Parenting course for parents of children with fetal alcohol spectrum disorders (FASD) versus waitlist: a randomised controlled feasibility study of the SPECIFiC (Salford Parents and carers' Education Course for Improvements in FASD outcomes In Children) Programme

SPECIFiC RCT Feasibility Study

Statistical Analysis Plan

Prepared by Kate Bennett

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Name/Role	Signature	Date
Professor Penny Cook University of Salford; Chief Investigator)		25/11/24
Professor Raja Mukherjee (University of Surrey; Principal Investigator		20/11/24
Kate Bennett (QMUL; Trial Statistician)		27/11/2024
Professor Simon Skene (University of Surrey; Co-Investigator; statistical oversight)		21-NOV-2024

Version Control Log

Version No.	Page No.	Section	Change Details
V2.0	12	3.3	Change to the definition of the per-protocol analysis population
V2.0	19	5.3.1	Change to the definition of the per-protocol analysis

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1. LIST OF ABBREVIATIONS

AE	Adverse event
CI	Chief Investigator
CRA	Clinical Research Associate (Monitor)
CRF	Case Report Form
CRO	Contract Research Organisation
CT	Clinical Trials
CTRG	Clinical Trials and Research Governance
CTU	Clinical Trials Unit
FASD	Fetal Alcohol Spectrum Disorder
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
NHS	National Health Service
PAE	Prenatal Alcohol Exposure
PI	Principal Investigator
PIS	Participant/ Patient Information Sheet
PPI(E)	Patient and Public Involvement (Engagement)
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RSI	Reference Safety Information
SABPT	Surrey and Borders Partnership NHS Foundation Trust
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

UoSa	University of Salford
UoS	University of Surrey
QMUL	Queen Mary University of London

1 INTRODUCTION

1.1 Background and rationale

Good parenting is vital for healthy child development, whilst ineffective parenting can lead to long-term adverse consequences for the child. Parenting children with neurodevelopmental disorders and/or behaviour problems can be associated with less positive, less consistent, and more ineffective parenting behaviours. Fetal Alcohol Spectrum Disorder (FASD) is a pervasive disorder that is increasingly recognised in the UK. Parenting these children is challenging, even for parents who have previously demonstrated parenting competence. Despite courses being developed for special groups such as autism spectrum disorders and attention deficit hyperactivity disorder, no effective parenting programmes exist for FASD.

Parents need support because FASD has significant added complexity compared to other conditions (3). This research addresses the vacuum caused by a lack of effective interventions by offering a bespoke FASD parenting programme, SPECIFiC, that is suitable for families with a child with a diagnosis of FASD. It aims to reduce family stress, and improve children's behaviour, ultimately changing children's life trajectories to improve their long-term outcomes.

In partnership with families, using funding from the Medical Research Council, we created 'SPECIFiC', an FASD parenting programme for those who care for children with a recent FASD diagnosis. SPECIFiC is a seven-week programme, where groups of six families meet weekly using video conferencing, along with an experienced trainer/therapist and an FASD-experienced parent.

1.2 Objectives

- To estimate recruitment and retention rates using a margin of error approach
- To demonstrate a signal of efficacy sufficient to justify progression to a full/definitive trial
- To establish a minimum clinically important difference (MCID) on the chosen primary outcome (Parenting Stress Index, PSI)
- To evaluate data collection completeness and the utility of secondary outcome measures
- To explore whether there are differences in outcomes depending on factors such as the facilitators, time since diagnosis and age of child.
- To estimate resource implications and costs of delivering SPECIFiC (not part of this SAP)
- To explore participants' experiences of SPECIFiC or being on the waiting list, and views on the design of the future definitive study (not part of this SAP).

2 Study Methods

2.1 Trial design

A two-arm randomised feasibility study of SPECIFiC training course against waitlist controls. The control group will receive treatment as usual during the intervention period and will receive the parenting intervention after the intervention period (see appendix A of the protocol). Families will be randomised 1:1 into the intervention or control arm. The study will not affect any aspect of the participants' clinical care. The 7-week course will be delivered by trained facilitators, following the manual created in a prior study funded by the Medical Research Council (MRC). All materials and information are incorporated into this

manual. The intervention was set up to be delivered online to groups of 6 on a rolling basis. This will minimise wait times and allow for timely access to the intervention for the controls, who will be on a waitlist. All participants are to be eventually offered the intervention. The primary outcome measure for efficacy (Parenting Stress Index, PSI) will be used to compare the SPECIFiC arm against treatment as usual at 16 weeks. Following this, those on the control group will receive the intervention. See Appendix A (protocol) for the trial flowchart.

2.2 Randomisation

Following a protocol amendment on 22 November 2023 (V3), the randomisation protocol was simple 1:1 allocation of families (index child and parent(s)) to (a) intervention arm or (b) waiting list control arm, using the online randomisation service SealedEnvelope.com. Prior to the protocol amendment, randomisation was balanced across cohorts of twelve (six in the intervention group, six waiting list controls).

2.3 Sample size

The target sample size is 120 families, randomly allocated in a 1:1 ratio between trial arms. This will be sufficient to demonstrate the feasibility outcomes of recruitment, retention, and adherence with satisfactory precision, but also to generate proof-of-principle that the intervention is likely to prove effective to support a funding application for a definitive trial. Data from the pre-feasibility study supports an average reduction pre- post-intervention on the PSI parenting stress scale of 11.44 (SD 14.62), representing an effect size of ~0.8 on Cohen's scale. If a moderate to large effect size was replicated in comparison to a control group measured at similar time points, this would justify moving to a definitive trial. To determine a significant effect size of >0.5 on Cohen's scale (~7.3 points on the PSI parent scale) comparing intervention with standard of care, with 80% power and at a one-sided significance level of 0.05, would require 102 families to be evaluated. To allow for an

attrition rate of 10% (withdrawal/loss to follow-up) we will seek to recruit >114 families. In our small-scale test-run of 9 families, retention was 100% and attendance was 97%, with 8 families attending all sessions and one family missing 2 sessions due to work commitments.

2.4 Framework

As this is a feasibility trial, the focus is on the feasibility outcomes; we are not seeking to demonstrate superiority in this trial, although proof-of-concept will be investigated around the potential efficacy of the intervention in justifying a larger trial.

2.5 Statistical interim analyses and stopping guidance

No interim analyses were planned for this trial, and none have been undertaken.

2.6 Timing of final analysis

Final data collection was 30 September 2024 2024. Data will be transferred to the study statistician at QMUL once preliminary checks have been completed and queries resolved by the trial team. Further data cleaning will be carried out by the statistician following receipt of the data and queries resolved with the trial team. The final analysis will start once all data queries have been resolved and the database has been locked.

2.7 Timing of outcome assessments

The timepoint for the proof-of-concept primary efficacy outcome assessment will be at 16 weeks, following the extended follow-up period. Note that the control group will have been receiving treatment as usual until the primary efficacy outcome assessment and the efficacy effect estimate will be the difference between intervention and no intervention. Data will

be collected from the control group 16 weeks after their intervention-baseline for future analyses but do not form part of this SAP.

Other questionnaire outcomes will also be assessed at 16 weeks. A secondary outcome is the comparison of the primary efficacy outcome at 8 weeks and 16 weeks, in the intervention group only. This outcome was added as part of a protocol amendment on 22 November 2023.

3 Statistical Principles

3.1 Confidence intervals and P values

All applicable statistical hypothesis tests will be 2-sided and will be performed using a 5% significance level, unless otherwise specified. All confidence intervals presented will be 95% and two-sided.

3.2 Adherence and protocol deviations

Adherence to the trial processes will be summarised by reporting key questionnaire completion rates by randomised group and timepoint. Adherence to the intervention will be summarised by reporting the number of sessions attended. Documented protocol deviations will be reported.

3.3 Analysis populations

The primary analysis will be conducted following the intention-to-treat (ITT) principle, in accordance with the randomised intervention. All randomised families with baseline data and at least one follow-up timepoint will be included in the primary analysis, regardless of adherence to the protocol. Participants that withdraw from completing further follow-up data

collection but do not withdraw consent for the use of their data collected so far, will be included in the intention-to-treat analysis. Per-protocol analysis for the candidate primary outcome (PSI-4-SF) will be performed to analyse the difference between arms only in those parents and children where the family was deemed to be protocol compliant, defined as attending five or more of the seven session. Per-protocol analyses will not be carried out for secondary outcomes, i.e. an ITT analysis will be performed for all secondary outcomes.

4 Trial Population

4.1 Screening, recruitment, withdrawal/follow-up

Families screened but not enrolled in the trial and reasons for exclusions will be reported; recruitment will be presented by site. The period of data collection, including the date of the first randomisation and first parenting course, and date of the final follow up visits will be described.

The number of families who have withdrawn or were unwilling to continue follow-up will be reported by treatment arm.

The throughput of families from those screened to those who are enrolled and assessed for trial endpoints, and included in the analysis, will be summarised in a CONSORT flowchart.

4.2 Eligibility

4.2.1 Inclusion Criteria

Index child inclusion criteria:

- Age 4-16 years (school years R to 11)

- Diagnosis in line with internationally agreed criteria for FASD (or if a medical professional has stated that the index child probably has FASD – these cases were screened by our clinical partner Professor Raja Mukherjee)
- Diagnosed within previous five years

Parent inclusion criteria

- Able to commit to all seven sessions
- Willing to wait for the intervention if required
- Lives with and is the legal guardian of the index child

4.2.2 Exclusion Criteria

- Parent exclusion criteria
- Ever previously undergone specialist parenting training for FASD
- Severe depression (identified at the eligibility assessment screening (DASS-21)
- Presence of acute safeguarding issues or concerns (including current harmful use of alcohol (identified at the eligibility assessment screening (AUDIT)

See protocol section 8.3 for further detail.

4.3 Baseline patient characteristics

The following baseline characteristics will be summarised by randomised group with mean (standard deviation) or median (interquartile range) for continuous variables, and frequency (percentage) for categorical variables.

- Parent characteristics
    - Age at consent
    - Gender
    - Country
    - Education

- Household income
- Family characteristics (how many children, how many children with FASD diagnosis)
- Relationship to child

- Child demographics
  - Age at consent
  - Gender
  - Ethnicity
  - FASD diagnosis

5 Analysis

5.1 Outcomes

5.1.1 Primary outcomes for this feasibility study:

- Percentage of eligible parents invited who agree to participate.
- Percentage of those participating who complete the study.
- Primary efficacy outcome (proof-of-concept): **Parent stress** post-intervention extended follow-up (16 weeks - Time 3) using the *Parenting Stress Index 4th edition Short Form (PSI-4-SF)* total score.

5.1.2 Pre-specified criteria for progression to a definitive RCT

The assessment for the next phase would consider progression criteria using a traffic light system if the Trial Steering Committee are satisfied that the following feasibility criteria are met (or can be reasonably mitigated with changes to the suggested protocol):

- *Recruitment: 0-25% = red; 26-50% = amber; 51-100% = green*
  - *Percentage of eligible parents invited who agree to participate.*
- *Retention: 0-50% = red; 50-70% = amber; 71-100% = green*

- *Percentage of those participating who complete the study.*

- *Satisfaction: 0-50%=red; 51-70%=amber; 71-100% =green*
    - *Percentage of those who express satisfaction with the session, as captured by the SPECIFiC session evaluation form.*
- *Estimated differences in primary outcome (PSI-4-SF total score) at 16 weeks: does not favour SPECIFiC=red; does not favour either SPECIFIC or TAU=amber; favours SPECIFiC = green.*

If red/amber results are obtained, the qualitative evaluation will be used to potentially remedy problems. Where it is deemed that identified problems cannot be managed, an RCT will not go ahead.

5.1.3 Secondary outcomes included in the SAP:

- MCID PSI-4-SF:
    - Estimate the difference in PSI-4-SF scores at 16 weeks with sufficient precision to inform a wider discussion around the clinical efficacy of the intervention and how the PSI-4-SF performs as a primary efficacy outcome for a future RCT.
- Data completeness:
    - Levels of missing data for the proof-of-concept primary efficacy outcome by timepoint
- Parent stress:
    - *(PSI-4-SF)* at Time 2 (8 weeks): to compare with the primary outcome (Time 3 PSI-4-SF) to determine whether intervention effects change over time. Note this outcome is only measured in the intervention group, due to the trial design (waitlist controls).
- Children's behavioural difficulties:
    - The Strengths and Difficulties Questionnaire (SDQ)
    - The Eyberg Child Behaviour Inventory (ECBI)

- Parents' psychological wellbeing:
    - *The Clinical Outcomes in Routine Evaluation–Outcome Measure (CORE-OM*
- Parental mental health scale:
    - Depression Anxiety Stress Scales (DASS-21).
- Parenting self-efficacy:
    - Tool to measure Parenting Self-Efficacy (TOPSE)
- Group sizes

5.1.4 Other outcomes (not within scope of the SAP)

- Acceptability (qualitative)
- Fidelity to training manual (qualitative)
- Performance of the research instruments and outcome measures (including economic outcomes instruments and measures)

5.2 Outcome definitions

All validated questionnaires will be scored according to the appropriate scoring manual, unless stated otherwise.

- **Parent stress** post-intervention extended follow-up (16 weeks) using the *Parenting Stress Index 4th edition Short Form (PSI-4-SF)*. This is a 36-item respondent-based rating scale, selected as a valid and reliable measure of internal stress and dynamics within a family system. It is highly cited, reliable instrument which has been used in similar studies. This is chosen as the candidate primary outcome at Time 3 (16-week extended follow-up) because the theoretical basis of the intervention assumes that there will be reduction in parent stress in the medium term.
- **Children's behavioural difficulties:** The Strengths and Difficulties Questionnaire (SDQ) and the Eyberg Child Behaviour Inventory (ECBI); are parent-reported measures, both well-established for measuring behavioural difficulties in children.

- **Parents' psychological wellbeing**: *The Clinical Outcomes in Routine Evaluation–Outcome Measure (CORE-OM)*, which measures change following psychological interventions. It covers subjective wellbeing, anxiety and depression, physical symptoms, effects of trauma, social isolation, life satisfaction, and risks to oneself and others.
- **Progression criteria – satisfaction:** Parents were asked to complete the SPECIFiC session evaluation form after each session of SPECIFiC, with 16 questions. Question 1 refers to the facilitators and is not included in the scoring. Questions 2 to 16 have five possible responses; Strongly disagree, Disagree, Neutral, Agree, Strongly agree, mapping to scores of 0 to 4 respectively. These will be summed, giving a total satisfaction score ranging from 0 to 60, with 60 indicating total satisfaction with that session. For each participant, their total scores from each of the seven sessions (or every session attended) will be averaged, giving each participant a single score ranging from 0 to 60. These scores will then be averaged across all participants and expressed as a percentage to which the progression criteria cut-offs can be applied.
- **EQ-5D-5L** was chosen as the preferred measure of health-related quality of life for intervention studies and its use will inform the health economics assessment in the feasibility trial and full randomized controlled trial.
- The **CORE-OM** was chosen as a measure of change following psychological interventions, and the **FASD Knowledge Questionnaire** was designed especially for this study as a measure of knowledge improvement.
- **The Tool to Measure Parenting Self-Efficacy (TOPSE)** is a 48-item caregiver-report questionnaire designed to assess the impact of parent-related interventions on caregivers' sense of their own parenting self-efficacy.

Further details of questionnaires including references can be found in the Appendix attached to this SAP, or in the protocol.

5.3 Analysis methods

Statistical analysis will be mainly descriptive and focus on establishing the recruitment and retention rates that would indicate a trial is feasible, and to estimate parameters which will inform the sample size for the main trial. Recruitment, retention, and satisfaction rates will be presented by group with 95% exact confidence intervals.

Observed data from all randomised participants will be included in the analysis following the intention-to-treat principle.

5.3.1 Primary outcome analysis

Primary analysis (ITT)

Candidate outcomes for the definitive trial including Parent stress (PSI-4-SF) will be compared between groups using a mixed model approach including all observed data at 16 weeks and adjusting for baseline measures and recruiting site. A binary variable will be included as fixed effect to indicate treatment allocation. Site, cohort, and baseline measure will be included as covariates; all control participants will be allocated a single cohort indicator. Inclusion of random subject effects will account for correlation between repeated outcomes on individual families. Estimated differences between groups and their 95% confidence intervals will be presented. The lower level of the 95% confidence interval for the difference between groups not ruling out an adjusted difference between groups of 7.3 points on the PSI-4-SF (as per the sample size calculation, section 3.4) will be considered sufficient to demonstrate proof-of-concept in the intervention. Subgroup analysis, such as whether outcomes differ according to time from diagnosis or age of index child will inform inclusion criteria and potential stratification factors for a larger trial. The PSI-4-SF outcome will also be available at 8 weeks in the intervention group only and will be reported; these data will not be included in the primary endpoint analysis. We will examine outcome profiles within the intervention group to see if any treatment effect is maximal during

training. These analyses are exploratory in nature and intended to help inform future research.

Per-protocol analysis

Sensitivity analyses will be conducted on the primary outcome to assess the robustness of results to failure to adhere to the protocol.

Per-protocol analysis for the candidate primary outcome (PSI-4-SF) will be performed to analyse the difference between arms in those parents and children where the family was deemed to be protocol compliant (see definition in Section 3.3). Per-protocol analyses will not be carried out for secondary outcomes.

Subgroup analyses

Subgroup analysis, such as whether outcomes differ according to time from diagnosis or by the age of the child will be done by adding the relevant factors to the mixed model as additional covariates and including an interaction term. The results from these analyses will inform inclusion criteria and potential stratification factors for a larger trial.

5.3.2 Secondary outcomes analyses

Analysis of other questionnaire outcomes, such as the SDQ, DASS etc. will be summarised by group using the appropriate summary measures and compared between groups using a mixed model approach as described above. Estimated difference and 95% confidence interval will be presented for each outcome.

5.4 Missing data

Missing data will be summarised. The reasons for systematic missingness will be explored.

5.5 Additional analyses

This document describes the final statistical analyses to be undertaken. Qualitative analyses of patient interviews to be undertaken are described elsewhere. Health economic analysis is described elsewhere.

5.6 Harms

AEs will be summarised by group, both by the number of events and the numbers of participants experiencing them.

The proportion of patients experiencing at least one adverse event and those experiencing at least one serious adverse event will be summarised by treatment arm. The number and percentage of serious adverse events will be presented descriptively by arm. Information on grades of events and whether the events are expected or unexpected, will be presented. The number of participants withdrawing from the trial due to an AE or an SAE will be summarised by treatment.

5.7 Statistical software

Analyses will be carried out using StataCorp, 2021. Stata: Release 18. Statistical Software. College Station, TX:StataCorp. LLC or later.

6 Appendices

6.1 Dummy tables

Table 1a: Baseline characteristics

Demographics	Control	Intervention	Total
Index child			
Number randomised, n (%)			
Age, mean (sd)			
Sex, n (%)			
Female			
Male			
Missing			
Ethnicity, n (%)			
Missing			
Site subject recruited at, n (%)			
Parent			

Table 1b: Baseline questionnaire values

DCI						
PSI-4-SF	n					
	mean (sd)					
	missing					
	n					
	mean (sd)					

	missing					
	withdrawn from trial					

Table 2a: Feasibility outcomes

Recruitment						
Retention						
Satisfaction						

Table 2b: Primary efficacy outcome: PSI-4-SF

		Control N=	**Intervention** N=	**Total** N=	**Coefficient (95% CI)**	**p-value**
Baseline	n					
	mean (sd)					
	missing					
	n					
	mean (sd)					
	missing	*13*	*20*	*33*		
	withdrawn from trial					
16 weeks	n					
	mean (sd)					
	missing					
	withdrawn from trial					

Table 2c: Progression criteria

	Result	RAG rating	
Recruitment			
Retention			
Satisfaction			
PSI-4-SF			

Secondary outcomes

Table

		Control N=	**Intervention** N=	**Total** N=	**Coefficient (95% CI)**	**p-value**
SDQ						
	n					
	mean (sd)					
	missing					
	withdrawn from trial					
	n					
	mean (sd)					
	missing					
	withdrawn from trial					

6.2 Questionnaire details

The following details are taken verbatim from the published pre-feasibility paper by Price, A. et al (2023) *https://doi.org/10.1007/s10826-023-02637-6*

The EQ-5D-5L was chosen as the preferred measure of health-related quality of life for intervention studies and its use will inform the health economics assessment in the feasibility trial and full randomized controlled trial. The CORE-OM was chosen as a measure of change following psychological interventions, and the FASD Knowledge Questionnaire was designed especially for this study as a measure of knowledge improvement. The Parenting Stress Index Short Form (PSI-4-SF) (Abidin, 2012) is a 36-item questionnaire for caregivers of children aged one month to twelve years, which provides a total stress score and three subscales: parental distress, parent-child dysfunctional relationship, and difficult child. Statements related to parenting stress are responded to on a five-point scale from strongly disagree to strongly agree, with higher scores indicating higher stress levels. Outcomes can be described in terms of raw scores and percentiles, with the normal range

between the 16th and 84th percentiles, and the clinically significant cut-off at the 90th percentile. Internal consistency for the PSI-SF is good to excellent, with Cronbach's alpha scores of .90 for the parental distress subscale, .89 for the parent-child dysfunctional relationship subscale, .88 for the difficult child subscale, and .95 for the total stress score (Abidin, 2012). The Strengths and Difficulties Questionnaire (SDQ) (Goodman, 1997) is a 25-item questionnaire for caregivers or teachers of children aged 4–17 years. There are five subscales covering conduct, hyperactivity, emotional problems, peer problems, and prosocial behaviour as well as an overall difficulties score. Participants respond to statements relating to their children's behaviour on a three-point scale from not true to certainly true. Higher scores indicate more severe difficulties, except for the prosocial behaviour scale, where higher scores indicate more prosocial behaviour. The SDQ total difficulties scale has good internal consistency, with a Cronbach's alpha of .82 when scored by parents (Goodman, 2001). The Eyberg Child Behaviour Inventory (ECBI) (Boggs et al., 1990) is a 36-item questionnaire for caregivers of children aged 2–16 years. Statements related to children's behavioural difficulties are rated on two scales: a seven-point scale from never to always to produce an intensity score, and by a yes or no option that determines the problem score. Higher scores indicate higher levels of problems on both scales. Both the problem and intensity scales of the ECBI have excellent internal consistency, each with a Cronbach's alpha score of .98 (Boggs et al., 1990). The Tool to Measure Parenting Self-Efficacy (TOPSE) is a 48-item caregiver-report questionnaire designed to assess the impact of parent-related interventions on caregivers' sense of their own parenting self-efficacy (Kendall & Bloomfield, 2005). Caregivers respond to statements on emotion and affection, play and enjoyment, empathy and understanding, control, discipline and setting boundaries, pressures, self-acceptance, and learning and knowledge on a 10-point scale from (0) completely disagree to (10) completely agree. Higher scores indicate higher levels of parenting self-efficacy. The full scale has excellent internal consistency, with a Cronbach's alpha of .95 (Kendall & Bloomfield, 2005). The EQ-5D-5L is a 26-item adult self-report measure of health-related quality of life. It is formed of five subscales related to mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, in which

participants indicate to what extent they have difficulties with those issues on a five-point scale from (1) no problems to (5) severe problems. The five scales can be combined to calculate a composite index value. Higher scores indicate better health. A recent systematic review (Feng et al., 2021) found high rates of test-retest reliability and convergent validity have been demonstrated across clinical and nonclinical populations, not including FASD. The CORE-OM is a 34-item self-report instrument, designed to measure the effectiveness and efficacy of psychological therapies. Participants respond to statements about subjective wellbeing, mental health symptoms, function, and risk to self and others on a 5-point scale from (0) not at all, to (4) most or all of the time. Higher scores indicate more severe problems. Its internal consistency has been shown to be excellent, with a Cronbach's alpha of .94 in both clinical and non-clinical populations (Evans et al., 2002). The FASD Knowledge Questionnaire was designed for this project as a tool to assess improvements in participants' knowledge of FASD. Participants responded to 25 multiple-choice questions based on course content, each with four possible answers. The questions were designed by the research fellow and were based on information provided in Journal of Child and Family Studies the sessions. For example, participants were asked, "The brain area most associated with executive functioning is a) the temporal lobe, b) the parietal lobe, c) the frontal lobe, or d) the occipital lobe". Two questions had two correct answers, giving a maximum score of 27.