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| **A national survey of parents’ and therapists’ views about evaluation trial designs in children’s therapy and willingness to take part in a trial.** |
| STATISTICAL ANALYSIS PLAN |

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1. SUMMARY

A survey of children’s occupational therapists, physiotherapists, speech and language therapists, children’s therapy service managers and parents of children with disabilities in the UK will be conducted. Data will be collected by an online self-report questionnaire, administered by Qualtrics software©. Therapists and parents will be directed, in the questionnaire, by survey flow logic to follow two separate question flows. Therapist and parent responses will be handled and analysed as two separate data sets. Qualtrics will assist analysis by assigning numerical codes to categorical questionnaire data responses. Qualtrics coding will be checked manually during analysis, recoded if necessary and additional codes added to record missing and improbable data. Data manipulation will include dichotomous and re-categorisation variables as required. Data cleaning processes will be conducted prior to and during data entry (section 2 below). A data dictionary (section 3) will specify all the variables for analysis, codes and coding instructions. Univariable analysis will be conducted and descriptive statistics used to summarise quantitative data. The Statistical Package for the Social Sciences (SPSS) software will be used for analysis. Text response variables will be analysed qualitatively using content analysis.

1. DATA CLEANING AND DATA ENTRY

Data cleaning will occur prior to and during data entry to detect and correct data errors. Each individual questionnaire submitted to the study will be assigned an ID and responses checked. Questionnaires will be checked against study inclusion and exclusion criteria as follows:

Inclusion criteria:

* Children’s occupational therapists, physiotherapists or speech and language therapists, therapy service managers or parents of children with disabilities.

Exclusion criteria:

* Health professionals that are not an occupational therapist, physiotherapist or speech and language therapist
* Parents of children with no health condition

Questionnaires with responses to two or more variables will be included in analysis. Preview and test responses will be excluded and removed from the data set. All inclusion and exclusion decision making will be documented in an excel workbook. Questionnaires and variable responses will be checked and the following data handling techniques will be applied:

* Variables with no response option(s) selected (numerical variables) or text written (textual variables) will be coded as missing data. Missing data values will not be included in analysis.
* Text data recorded in text response variables will be recorded verbatim unless fictitious text is recorded. Fictitious text will be coded ‘missing data’.
* Variable responses provided in a scale different to that requested will be converted e.g. number of years qualified provided in months will be converted to years

Gender variable will be re-coded from text to numerical (nominal) data

Multiple response variable will be recoded to a dichotomous variable

Variable responses re-categorised as separate variables e.g. NHS Trust as UK country

A data cleaning table, for example see table 1, will document data errors and actions taken for each included questionnaire during data cleaning and entry.

Table 1: Example of data cleaning table and records

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Questionnaire ID** | **Q number and variable name** | **Format** | **Error** | **Action** |
| ID004 | Q2 ClusterUnderstanding | Numeric | Missing data | Coded 99 |
| ID060 | Q16 YearsQualified | Numeric | Not applicable | Coded 100 |

Coding and data entry checks will be conducted throughout analysis. Continuous checks between the original data source (questionnaire) and SPSS, and logic checks will be conducted. Value checking rules within SPSS will be used to identify out-of-range codes and frequency distributions will be checked for potential erroneous values. Outliers will be checked against the original data source for potential coding and data entry errors.

1. DATA DICTIONARY

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Question number | Construct | Variable name | Description | Field type | Response options | Code | Coding instructions and data checks | Level of measurement |
| Q1: Are you completing the survey as a healthcare professional or parent? | Demographic data | RespondentRole | Role in which the respondent is completing the questionnaire | Numeric | Healthcare professional  Parent | 1  2 | Code as single response variable.  Forced response field | Nominal |
| Q2: It is clear to me how research trials improve children’s therapies and outcomes | Intervention coherence | TrialUnderstanding | The individual’s understanding of research and trials | Numeric | 1 (disagree)  2  3  4  5  6  7 (agree) | 1  2  3  4  5  6  7 | Code as single response variable.  Forced response field | Ordinal |
| Q3: It makes sense to me how a cluster trial might work in my therapy situation | Intervention coherence | ClusterUnderstanding | The individual’s understanding of how a cluster randomised trial might work in their healthcare provision context | Numeric | 1 (agree)  2  3  4  5  6  7 (disagree) | 1  2  3  4  5  6  7 | Code as single response variable.  If no response given, code as 99 (error: missing) | Ordinal |
| Q4: A trial of treatments for children is likely to inform actual front-line care | Perceived effectiveness | ImpactonCare | The extent to which a research trial is perceived to be likely to achieve its purpose. | Numeric | 1 (agree)  2  3  4  5  6  7 (disagree) | 1  2  3  4  5  6  7 | Code as single response variable  If no response recorded code as 99 (error: missing) | Ordinal |
| THERAPIST QUESTIONNAIRE | | | | | | | | |
| Q5a: What do you like and dislike about the scenario? | Affective Attitude | Likes1 | How an individual feels about agreeing to take part in a trial | String | Likes: | Text | Code text verbatim.  If no response recorded code ‘missing data’ | Text |
| Q5b: What do you like and dislike about the scenario? | Affective Attitude | Dislikes1 | How an individual feels about agreeing to take part in a trial | String | Dislikes: | Text | Code text verbatim.  If no response recorded code ‘missing data’ | Text |
| Q6: How confident are you that you can agree to take part in the trial? | Self-efficacy | ConfidenceToTakePart | The respondents confidence that they can take part in the trial | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code as 99 (error: missing) | Ordinal |
| Q7: How much effort and resource do you think taking part in the trial will take from you? | Burden | EffortToTakePart | The effort that the individual perceives is required to take part in the trial | Numeric | 1 (a little)  2  3  4  5 (a lot) | 1  2  3  4  5 | Code as a single response variable.  If no response recorded, code as 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Ordinal |
| Q8: In this scenario, how likely are you to take part in the trial? | Intention | LiklihoodToTakePart | How likely the respondent is to take part in the trial | Numeric | Extremely unlikely  Very unlikely  Unlikely  Maybe  Likely  Very likely  Extremely likely | 1  2  3  4  5  6  7 | Code as a single response variable.  If no response, code as 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Ordinal |
| Q9a: What do you like and dislike about the scenario? | Affective Attitude | Likes2 | How an individual feels about discussing the study with a parent and child | String | Likes: | Text | Code text verbatim.  If no response recorded code ‘missing data’  If skip logic applied code ‘not applicable’ | Text |
| Q9b: What do you like and dislike about the scenario? | Affective Attitude | Dislikes2 | How an individual feels about discussing the study with a parent and child | String | Dislikes: | Text | Code text verbatim.  If no response recorded code ‘missing data’  If skip logic applied code ‘not applicable’ | Text |
| Q10: How confident are you that you can discuss the trial with the parent and child at the appointment? | Self-efficacy | ConfidenceToDiscuss | The respondents confidence that they can discuss the trial | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code as 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Ordinal |
| Q11: How much effort and resource do you think discussing the trial will take from you? | Burden | EffortToDiscuss | The effort that the individual perceives is required to discuss the trial | Numeric | 1 (a little)  2  3  4  5 (a lot) | 1  2  3  4  5 | Code as a single response variable.  If no response recorded code as 99 ‘missing data’.  If skip logic applied code 999 (not applicable) | Ordinal |
| Q12: What do you like and dislike about the scenario? | Affective Attitude | Likes3 | How the individual feels about sharing information | String | Likes: | Text | Code text verbatim  If no response recorded, code ‘missing data’.  If skip logic applied code ‘not applicable’ | Text |
| Q12: What do you like and dislike about the scenario? | Affective Attitude | Dislikes3 | How the individual feels about sharing information | String | Dislikes: | Text | Code text verbatim  If no response recorded, code ‘missing data’.  If skip logic applied code ‘not applicable’ | Text |
| Q13: How confident are you that you can share information with the research team? | Self-efficacy | ConfidenceToShareInfo | The respondents confidence that they can share information | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code as 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Ordinal |
| Q14: How much effort and resource do you think sharing information will take from you? | Burden | EffortToShareInfo | The effort that the individual perceives is required to share information | Numeric | 1 (a little)  2  3  4  5 (a lot) | 1  2  3  4  5 | Code as single response variable.  If no response recorded, code as 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Ordinal |
| Q15: What is your profession? | Demographic data | Profession | Professional group of respondent | Numeric | Physiotherapist  Occupational therapist  Speech and language therapist  Other | 1  2  3  4 | Code as single response variable.  If no response is recorded, code 99 ‘missing data’.  If skip logic applied code 999 (not applicable)  If text data provided, code verbatim | Nominal |
| Q16: How many years have you been qualified as a therapist? | Demographic data | YearsQualified | Number of years qualified | Numeric | Free text number | 0-46 | Code number recorded.  If number recorded to a decimal place code to lowest denominator  If number recorded in months (and stated as so), convert data to years  If no response is recorded, code 99 ‘missing data’.  If skip logic applied code 999 (not applicable) | Ratio |
| Q17: What is your primary professional role? | Demographic data | ProfessionalRole | Professional role | Numeric | Therapist  Service manager  Other | 1  2  3 | Code as single response variable.  If code 3 (other) is recorded, add text entry.  If no response is recorded, code 99 ‘missing data’.  If skip logic applied code 999 (not applicable) | Nominal |
| Q18: What is the name of the organisation that employs you? (NHS Trust or company) | Demographic data | Employer | Employing organisation | String | Free text | Text | Code text verbatim  If no response recorded, code ‘missing data’ | Text |
| PARENT QUESTIONNAIRE | | | | | | | | |
| Q19: What are your initial thoughts and feelings about the scenario? | Affective attitude/ethicality | ThoughtsandFeelings1 | How an individual feels about the discussing the trial | String | Essay text | Text | Code text verbatim  If no response recorded, code ‘missing data’ | Text |
| Q20: How confident are you that you can discuss the trial with your therapist at a routine appointment? | Self-efficacy | ConfidencewithTherapist | The respondents confidence that they can discuss the trial with their therapist | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code as 99 ‘missing data’. | Ordinal |
| Q21: How confident are you that you can discuss the trial with a research team member over the phone, at home or at an extra extra session at the local healthcare clinic? | Self-efficacy | ConfidencewithResearcher | The respondents confidence that they can discuss the trial with a research team member | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code as 99 ‘missing data’. | Ordinal |
| Q22: How much effort and resource do you think discussing the trial with your therapist will take from you? | Burden | EffortwithTherapist | The effort that the individual perceives is required to discuss the trial with their therapist | Numeric | 1 (a little)  2  3  4  5 (a lot) | 1  2  3  4  5 | Code a single response variable.  If no response recorded, code as 99 ‘missing data’ | Ordinal |
| Q23: How much effort and resource do you think discussing the trial with a research team member will take from you? | Burden | EffortwithResearcher | The effort the individual perceives is required to discuss the trial with a research team member | Numeric | 1 (a little)  2  3  4  5 (a lot) | 1  2  3  4  5 | Code a single response variable.  If no response recorded, code as 99 ‘missing data’ | Ordinal |
| Q24: What are your initial thoughts and feelings about the scenario? | Affective attitude/ethicality | ThoughtsandFeelings2 | How an individual feels about opting in or opting out of the trial | String | Essay text | Text | Code text verbatim.  If no response recorded, code ‘missing data’ | Text |
| Q25: On balance, what would you choose to do? | Intention | OptingInorOut | What choice the individual is likely to make | Numeric | Allow non-identifiable information to be shared, unless I specifically opt out  Actively opt-in for my chosen trials, and no information to be shared otherwise  I have no preference | 1  2  3 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Nominal |
| Q26: How confident are you in your choice? | Decisional confidence | ChoiceConfidence1 | How confident the individual feels about the choice they have made | Numeric | 1 Not at all confident  2  3 Somewhat confident  4  5 Very confident | 1  2  3  4  5 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Ordinal |
| Q27: In a situation where you want to take part in the trial, and the only option is to opt-in, how confident are you that you can opt in to the trial? | Self-efficacy | ConfidenceOPtIn | How confident the individual is that they can opt in to the trial | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Ordinal |
| Q28: In a situation where you do not want to take part in the trial, and the only option is to opt-out, how confident are you that you can opt-out of the trial? | Self-efficacy | ConfidenceOptOut | How confident the individual is that they can opt out of the trial | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Ordinal |
| Q29: How much effort and resource do you think the action of replying to the research team will take from you? | Burden | EffortReplying | The effort the individual perceives is required to reply to the research team | Numeric | 1 (a little)  2  3  4  5 (a lot) | 1  2  3  4  5 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Ordinal |
| Q30: What are your initial thoughts and feelings about this situation? | Affective attitude/ethicality | ThoughtsandFeelings3 | How an individual feels about sharing information | String | Essay text | Text | Code text verbatim.  If no response recorded code ‘missing data’ | Text |
| Q31: On balance, what would you choose to do? | Intention | SharingInfoChoice | What choice the individual is likely to make about sharing information | Numeric | Share information with the research team by completing questionnaires, taking part in interviews, and being observed.  Give permission for the research team to access existing health information stored in my child’s health record.  I have no preference | 1  2  3 | Code as single response variable.  If no response recorded. Code 99 ‘missing data’. | Nominal |
| Q32: How confident are you in your choice? | Decisional confidence | ChoiceConfidence2 | How confident the individual feels about the choice they have made | Numeric | 1 Not at all confident  2  3 Somewhat confident  4  5 Very confident | 1  2  3  4  5 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Ordinal |
| Q33: How confident are you that you can share information directly with the research team? | Self-efficacy | ConfidenceSharingDirectly | How confident the individual is that they can share information with the research team | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code 99 ‘missing data | Ordinal |
| Q34: How confident are you that you can agree to a healthcare professional sharing information from your child’s health record? | Self-efficacy | ConfidenceSharingRecord | How confident the individual is that they can agree to their therapist sharing information from their child’s record | Numeric | 1 (can not do at all)  2  3  4  5  6  7  8  9  10 (can definitely do) | 1  2  3  4  5  6  7  8  9  10 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Ordinal |
| Q35: How much effort and resource do you think sharing information directly with the research team by completing questionnaires, taking part in interviews and being observed will take from you? | Burden | EffortSharingInfo | How much effort the individual perceives it will take to share information directly with the research team | Numeric | 1 (a little)  2  3  4  5 (a lot) | 1  2  3  4  5 | Code as single response variable.  If no response recorded, code 99 ‘missing data’ | Ordinal |
| Q36: What is your gender? | Demographic data | Gender | Gender | String | Form text | Text | Re-code to numerical response:  1=Female  2=Male  99=missing data | Nominal |
| Q37: What language do you speak at home? | Demographic data | HomeLanguage | Language the family speak at home | String | Form text | Text | Re-code into numerical variable:  1=English  99=missing data  999=not applicable | Nominal |
| Q38: How old is your child? | Demographic data | ChildsAge | Age of the respondents chid | Numeric | Free text | 0-25 | Code number recorded.  If recorded with text or decimal, code to lowest denominator.  If no response recorded, code 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Ratio |
| Q39: Does your child have any diagnosed health conditions? | Demographic data | Diagnosis | Presence of a health condition | Numeric | Yes  No | 1  2 | Code as single response variable.  If no response recorded code 99 ‘missing data’ | Nominal |
| Q40: What diagnosed health conditions does your child have? | Demographic data | HealthConditions | Diagnosed health conditions | Numeric | Developmental coordination disorder, dyspraxia or verbal dyspraxia  Autistic Spectrum Disorder, Aspergers syndrome or Specific Language Impairment  Cerebral Palsy  Developmental delay or speech delay  Cognitive delay, learning disability  Other | 0=No, 1=Yes  0=No, 1=Yes  0=No, 1=Yes  0=No, 1=Yes  0=No  1=Yes  0=No  1=Yes | Recode to dichotomous responses  If no response recorded code each response as 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Nominal |
| Q41: Who is the main carer for your child? | Demographic data | MainCarer | Main carer for the child | Numeric | Mother  Father  Grandparent  Other | 1  2  3  4 | Code as single response variable.  If no response recorded, code 99 ‘missing data’  If skip logic applied code 999 (not applicable) | Nominal |
| Q42: What is the main carers highest educational qualification? | Demographic data | CarerQualification | The highest qualification for the child’s main carer | Numeric | Secondary education certificate (0-Level/GCE/GCSE)  College level qualification (HSC/A-Level)  University Bachelors Degree  University Masters Degree  University Doctorate  Other  None of the above | 1  2  3  4  5  6  7 | Code as single response variable.  If coded 6 (other), record text response.  If no response reorded, code 99 ‘missing data’.  If skip logic applied code 999 (not applicable) | Nominal |
| Q43: What is the name of the NHS Trust that provides services to your child? | Demographic data | NHS Trust | NHS Trust providing the child’s care | Text | Form text | Text | Re-code to?? | Text |

## ANALYSIS

Variables with numerical response fields (see section 3) will be analysed by descriptive statistics. Measures of central tendency and variability will be reported for each variable.

Nominal and ordinal variables will be measured by absolute numbers and percentages. The Mode will be used as a measure of central tendency and frequency distributions will report variability. Two variables in the dataset collect ratio data:

* **YearsQualified**: Number of years qualified
* **ChildsAge**: Age of the respondents child

Ratio level values will be tested for a normal distribution curve and analysed based on results. The Mean and Standard Deviation will be used as measures of central tendency and variability if the values follow a normal curve distribution. For a skewed curve distribution, the Median and Interquartile Range will be used as measures of central tendency and variability. Analysis will be univariable.

Content analysis techniques will be used to analyse variables with text response fields. The Theoretical Framework of Acceptability will be used to code text data responses and coded text grouped into TFA domains. From the groups, coded text will be developed into operationalised factors related to trial designs.

## STATISTICAL PACKAGE FOR THE SOCIAL SCIENCES (SPSS)

Statistical analysis will be carried out using SPSS software. Multiple response sets will be created to analyse multiple response variables.

Commands and syntax:

*Single response categorical data:*

FREQUENCIES VARIABLES=Variable name

/ORDER=ANALYSIS.

*Tests for the normal distribution:*

DATASET ACTIVATE DataSet#

EXAMINE VARIABLES=Variable Name

/PLOT BOXPLOT HISTOGRAM NPPLOT

/COMPARE GROUPS

/STATISTICS DESCRIPTIVES

/CINTERVAL 95

/MISSING LISTWISE

/NOTOTAL.

*Ratio data:*

DATASET ACTIVATE DataSet#

FREQUENCIES VARIABLE=Variable name

/NTILES=#data entries

/STATISTICS=STDDEV RANGE MINIMUM MAXIMUM MEAN MEDIAN MODE SKEWNESS SESKEW

/ORDER=ANALYSIS

## DATA REPORTING PLAN

Data will be reported to describe sample characteristics,

Table 2: Variables to describe sample characteristics

|  |  |  |
| --- | --- | --- |
| Q number | Variable name | Variable description |
| Q1: Are you completing the survey as a healthcare professional or parent? | RespondentRole | Role in which the respondent is completing the questionnaire |
| Q15: What is your profession? | Profession | Professional group of respondents |
| Q16: How many years have you been qualified as a therapist? | YearsQualified | Number of years qualified |
| Q17: What is your primary professional role? | ProfessionalRole | Professional role |
| Q18: What is the name of the organisation that employs you? (NHS Trust or company) | Employer | Employing organisation |
| Q36: What is your gender? | Gender | Gender |
| Q37: What language do you speak at home? | HomeLanguage | Language spoken at home |
| Q38: How old is your child? | ChildsAge | Age of the respondents chid |
| Q39: Does your child have any diagnosed health conditions? | Diagnosis | Presence of a health condition |
| Q40: What diagnosed health conditions does your child have? | HealthConditions | Diagnosed health conditions |
| Q41: Who is the main carer for your child? | MainCarer | Main carer for the child |
| Q42: What is the main carers highest educational qualification? | CarerQualification | The highest qualification for the child’s main carer |
| Q43: What is the name of the NHS Trust that provides services to your child? | NHS Trust | NHS Trust providing the child’s care |

Table 3: variables to describe acceptability of trial designs using the TFA constructs:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TFA construct title | Construct description | Q number | Variable name | Variable description |
| Intervention coherence | The extent to which the participant understands the intervention and how it works | Q2  Q3 | TrialUnderstanding  ClusterUnderstanding | The individual’s understanding of research and trials  The individual’s understanding of how a cluster randomised trial might work in their healthcare provision context |
| Perceived effectiveness | The extent to which the intervention is perceived to be likely to achieve its purpose | Q4 | ImpactonCare | The extent to which a research trial is perceived to be likely to achieve its purpose. |
| Affective attitude | How an individual feels about the intervention | Q5  Q9  Q12  Q19  Q24  Q30 |  |  |
| Burden | The perceived amount of effort that is required to participate in the intervention | Q7  Q11  Q14  Q22  Q23  Q29  Q35 | EffortToTakePart | The effort that the individual perceives is required to take part in the trial |
| Self-efficacy | The participant’s confidence that they can perform the behaviour(s) required to participate in the intervention |  |  |  |

Additional behavioural factors

Intention

Decisional confidence