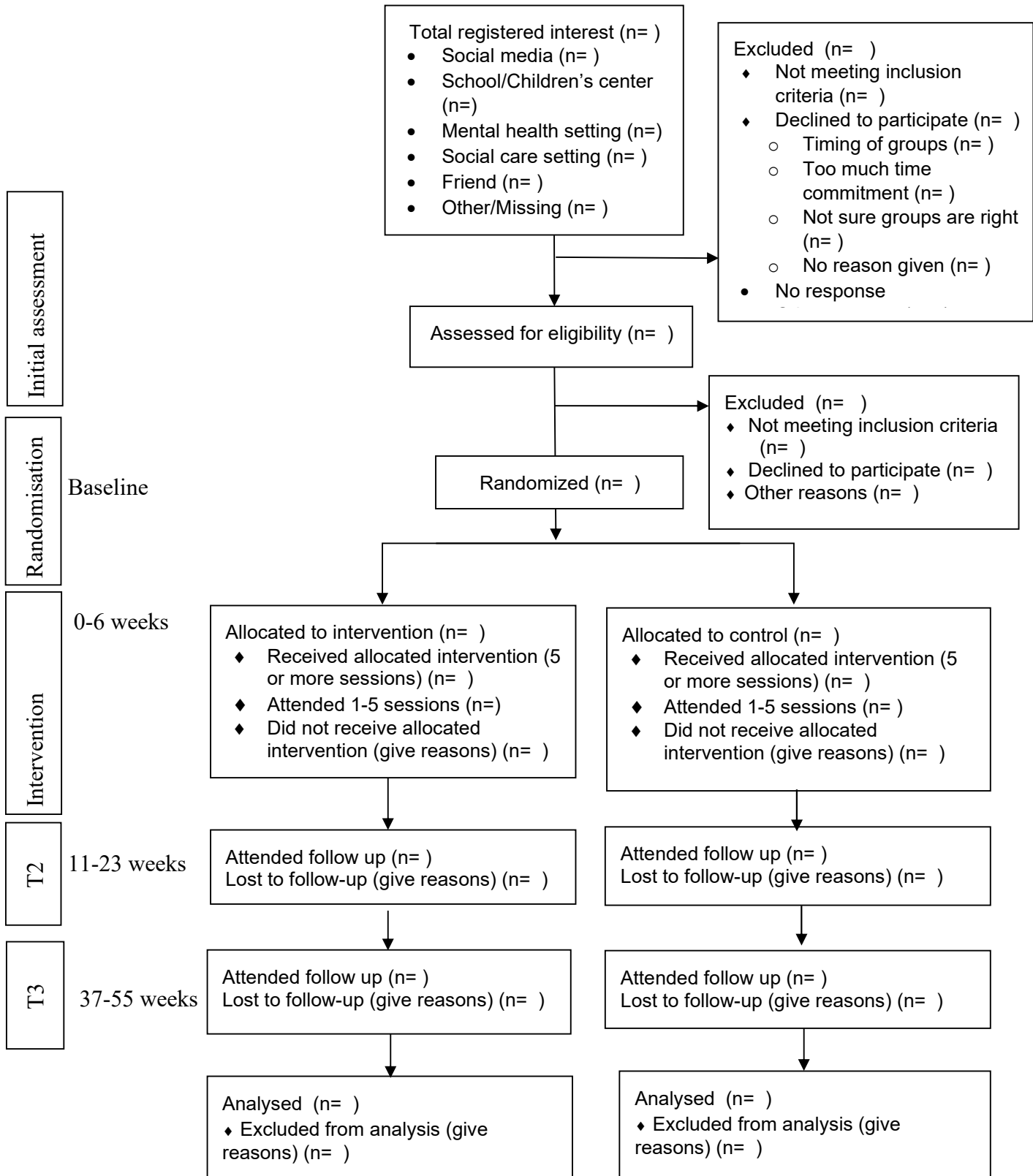
## **2. Data description**

### **2.1 Recruitment and representativeness of recruited patients**

CONSORT flow chart will be constructed (Eldridge et al., 2016; Moher et al., 2001) – see Figure 2. This will include the number of eligible patients, number of patients agreeing to enter the trial, number of patients refusing, then by treatment arm: the number of patients completing/non-completing treatment, the number continuing through the trial, the number withdrawing, the number lost to follow-up and the numbers excluded/analysed.

Completed treatment: defined by attending 5 or more sessions (not including coffee morning); Non-completion: defined as less than 5 completed sessions.

**Figure 2. Template CONSORT diagram for BAP-EFL trial**





## **2.2 Baseline comparability of randomised groups**

Baseline descriptions (demographics and all outcome measures) of participants by treatment arm and overall will be reported as: means and standard error or numbers and proportions as appropriate. No significance testing will be conducted.

## **2.3 Adherence to allocated treatment and treatment fidelity**

Compliance with treatment will be described in terms of number of group sessions attended in each trial arm. The reasons for withdrawal from treatment or non-attendance where available will be summarised. The mean number of sessions attended will be compared across arms. The baseline demographic characteristics of those in each attendance group (Low attenders (<5 sessions), high attenders (5 or more) and non-attenders) will be compared in each trial arm and any statistically significant patterns reported.

Treatment fidelity will be summarised by trial arm. Checklists measuring fidelity developed for both arms will be completed by Parent Group facilitators together after each session. Fidelity to session content and delivery is scored from 0-2 (0=no, 1= not sure, 2= yes) across four items (content, time management, facilitation methods, delivery). Fidelity will be reported as a total score (out of 80 for EFL groups and 72 for BAP) and percentage for each group in each arm. Any missed content identified in the fidelity measure will be reported.

## **2.4 Loss to follow-up and other missing data**

The proportions of participants missing each variable will be summarised in each arm and at each time point. The baseline demographic characteristics of those missing follow up will be compared to those with complete follow up and any statistically significant patterns reported. The reasons for withdrawal from the trial will be summarised.

## **2.5 Adverse event reporting**

Serious adverse events (SAE) and Serious adverse reactions (SAR) will be summarised by arm. Individual adverse events (AE), adverse reactions (AR) will also be summarised and reported.

## **2.6 Assessment of outcome measures (unblinding)**

This is a single blind study, with the researcher only blind to intervention arm. Evidence for unblinding of treatment to researchers will be recorded and reported.

## **2.7 Descriptive statistics for outcome measures**

Each outcome measure will be described by treatment group. A description of the T1, T2 and T3 outcomes total and subscales scores will be presented in a table using means and standard error for continuous data, or medians and interquartile ranges if data are skewed. Frequencies and proportions will be reported for categorical variables.

## **2.8 Description of therapists/therapies**

The number of sessions offered per group and training for parent group leaders in each arm will be outlined in text or table format in line with TiDIER framework (Hoffmann et al., 2014).

# **3. Data analysis plan**

## **3.1. Feasibility outcomes, adherence outcomes and progression criteria**

Feasibility and adherence outcomes will be summarising using descriptive statistics: number, percentages and proportions, mean and standard deviation as appropriate. These outcomes will be presented overall and also separately by arm in the

CONSORT diagram. The outcomes will be evaluated against pre-specified feasibility parameters as above (page 5) . No inferential statistics will be carried out on these feasibility outcomes.

### **3.2 Preliminary estimation of treatment differences**

The aim of analysis of treatment differences is to give an indication of the potential range of effect sizes from BaP-EFL compared to standard BaP. Analyses will estimate the difference in mean outcomes between patients randomised to BAP-EFL and EPEC-BAP following an intention-to-treat principle (i.e. all data from randomised participant will be included in analysis, regardless of attendance). Group difference estimates (i.e. change from baseline) and associated 95% confidence intervals will be reported comparing BaP-EFL and EPEC-BaP across T2 and T3. Cohen's d will indicate size of effect. Inferential statistics and p-values will not be reported and estimates obtained will not be used to claim strong evidence for the effectiveness or ineffectiveness of the intervention as the trial is not powered to detect differences between arms.

#### **3.2.1 Analysis of primary and secondary outcomes**

No inferential statistics will be conducted on primary or secondary clinical outcomes, instead descriptive statistics will estimate the likely range of treatment effects (by reporting means and standard deviation) at post-treatment and 6-month follow up. Cohen's d and 95% CIs will be reported. For the primary clinical outcome of child behaviour, proportions of children scoring above the clinical cut off of  $\geq 131$  for the Intensity Scale and  $\geq 15$  for the problem scale will be reported at each time point. Mean difference in change from baseline, and 95% confidence intervals will be reported for all outcomes and subscales, but no comparison of treatment effect will be carried out.

Population variances for future power calculation will be determined using the upper 80<sup>th</sup> percentile of confidence intervals around the estimated population variance, as recommended by Browne (1995).

#### **3.1.2 Statistical considerations**

##### *Time points*

There are three time points in this study, pre-randomisation, 3-5 months post-randomisation and 9-12 months post randomisation. Deviation of measurement of the planned post-intervention timepoint will be summarised and reported by treatment group. Data will be collected within a six-week window of the planned time-point (i.e. 6 weeks prior to group start date, 6 weeks post group end date, 6 weeks from 6-months post group ending)

##### *Stratification and clustering*

Randomisation was stratified by covariates: online or in person preference and currently receiving mental health treatment. These will be included as co-variates in the analysis. As the intervention occurs in groups, a group effect is possible and the model will include group as a co-variate to account for clustering within group.

##### *Missing items in scales and subscales*

The number (%) with complete data will be reported. Where available the missing value guidance provided by authors of scales will be used. In it's absence, scales will be pro-rated for an individual if 20% or fewer items are missing. For example, in a scale with 10 items, pro-rating will be applied to individuals with 2 or less items missing. The average value for the 8 or more complete items will be calculated for

that individual and used to replace the missing values. The scale score will be calculated based on the complete values and these replacements.

#### *Missing baseline data*

Missing baseline data should not be an issue for the primary analysis as individuals were not randomised and offered the group if they did not complete baseline assessments.

#### *Missing outcome data*

No inferential statistics will be conducted. Correlational analysis will assess whether attendance correlates with missing outcome data. T-tests will be used to compare number of missing outcomes in intervention and control arms. If there is missing outcome data, we will investigate to see if any baseline variables are predictors of outcome missingness. Such variables could then be included as covariates in the model if deemed suitable for adjustment.

#### *Method for handling multiple comparisons*

This study is underpowered to report significance test, therefore no correction for multiple comparison need be applied.

#### *Method for handling non-compliance (per protocol/CACE analyses)*

In addition to the primary intention-to-treat analysis, the effect of actually receiving treatment as defined in the protocol will also be estimated. Per-protocol analysis will be conducted on participants who completed 5 or more sessions. Demographic factors and descriptive statistics for clinical outcomes will be reported for the per-protocol analysis. Results from the per-protocol analysis will be considered secondary to results of the primary analysis.

#### *Model assumption checks*

The models assume normally distributed outcomes; this will have been checked when describing the data and if substantial departures from normality occur, transformations will be considered. Residuals will be plotted to check for normality and inspected for outliers.

### **3.1.3 Sensitivity analyses**

None planned.

### **3.1.4 Planned subgroup analyses**

None planned

### **3.2 Exploratory analyses**

None planned.

### **3.3 Exploratory mediator and moderator analysis**

None planned.

### **3.4 Interim analysis**

None planned.

## **4. Software**

Data management: Data will be collected in Qualtrics and saved in SPSS database. Analyses will be performed in SPSS and R. Excel may be used for the production of graphs.

## B) QUALITATIVE ANALYSIS PLAN

### 5. Aims of qualitative analysis

In feasibility studies, process evaluation are important in the ongoing refinement and development of both the intervention and trial design prior to a full RCT through evaluating trial and intervention acceptability and identifying potential barriers to research and treatment participation. The Qualitative data and analysis collected form part of a nested process evaluation which seeks to develop a fine grain understanding of the participant's experience of trial methods, intervention acceptability and implementation to inform further development and modifications to both the trial and intervention.

Key areas of uncertainty the qualitative interviews aims to address are:

- Trial implementation and acceptability (*Qualitative semi-structured interview, structured intervention records*)
- Intervention acceptability (*Qualitative semi-structured interview, parent-report questionnaires*)
- Intervention impact and implementation (*Qualitative semi-structured interview, fidelity and structured intervention records*)

#### 5.1. Specific research questions

- 1) Trial implementation:
  - a. What were participant's experiences of the engagement and recruitment processes used?
  - b. What helped to engage and recruit participants with the research project?
  - c. What did participants experience as barriers and facilitators to completing data collection?
  - d. How do participants experience and understand the research procedures, including randomisation?
- 2) Intervention acceptability: How acceptable is the intervention to parents?
  - a. What were participants experience of the intervention content?
  - b. What were participants experience of the delivery factors e.g. peer-led, timing of activities?
  - c. What were the areas of meaningful change for parents as a result of the intervention?
  - d. How did the intervention meet or not meet parents needs?
- 3) Intervention impact and implementation
  - a. What barriers did parents experience to attending intervention?
  - b. Were there commonalities in the strategies reported which may help improve attendance?
  - c. What were the areas of commonality and difference between the experience of parents receiving online vs. in person groups?
  - d. What were parents experience of positive recruitment strategies to parenting groups?

### Data Analysis plan

#### 6.1 Sample

A purposive sample of 24 parent participants from both intervention and control arms of the trial to semi-structured interview. Purposive sampling will occur to recruit equal proportions of participants based on attendance and trial arm.

## 6.2. Data collection

Semi-structured interviews using topic guides will be audio-recorded. Interviews will be transcribed using a transcription service. A semi-naturalistic approach (e.g. including stutters, pauses, laughter) to transcription will be taken to ensure language reflects the participants real world (Oliver et al., 2005). The researcher will review transcripts alongside audio recording during familiarisation and clarify any mistakes in transcription

Data will be analysed using Nvivo software.

## 6.3. Analysis approach:

The Reflexive thematic analysis will follow an adapted version of the six phases laid out by Braun and Clark (2006, 2019; see Table 1). Thematic analysis will be inductive, aiming to represent patterns in participant's experiences. All data will be coded, and all codes will be noted. Analysis will also be semantic, with data organized to show patterns in semantic content and then interpreted. Themes will be presented and discussed with PhD supervisors and intervention stakeholders (e.g. PGLs, parents with significant emotional and interpersonal difficulties) throughout analysis, especially during phase 4-6.

**Table 1. Thematic analysis phases (adapted from Braun & Clark, 2006)**

| Phase          | Description  |
|----------------|--|
| <b>Phase 1</b> | Familiarization with the data through re-reading and free coding the interview transcripts   |
| <b>Phase 2</b> | Transcription will be checked against the tapes for accuracy.<br>Line-by-line coding of each transcript<br>Each data item will be given equal attention; surrounding data and question asked will be kept to give context to codes   |
| <b>Phase 3</b> | Generation of themes from the line-by-line coding<br>An interactive processes using mind-maps and/or tables will be used to think about relationship between codes and themes.   |
| <b>Phase 4</b> | Reviewing of themes in comparison with the coded extracts<br>Internal homogeneity and external heterogeneity will be checked to establish whether data within themes cohere together meaningfully and are demarcated from other themes. This will be done at 2 levels: 1) all codes and extracts will be reviewed and consider whether they form a coherent pattern and 2) each individual themes validity in relation to the data set will be considered. |
| <b>Phase 5</b> | Refining and organization of themes into an internally consistent structure.<br>The essence of each theme and the aspects of the data captured will be identified and fitted into a broader overall story.   |
| <b>Phase 6</b> | Writing of interpretation and thematic framework into a coherent results section<br>This phase involves going beyond the description to make an argument in relation to the research questions.  |

## 6.4. Ontological and epistemology positioning

A critical realist epistemology will inform analysis, with the researcher considering the data at the empirical level (as reported by the participant) whilst also being critical of the influence of the participants and researcher's implicit ideology and the interaction between the interviewer and interviewee on the construction of experience (Fletcher, 2017). Data analysis will occur iteratively alongside data collection to allow the

researcher to explore emergent themes with participants, whilst also maintaining flexibility and adherence to original interview schedules.

## 6.5. Reflexivity

The research coordinator will carry out semi-structured interviews and analyse the data. The research coordinator is a female white British PhD student in her mid-twenties with no children. She has previous experience working clinically supporting individuals with complex PTSD. She has interests in trauma, adversity and how this impacts development, and strongly believes in the importance of understanding an individual's behaviours, thoughts and affect in the context of their past and current experiences. She is critical of diagnostic frameworks and medical models of treatment.

She was heavily involved in study design and selection of measures in collaboration with the chief and co-investigators, and solely responsible for recruitment and data collection, meaning she has built relationships with the participants interviewed. She also edited and developed the Being a Parent-Enjoying Family Life manual. The researcher's motivation to develop and improve support for parents experiencing significant emotional is in line with the research aims. The researcher will keep reflective records throughout interviewing and data analysis to record thoughts, feelings and concerns which come up during the process.

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