ComBAT

Community-Based Behavioural Activation Training (ComBAT) for Depression in Adolescents: Randomised Controlled Trial (RCT) with Economic and Process Evaluations

STATISTICAL ANALYSIS PLAN

V1.0

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Contents

1. Document Version History

Version Number	Version Date	Summary of Changes
V1.0		*SAP signed off*

2. General

2.1 Document Scope

This statistical analysis plan (SAP) covers the reporting of the trial progress and planned effectiveness analyses of the ComBAT trial. Analyses relating to qualitative data and further exploratory post-hoc analyses are not covered by this SAP, along with health economic analyses, which are covered by the health economics analysis plan.

2.2 Glossary

AE	Adverse Events
BA	Behavioural Activation
BADS-SF	Behavioural Activation for Depression Scale – Short Form
CAMHS	Child and Adolescent Mental Health Services
CBT	Cognitive Behavioural Therapy
CDRS-R	Children's Depression Rating Scale-Revised
CHU-9D	Child Health Utility Index
ComBAT	Community-Based Behavioural Activation Training
CRF	Case Report Form
IPT	Interpersonal Psychotherapy
ITT	Intention to Treat
MAR	Missing At Random
PHQ-9A	Patient Health Questionnaire – Modified for Adolescents
PPI	Patient-Public Involvement
PROM	Patient Reported Outcome Measure
RA	Research Assistant
RAG	Red-Amber-Green
RCADS	Revised Children's Anxiety and Depression Scale
RUQ-A	Resource Utilisation Questionnaire for Adolescents
SAE	Serious Adverse Events
SOPs	Standard Operating Procedures
UC	Usual Care
YTU	York Trials Unit

2.3 Procedural documentation

2.3.1 Standard operating procedures

The following York Trials Unit (YTU) Standard Operating Procedures (SOPs) and guidance documents will apply to the conduct and documentation of the ComBAT trial analysis.

S01	Statistical Considerations	Latest version: 6.0
SG02	Statistical and Health Economics Reporting	Latest version: 4.0
TP30	Statistical Quality Control Log	Latest version: 2.0

SG05	Using the Statistical Quality Control Log	Latest version: 1.0

2.3.2 Associated documentation

Appropriate YTU standard forms apply. Any assumptions made during the processing and merging of data as well as for the analysis will be documented (internal document reference numbers in bracket) using an Assumptions Log (TP31). In the event of necessary changes or additions to analyses detailed here, these will be documented on an Analysis Plan Departure Log (F27). The statistical analysis will be signed off using a Primary Analysis Sign-off Form (F16) and Statistical Quality Assurance Checklist (C03).

3. Trial Summary

This section gives a summary of the ComBAT trial.

3.1 Objectives

The aim of this study is to evaluate the effectiveness of Behavioural Activation (BA) against usual care to reduce depression in young people.

3.2 Design

This study is a parallel two-arm randomised control trial (RCT), aiming to recruit 236 young people with mild to moderate depression, to compare the effectiveness of behavioural activation (BA) against usual care. The study will include an internal 9-month pilot, whereby a red-amber-green (RAG) rating will be applied to assess the capability of the RCT to recruit and retain young people at the required rate.

Nested within the study will be a phenomenological study to examine the acceptability of BA, an ethnographic study to investigate how BA has been delivered in different sites and an economic evaluation of BA's cost-effectiveness relative to usual care.

Full details of the background and design of the trial are presented in the study protocol.

3.3 Interventions

3.3.1 Behavioural activation

A bespoke, standardised BA package was developed which was inspired and informed by published literature, public and patient involvement (PPI) activities and a feasibility study.

The BA sessions with a professional will guide and support each young person to identify, schedule, complete and monitor pleasures, necessities and goals in day-to-day life that connect with what and who is important to them. These may be things that the young person has stopped doing or doing less, which they can start doing again or more. There may be things that the young person would like to do or things that the young person never thought of doing for which they need help to start. There may be things that they have been doing routinely but no longer enjoy and need to change them in some way.

The young person will keep a diary in which they will make a note of each activity that they complete. Some of these activities will be scheduled and others will be unplanned, routine or spontaneous. The young person will score enjoyment, achievement and/or connection for each activity on a 0-10 scale (0=no enjoyment/achievement/connection, 10=great enjoyment/achievement/connection). Over the course of the week, activities that score high

on enjoyment, achievement and connection are highlighted and encouraged. Activities that score low can be reduced or changed so that they become more enjoyable or rewarding.

Activities that have not been completed can be postponed, cancelled, or changed – depending on the reasons for not being completed (the young person did not consider them important, or they were too difficult or other activities took priority). A graded and stepped approach to activities will help young people overcome obstacles such as hesitation and tiredness that are to be expected with depression. Some activities may actually make young people feel worse or may be harmful, destructive or counterproductive; these need to be identified and reduced/stopped.

The BA programme is organised in 5 "modules" which can be completed in up to 8 weekly sessions of 30-40 minutes each in a blended model of professional-guided sessions and self-directed activities. A 5-module approach has been used by McCauley et al (2016a) in their published guide (pp. 12-13). The content of these 5 modules is bespoke to ComBAT.

Table 1: The Five BA modules in ComBAT.

Module	Topics covered
Module 1: Starting Up	• What is depression? • What is behavioural activation? • Emotional rewards or 'positive reinforcement' • The depression cycle. • Behavioural activation: breaking the depression cycle. • Take away activities: Activity monitoring and making the most of good feelings
Module 2: Getting Active	• Reviewing the weekly calendar • Understand what the PAC scores mean. Compare high vs low PAC activities and identify what makes a difference. • Introduction to the "Life Pie": personal areas of importance and values • Turning values into activities: pleasures, necessities and goals across the life pie. • Introduction to activity scheduling • Activity monitoring

Module 3: Building Skills	• Building on activity review
	  ○ Identify activities with high and low PAC scores.
	• Activity scheduling:
	  ○ Repeat activities with high PAC scores.
	  ○ Introduce pleasures, necessities and goals across more areas of the life pie.
	  ○ Reduce, remove or modify activities with low PAC scores.
	• Activity monitoring

Module 4: Overcoming Obstacles	• Reviewing the weekly calendar
	  ○ Identify activities with high and low PAC scores.
	  ○ Identify non-completed scheduled activities.
	  ○ Identify barriers and problems.
	  ○ Identify harmful or counterproductive activities.
	• Identify and manage barriers and problem solve.
	• Mastering activity scheduling:
	  ○ Repeat activities with high PAC scores.

	○ Introduce new pleasures, necessities and goals for more areas of the life pie. ○ Reduce, remove or modify activities with low PAC scores. ○ Reduce, remove or modify harmful or counterproductive activities. ○ Introduce activities that counteract avoidance, overcome barriers and solve problems.
Module 5: Moving Forward	• Review weekly calendar. • Create an activities bank by looking through the previous weekly calendars. • Plan pleasures, necessities and goals to focus on in the next 4 weeks. • Create a relapse prevention plan.

3.3.2 Usual care

Usual practice for child and adolescent mental health can be widely varied and inconsistent, as we have learnt from the mapping exercise, we carried out within our feasibility study and from our experiences of completing similar NIHR-funded studies, including ASPECT (Wright, et al., 2018), I-SOCIALISE (Varley et al., 2019), CCBT (Wright et al., 2017), Young SMILES (Gellatly et al, 2019). Usual care may be no intervention, signposting to alternative sources of support, general discussion, supportive counselling, relaxation, recreation groups, guided self-help or psychological therapies including CBT and IPT.

Professionals who are involved in usual care also vary greatly from one community setting to another: from assistants and support workers (e.g. family support workers, teaching assistants, emotional literacy support workers) to professionals who are trained in counselling, low intensity interventions (e.g. psychological wellbeing practitioners) and specialist high intensity interventions (e.g. CBT therapists, family therapists). This was reflected in our mapping exercise completed within our feasibility study where we also found much variation in the frequency, and both session number and length of support offered to young people with depression across services.

3.4 Outcomes

3.4.1 Primary Outcome

- *Revised Children's Anxiety and Depression Scale-Brief Version*:
  - *Variable type*: Continuous.
  - *Range and polarity*: Each item can take a score from 0-3, and the total raw score ranges from 0-75. Raw scores are then converted to T-scores for the appropriate gender and school year. Derivation of T-scores are given in more detail in Section 5.3.1. Higher raw scores and t-scores represent higher levels of depression and anxiety.
  - *Timepoints*: The RCADS-25 was collected at baseline, 6 months post-randomisation and 12-months post-randomisation.

3.4.2 Secondary Outcomes

The secondary outcomes are:

- *Children's Depression Rating Scale-Revised (CDRS-R):*

    - *Variable type:* Continuous
    - *Range and polarity:* This 17-item researcher administered interview has 3 items scoring between 1-5 and 14 items between 1-7. The total score ranges between 17-113. A higher score suggests greater levels of depressive symptoms, with a score of 40 indicating diagnosable depression.
    - *Follow-up:* The CDRS-R is collected at baseline, 6 months post-randomisation and 12-months post-randomisation.
- *Behavioural Activation for Depression Scale (BADS-SF):*
    - *Variable type:* Continuous
    - *Range and polarity:* Each item is scaled from 0-6, giving a total score ranging between 0-54. A higher score represents increased behavioural activation.
    - *Follow-up:* The BADS-SF is collected at baseline, 6 months post-randomisation and 12-months post-randomisation.

3.4.3 Other Collected Data

- **Screening CRF**
    - PHQ-9A:
        - items 1-9
        - supplementary items 10-13 (risk questions)
        - total raw score
    - Date of screening
    - Inclusion criteria:
        - Aged between 12-18 years of age.
        - Scored at least 65 on the RCADS Depression Subscale.
        - Scored at most 14 on the PHQ-9A and did not answer risk questions in the affirmative (if scored greater than 14 – attends a secondary eligibility assessment with clinical member of the ComBAT team).
    - Exclusion criteria:
        - Young person eligible for secondary care CAMHS
- **Screening log**
    - Young person's initials (ID given if randomised)
    - Site name
    - Site ID
    - Name of location young person referred from:
        - Child and Adolescent Mental Health Services (CAMHS) name
        - Charity/Service name
        - School name
    - Referring professional
    - Research assistant
    - Date expression of interest received
    - Date of screening
    - RCADS Depression subscale score (as determined by screening CRF)
    - PHQ-9A score (as determined by screening CRF)
    - Young person eligible
    - Clinician follow-up call
    - Reason for screen failure/reason for ineligibility
    - Young person contacted for consent
    - Young person consented
    - Reason for non-consent
    - Additional notes

- **Baseline CRF**
    - Participant ID
    - Date completed
    - Date of birth
    - Gender
    - Ethnicity
    - Religion
    - Current living status
        - Living with parents, friends, alone, etc.
        - Number of people living in the same household
        - Number of people under 18 in the same household
    - Current education status
        - In education
        - Type of education
    - Employment status
    - Preference of support delivery
- **Therapist Demographic Information**
    - Therapist initials
    - Role (e.g. Child wellbeing practitioner, Nurse, Counsellor)
    - Grade
    - Organisation
    - Age (Grouped)
    - Gender
    - Time working with young people
    - Approaches used when supporting young people
- **Session record (behavioural activation)**
    - Participant ID
    - Date completed
    - Location of session (online, telephone, in person)
    - Professional's name
    - Session recorded
    - Adverse events
    - Anyone else present (parent, sibling etc.)
    - Type of session (assessment, intervention, or review)
    - Strategies used during the session
    - Time spent preparing the session (mins)
    - Length of session (mins)
    - Time spent on administration after the session (mins)
- **Session record (usual care)**
    - Participant ID
    - Date completed
    - Location of session (online, telephone, in person)
    - Professional's name
    - Session recorded
    - Adverse events
    - Anyone else present (parent, sibling etc.)
    - Approach and support offered during the session
    - Strategies covered during the session
    - Time spent preparing the session (mins)
    - Length of session (mins)

    - Time spent on administration after the session (mins)
- **Month 6 CRF**
    - Participant ID
    - Date completed
    - Aspects of care questionnaire (8-items)
- **Month 12 CRF**
    - Participant ID
    - Date completed
    - Aspects of care questionnaire (8-items)
- **Fidelity assessment**
    - Professional's name
    - Name of person assessing fidelity
    - Participant ID
    - Date of session
    - Session number
    - Professional's ability to deliver intervention (behavioural activation sessions only, 10-items scaled 1-Limited, 2-Sufficient, 3-Excellent)
- **Change of Status**
    - Participant ID
    - Date completed
    - Date of birth
    - Pre-randomisation withdrawal
    - Post-randomisation withdrawal (treatment only, follow-up only, full withdrawal)
    - Reason for change in status
    - Date of death (if applicable)
    - Further information of change in status
    - Researchers name
    - Researchers signature
- **Unblinding**
    - Participant ID
    - Date of unblinding
    - Source of unblinding
    - Reason for unblinding
    - Method of unblinding
    - Additional details
- **Adverse events**
    - Participant ID
    - Date event reported
    - Event type (non-serious or serious AE)
    - Event reported by
    - Event reported to
    - Time point of adverse event
    - Date of onset of event
    - Description of event and how it was reported
    - Outcome of event (recovered/still ongoing)
    - Date recovered (if applicable)
    - Additional comments
    - Name of person reporting AE
    - Date report completed
    - Name of ComBAT team member reviewing the AE

    - Date report reviewed
- **Serious adverse events**
    - Participant ID
    - Date event reported
    - Event reported by
    - Event reported to
    - Time point of adverse event
    - Date of onset of event
    - Description of event and how it was reported
    - Classification of SAE
    - CI Assessment-Expected SAE
    - Relationship to support received
    - Outcome of event (fully recovered / partially recovered / still ongoing / died)
    - Date fully recovered (if applicable)
    - Date partially recovered (if applicable)
    - Date of death (if applicable)
    - Name of person reporting SAE
    - Date report completed
    - Name of ComBAT team member reviewing the SAE
    - Date report reviewed
- **Adverse event follow-up**
    - Participant ID
    - Date initial event reported
    - Date of event follow-up
    - Event follow-up reported by
    - Event follow-up reported to
    - Time point of event follow-up
    - Date of onset of event
    - Outcome of event (fully recovered / partially recovered / still ongoing)
    - Additional actions since initial report
    - Date recovered (if applicable)
    - Further comments
    - Name of person reporting AE
    - Date report completed
    - Name of ComBAT team member reviewing the AE
    - Date report reviewed
- **Serious adverse event follow-up**
    - Participant ID
    - Date initial event reported
    - Date of event follow-up
    - Event follow-up reported by
    - Event follow-up reported to
    - Time point of event follow-up
    - Date of onset of event
    - Outcome of event (fully recovered / partially recovered / still ongoing / died)
    - Date fully recovered (if applicable)
    - Date partially recovered (if applicable)
    - Date of death (if applicable)
    - Additional actions since initial report
    - Further comments
    - Name of person reporting AE

    - Date report completed
    - Name of ComBAT team member reviewing the AE
    - Date report reviewed
- **Trial Management System**
    - Participant Details
        - Participant ID
        - Site name and site ID
        - Allocation name and allocation ID
        - Date of randomisation
    - Participant Status
        - Participant ID
        - Participant status (e.g. full participation, full withdrawal) and corresponding status ID
        - Details of change
        - Date of change
        - Name of ComBAT team member making the change
    - Participant Forms
        - Participant ID
        - Form name and form ID
        - Stage form was added (e.g. at eligibility, at randomisation)
        - Date form is due
        - Date form is completed by site
        - Date form received by YTU
        - Indicator for switched to postal
        - Form status
        - Details of form status

3.5 Sample Size

The most recent meta-analysis of BA for depression in young people (Martin & Oliver, 2018) reported a large effect size of -0.7 (95% CI -1.20, -0.20). There is no widely accepted minimal important difference (MID) for the RCADS (our primary outcome measure); therefore, we are seeking to obtain an effect size of d=0.5, which is accepted (albeit with criticism) as a universal standard for MID (King 2011, Norman et al 2003) and is an effect size which NICE has previously used as a ballpark for the adoption of interventions (NICE, 2014). A sample size of 172 (86 in each group) will have 90% power to detect an effect size of 0.5 on the RCADS using a two-group t-test with a 0.05 two-sided significance level. Assuming an average of 5 participants per therapist, an ICC of 0.01 (DE=1.04) and 23% loss to follow-up (mean of drop-out rates 14-32% from 5 existing RCTs on BA), we will aim to recruit 236 young people (118 in each group).

3.6 Assessment of Eligibility and Randomisation

Potential individuals eligible for participation in ComBAT will be referred by professionals from schools, charities and CAMHS, or self-referred via posters with a contact for their site and/or embedded links to the ComBAT expression of interest form. Trained research assistants within the ComBAT team will conduct screening of the individuals. This includes completing the RCADS depression subscale, the PHQ-9A and determining eligibility based on prespecified inclusion/exclusion criteria specified within the screening CRF in Section 3.4.3. If the young person scores higher than 14 in the PHQ-9A and/or provides answers to the supplementary risk questions, related to suicidal thoughts or attempts, they will be invited to attend a secondary eligibility assessment conducted by a clinical member of the ComBAT

team to confirm if they are eligible. If an individual was deemed eligible, then a research assistant will contact the young person and their parent/guardian to arrange a time to obtain informed consent/assent and conduct a baseline visit. If the clinician felt that the young person's responses indicated more severe depression and complex risk, they would explain that the trial is not suitable for them and provide signposting for further support. The referring site (if applicable) would be informed of this.

Once informed consent/assent is obtained and baseline visit completed, young people will be randomised in a 1:1 ratio to either BA or usual care using simple randomisation. Randomisation will be implemented using a web-based system designed and developed by the data management team at York Trials Unit (YTU). The allocation sequence will be generated by an independent YTU statistician and embedded using a central, web-based randomisation system at YTU.

3.7 Follow-Up

Follow-up will take place 6-months and 12-months post-randomisation.

3.8 Blinding

All research assistants (RAs) collecting data at the 6-month follow-up will be blinded to the participant's treatment allocation. Should any unblinding occur prior to the 6-month follow-up time point, this information will be recorded, and a different RA will be assigned to the participant and will conduct the 6-month follow-up. Participants will be reminded at the start of their follow-up meeting not to give any information that could be used to determine their treatment allocation, such as, what they did during the course of treatment or names of involved therapists.

After all data is collected at the 6-month follow-up, RAs will be unblinded to treatment allocation. This is to aid in the completion of the embedded phenomenological study.

4. Study Data Sources

4.1 Case Report Forms

Case report forms (CRFs) that are received in paper format by York Trials Unit will be scanned by the data management team. Copies of the CRFs annotated with all variable names from the database are to be kept in the YTU analysis directory (Y:\ Project -- comBAT - Statistics).

Data (as detailed above in Section 3.4.3) will be collected from the following CRFs:

- Screening and Eligibility
- Baseline
- Month 6 Follow-up
- Month 12 Follow-up
- Adverse Events
- Serious Adverse Events
- Adverse Events Follow-up
- Serious Adverse Events Follow-up
- Change of Status
- Fidelity Assessment
- Unblinding

4.2 Other Data

4.2.1 Screening Log

Screening data will be collected and inputted by RAs onto Google sheets, updated regularly. The study statistician will clean the screening data in preparation of Programme Management Group and Programme Steering Committee meetings, with any queries being resolved by the ComBAT study team.

4.2.2 Intervention and usual care session logs

Session logs will be completed via Qualtrics using the appropriate Session Record CRF. These will then be reviewed by the ComBAT trial coordinators to remove any identifiable information before sending to the study statistician to be cleaned, with any queries being resolved by the ComBAT study team. The data collected is listed above in Section 3.4.3.

4.2.3 RCADS-25 Qualtrics questionnaire

At both 6 and 12 months, if the research team have been unable to make contact with a participant to arrange a follow-up appointment, a Qualtrics questionnaire containing only the primary outcome (RCADS 25 items) will be sent to the participant. This is to minimize any missing data of the primary outcome measure and ensure that we achieve 90% power as stated in section 3.5 above.

4.3 Trial Management System

Upon receipt, returned CRFs will be checked manually for inconsistencies and missing data, which will be resolved with ComBAT RAs where possible. Automated electronic checks according to comprehensive data validation plans for each CRF included checks for completeness, internal consistency as well as appropriate data formatting and range checks will be undertaken. Copies of the validation plans are held by data management and the study statistician. Violations of the validation rules will be queried with the RAs and sites as required. All violations and any resulting changes to the data will be documented in an error log file for each CRF, and data fields for which error log entries exist will be completed as ‘555’ or another error code as advised by the data management team in the data.

At the end of the trial, all CRF data, error logs and relevant management database data will be handed over to the trial statistician. The statistician will merge the data and conduct further data checks including checking for consistency of data across questionnaires. Any queries and resulting changes will be processed between the soft and hard lock of the data. The statistician will generate any necessary derived variables in the statistical master data set. Any further data changes and assumptions made to the hard locked data will be documented on a Trial Assumptions Form.

4.4 Location of Data and Associated Files

Data and documents relevant to the statistical analysis will be kept electronically in a folder on the Y Drive (Y:\ Project -- comBAT - Statistics).

5. Analysis

5.1 Analysis Principles

5.1.1 General Principles

Data will be analysed and reported in accordance with CONSORT guidelines. All analyses will be conducted following the principle of intention-to-treat unless stated otherwise. Statistical tests will be two-sided at the 5% significance level. Estimates of group differences will be presented with 95% confidence intervals.

5.2 Scoring of Questionnaire Data

The following sections outline how the participant completed questionnaires will be scored and state any methods used for dealing with missing data, if necessary. Copies of all questionnaires are provided in the Appendix (Section 8.2).

5.2.1 RCADS-25

The 25 items of the RCADS questionnaire are scored from 0-3. The 25 items are split into two sub-scales: anxiety scale (15 items) and depression scale (10 items). The raw scores for each sub-scale will be calculated and then an overall score will be calculated.

The total raw scores and overall raw score will be converted into T-scores (further details of conversions in Section 5.3.1 below). Higher t-scores denote greater clinical need. The t-scores will be arranged into the following clinical cut-offs: 0-64 non-clinical range, 65-69 borderline clinical range, and ≥70 clinical range.

For missing data, mean imputation will be used when at most three items are missing from the anxiety sub-scale and at most two items are missing for the depression sub-scale. If the child's date of birth/age is missing and/or the child's sex is missing, selected as 'Non-binary' or 'Prefer not to say', the RCADS-25 T-Score cannot be calculated.

Guidance for calculating T-scores and missing data refers to the RCADS-25 Child Version Scoring Program 3.1 (Ebesutani et al (2012)).

5.2.2 PHQ-9A

The PHQ-9A consists of 9-items with each item scoring from 1-5. The total score will be calculated, with higher scores demonstrating greater levels of depression. The 4 supplementary items referring to the 'at-risk' level of the young person will be scored individually and separate from the first 9-items.

If at least 3-items are not scored or are missing, then the total PHQ-9A score will not be calculated. For 1-2 missing items, a pro-rata score will be calculated based on the remaining completed items.

5.2.3 CDRS-R

The CDRS-R has 3 sub-scales containing 17 items overall. Items 4, 5 and 16 are scored from 1-5 and the remaining items are scored from 1-7. The raw scores for each sub-scale will be calculated and then an overall score will be calculated.

The overall raw scores will range from 17 to 113. These overall raw scores will be converted to corresponding T-scores as displayed on the questionnaire. The lower the T-score the less

likely for a depressive disorder diagnosis is to be made. The CDRS T-scores will be grouped into three categories, using a cut-off score of 54 and 64, such that a T-score of ≤ 54 is interpreted such that a depressive disorder is unlikely to be confirmed in any further evaluation, score of 55-64 suggests depression is possible to be diagnosed after further comprehensive testing (emerging depression) and scores >65 indicate likely depression.

Items 15 and 17 require the researcher to rate the child's facial expressions and body movement during the follow-up. The appointment may be via telephone or online (with no camera) which in these situations, the researcher would be unable to score these items. Only questionnaires with all items completed will be included in the secondary analysis model, however these participants will be included in a sensitivity analysis detailed in section 5.9.2.1.

Further information of the interpretation of the T-score for the CDRS-R can be found in the Appendix (section 8.2.2).

5.2.4 BADS-SF

The BADS-SF consists of 9 items that are scored from 0-6 and split across two sub-scales. For each item the greater the score suggests higher behavioural activation except for items 1, 6, 7 and 8 whereby the scoring is reversed. The total score ranges from 0-54 with the reversed scores considered e.g., a score of 0 would be included in the calculation as a 6, 1 as a 5 and so on.

There is no guidance for the BADS-SF regarding scoring questionnaires with missing items. Here we use the rule where the missing items of a Patient Reported Outcome Measure (PROM) should only be replaced with the means of the non-missing items to facilitate the calculation of a score, if the number of non-missing items is less than 10% of the total number of items in the PROM. In this case, mean imputation will be used if one item is missing in the BADS-SF and unable to be scored if more than one item is missing.

5.2.5 Aspects of care

The aspects of care questionnaire consist of 8 items, collected at 6- and 12-month follow-up points, that will be used to evaluate the level of compliance to the intervention and any contamination observed in the usual care group. Each item has discrete checkbox options of "Yes", "No" and "I don't know", with an answer of "Yes" suggesting that the young person did complete the activity specified. Items 2, 4, 6, and 8 are of particular interest as a positive answer to these items suggests that the young person had been involved in BA related activities during their time in the study.

5.3 Derivation of Variables and Outcomes

5.3.1 RCADS T-scores

The RCADS T-scores are derived by transforming the raw scores depending on sex and the grade they are in at school. As UK schools do not use grades, the young person's age will be used to approximate their school grade. This will be approximated by adding 6 to the young person's age as suggested by the RCADS-25 Child Version Scoring Resources (Ebesutani et al (2012)). Table 2 shows the specific transformations for each permutation of sex and age.

Table 2: RCADS raw score transformations to derive T-scores for each sub-scale and overall.

Sex	Age (Grade)	Depression T-score	Anxiety T-score	Overall T-score
Male	10 (4)	((Score - 9.90)*10)/ 4.93 + 50	((Score - 15.19)*10)/ 7.09 + 50	((Score - 25.10)*10)/ 11.10 + 50
	11-12 (5-6)	((Score - 7.13) *10)/ 4.22 + 50	((Score - 11.63)*10)/ 6.45 + 50	((Score - 18.76)*10)/ 9.38 + 50
	13-14 (7-8)	((Score - 7.56) *10)/ 3.75 + 50	((Score - 10.48)*10)/ 5.36 + 50	((Score - 18.04)*10)/ 7.92 + 50
	15-16 (9-10)	((Score - 7.50) *10)/ 4.18 + 50	((Score - 9.70)*10)/ 5.45 + 50	((Score - 17.20)*10)/ 8.53 + 50
	17-18 (11-12)	((Score - 7.64) *10)/ 4.37 + 50	((Score - 9.96)*10)/ 4.32 + 50	((Score - 17.60)*10)/ 7.24 + 50
Female	10 (4)	((Score - 9.68)*10)/ 4.97 + 50	((Score - 16.25)*10)/ 8.42 + 50	((Score - 25.93)*10)/ 12.24 + 50
	11-12 (5-6)	((Score - 8.03)*10)/ 5.00 + 50	((Score - 13.49)*10)/ 7.62 + 50	((Score - 21.53)*10)/ 11.73 + 50
	13-14 (7-8)	((Score - 8.08)*10)/ 4.34 + 50	((Score - 12.74)*10)/ 6.22 + 50	((Score - 20.82)*10)/ 9.46 + 50
	15-16 (9-10)	((Score - 8.14)*10)/ 4.37 + 50	((Score - 11.31)*10)/ 5.33 + 50	((Score - 19.45)*10)/ 8.63 + 50
	17-18 (11-12)	((Score - 8.59)*10)/3.67 + 50	((Score - 11.50)*10)/ 5.34 + 50	((Score - 20.09)*10)/ 7.79 + 50

5.3.2 Other variables

- Age: Derived from the child's date of birth at the time of baseline completion.
- Sex: Derived from the recorded gender at baseline with Male and Female options assumed to be the child's sex at birth.
- Therapist: Each participant will be assigned to a single therapist. In the scenario that a participant has seen more than one therapist, the therapist that conducted the majority of the participants sessions will be used (this is assuming that more sessions will lead to a greater rapport between the young person and the therapist).

5.4 Trial Progression

The flow of participants from eligibility, randomisation, to follow-up and analysis of the trial will be presented in a CONSORT flow diagram (Figure 1). Withdrawal and reasons for withdrawal will be summarised descriptively by treatment group.

5.5 Demographic and Baseline Data

All participant demographic and baseline characteristics will be summarised descriptively by trial group, both for patients 'as randomised' and 'as analysed'. The 'as randomised' population will comprise all eligible participants who were randomised, while the 'as analysed' population will comprise all patients included in the primary analysis. No formal statistical comparisons of characteristics will be undertaken between groups. Continuous measures will be summarised using descriptive statistics (n, mean, standard deviation, median, IQR, minimum and maximum), while categorical data will be reported as counts and percentages.

5.6 Treatment Delivery

Data involving the delivery of BA and UC sessions will be summarised descriptively by treatment group and overall (Table 4). The following information will be summarised:

- Number of sessions attended (with percentage of sessions booked / available to attend).
- Length of time to prepare for the session.
- Time taken to complete the session.
- Length of time spent on administrative activities after the session.
- Location of the session i.e. Online, in person or by telephone.
- Number and percentage of BA participants that fully completed the full course suggesting full compliance with the intervention.
- Number and percentage of UC participants marked with possible contamination of BA.
- Aspects of care items individually summarised at 6- and 12-month time points.

No formal statistical comparisons of characteristics will be undertaken between groups.

5.7 Primary Analysis

The RCADS-25 will be summarised descriptively at each collected time point by trial arm. Mean scores and confidence intervals will be illustrated graphically.

The primary analysis will be conducted on an intention to treat (ITT) basis, including patients in the groups to which they were randomised.

The primary analysis will compare the continuous RCADS-25 T-score between treatment arms at 6-months post randomisation. This will be analysed using a mixed-effects linear regression model, including all available follow-up time points. The model will adjust for the RCADS-25 at baseline and include as fixed effects: trial arm, arm-by-time interaction, age, sex, setting and site. Random effects will be included to account for the repeated measures within patients and for possible clustering by therapist, patient, and therapist nested within treatment arm.

Adjusted mean differences between treatment groups will be presented at each timepoint with an associated 95% confidence interval (CI) and p-value.

For the modelling of repeated measurements, the best fitting (based on Akaike information criteria (AIC) and Bayesian information criteria (BIC)) covariance pattern that is not significantly different from an unstructured pattern will be selected. The model will provide an overall treatment effect over 6 months as well as estimates at the 12-month time point. These will be reported as mean differences between treatment groups with 95% confidence intervals and associated p-values. The estimate at the 6-month time point will serve as the primary endpoint.

Data will be assumed missing at random. The assumptions of normality and homoscedasticity of residuals will be checked using graphical methods, and if the assumptions are in doubt the data will be transformed prior to analysis or alternative non-parametric analysis methods will be explored.

The primary analysis will be checked by a second statistician before the release of any results.

5.8 Secondary Analyses

The following sections detail any secondary analyses that will be performed on the primary outcome. For example, any sensitivity analyses to determine if results of the primary analysis change under different conditions.

5.8.1 Complier-Average-Causal-Effect (CACE) Analysis

Complier Average Causal Effect (CACE) analysis will be carried out for the RCADS-25 at the 6- month time point. Compliers are defined as participants who received their allocated treatment.

The CACE analysis will be implemented using an instrumental variable regression model with treatment allocation as the instrument and received treatment as the exogenous variable. The model will control for the following variables used in the primary analysis; treatment arm, age, and sex. Separate CACE analyses will be carried out for the following definitions of compliance:

1) Minimal compliance: for a participant to be classed as having met the conditions for minimal compliance to the intervention, they should have completed at least 5 sessions (this is the approximate number of sessions required to cover modules 1-3 of the BA intervention)
2) Full compliance: for a participant to be classed as having met the conditions for full compliance, they must have completed at least 8 sessions (this is the approximate number of sessions required to cover all components of the BA intervention).

5.8.2 Impact of Missing Data on the Primary Analysis

5.8.2.1 Missing covariates

To calculate the primary outcome measure of the RCADS T-scores, it requires the participants sex and age. As we are collecting gender, participants that select the options of ‘non-binary’ or ‘prefer not to say’ will be considered as missing and thus not be included in the primary analysis. We do not expect any missing data regarding the age of the participant as this is used to determine eligibility.

The impact of this on the primary analysis will be assessed using multiple imputation by chained equations. The imputation model will include key baseline variables (age, gender, baseline RCADS-25 T-score, baseline CDRS-R score, and baseline BADS-SF score). A ‘burn –in’ of 150 will be used and 50 imputed datasets will be created. The primary analysis will then be rerun within the imputed datasets and Rubin's rules will be used to combine the multiply imputed estimates.

In addition to the above analysis, patterns of missingness of covariates amongst participants will be summarised descriptively.

5.8.2.2 Pattern mixture model

The primary analysis will use a covariance-pattern, repeated-measures, mixed-effect linear regression model, which implicitly assumes missing outcome data are missing at random (MAR). However, it is possible that participants who failed to attend their follow-ups differed from those who did attend (e.g. had worse depression and anxiety symptoms, and therefore would have scored higher on the RCADS-25 if they had attended the follow-up). This would mean the data were missing not at random and would represent a departure from the MAR assumption. The sensitivity of the primary analysis results to departures from the MAR assumption will be explored using a pattern-mixture model, implemented using the `rctmiss`

command (White (2018); White et al (2011).This command currently supports the use of fixed-effect models only, and therefore a linear regression model comparing the primary outcome at 6-months post randomisation will be used, adjusting for treatment arm, age, and sex.

The pattern mixture model works by including a sensitivity parameter quantifying the departure from the MAR assumption. For example, if we expected that those who failed to complete the follow-up at 6-months post randomisation on average would have scored two points lower on the RCADS-25 T-score than those who did attend the follow-up, the sensitivity parameter would be equal to 2. The pattern-mixture model can then be used to obtain an estimate of the treatment effect given this level of departure from the MAR assumption. The `rctmiss` command estimates the treatment effect for varying values of the sensitivity parameter ranging from zero up to any positive value, which allows for the assessment of the impact of varying degrees of departure from the MAR assumption on the treatment effect estimate.

The `rctmiss` command will be used to produce a graph of the adjusted mean difference in RCADS-25 T-scores between treatment groups for varying values of the sensitivity parameter. This will be done assuming the value of the sensitivity parameter is equal in both groups (missing data are equally informative in both groups), and also assuming the sensitivity parameter is equal to zero in the UC group and varying in the BA group, and vice versa (missing data are only informative in one group and not the other).

While the results of this sensitivity analysis will not be directly comparable to the primary analysis model, it will be able to give an indication of how sensitive the estimate of the treatment effect is to departures from the MAR assumption in the primary outcome data.

5.8.3 Impact of timing of data collection on the Primary Analysis

For the collection of the primary outcome measure of the RCADS, a pragmatic approach is taken for data collection, whereby no definitive deadline has been made for participants to return the data at each follow-up time point. Therefore, it is possible that follow-up completion times will show some departure from the planned follow-up schedule. We will undertake the following sensitivity analyses to examine the potential influence that variation in follow-up time has on the results of the primary analysis.

We believe that a 1-2 month timeframe around each follow-up time-point for returning the data is a reasonable estimate for a participant to attend a follow-up appointment and complete/return the questionnaire. The primary analysis model will be repeated, firstly with participants that had completed their follow-up questionnaire within a window of one month either side the follow-up time points (i.e. 5-7 and 11-13 months post-randomisation respectively). This analysis will then be repeated but with a two-month window either side of the follow-up time-points.

If the planned primary analysis is not severely mis-specified, then we will repeat the primary analysis, but include the follow-up times as a continuous predictor, measured in weeks (as opposed to the binary time point indicator used for the primary analysis). Follow-up time will be modelled using a restricted cubic spline with three knots placed at the 10th, 50th and 90th percentiles of the observed values. As for the primary analysis, the effects of time will be allowed to vary across randomised groups (via interaction between the spline terms for time and the treatment group indicator). The fitted model will be used to estimate and plot the differences in RCADS score between groups over the whole follow-up period, together with

a two-sided 95% confidence band (based on a t-distribution with degrees of freedom calculated using the method of Kenward and Roger).

5.8.4 Subgroup Analyses

The primary analysis will be repeated for each subgroup. The subgroup analyses models will use the primary analysis model with an additional interaction term between treatment group and respective subgroup. The corresponding p-value will be presented, alongside descriptive summaries of the primary outcome for each combination of the treatment group and subgroup.

Subgroup analyses will be carried out for the following subgroups:

5.8.4.1 Age

Two groups will be defined as less than 16 years old, and 16 years and older. We predict that participants 16 years and older may benefit more as could be seen as having a greater sense of values as they have had more years of development. Older participants may also have greater skills that complement the intervention such as organisational skills, which are involved in activity scheduling.

5.8.4.2 Gender

Two groups will be defined as males and females. We predict that females will benefit more with the intervention compared to males because the stigma is stronger with young men, particularly within a school setting.

5.8.4.3 Baseline RCADS-25 depression subscale

Two groups will be defined as low and high severity as defined by the RCADS outcome. We predict there to not be much difference between the groups however meta-analyses in previous literature have shown a greater effect size for those with more severe symptoms.

5.8.4.4 Setting

Three groups will be defined as NHS sites, charity sites and school sites. No definitive prediction has been made for this subgroup analysis. We note that schools and charities have a greater diversity in terms of the kinds of practitioner and their levels of qualifications. Participants randomised within a school setting may be more comfortable in receiving the intervention as it is an environment they are familiar with. Therefore, it could be suggested that participants belonging to NHS or school sites may benefit more compared with charity sites.

5.8.4.5 Ethnicity

Two groups will be defined as white and non-white ethnicity. We predict that those from minority ethnic groups may do less well as the intervention may be more culturally removed for this group than for the white ethnicity group.

5.9 Analysis of Secondary Outcomes

All secondary outcomes will be reported descriptively at each collected time point by trial arm. This section provides details of the planned analyses for each secondary outcome. All secondary analyses will follow the same model selection process and missing data assumptions as the primary model.

5.9.1 RCADS-25 Grouped T-Scores

The continuous RCADS-25 T-score will be categorised into three groups as defined by the clinical cut-offs stated in section 5.2.1. This analysis will compare the odds ratio at 6- and 12-

months post randomisation of being in a higher category than the non-clinical range, which will act as the reference category. This will be analysed using a mixed ordinal logistic regression model, with the interpretation of one unit increase in the response variable, this would correspond to being within the next category level. The model will adjust for the same fixed and random effects as the primary model. The proportional odds assumption for ordinal regression models will be assessed using the Brant test.

5.9.2 CDRS-R

The CDRS-R will be analysed first using the T-scores as a continuous measure and second as an ordered categorical measure.

The continuous CDRS-R T-scores will be used as the response variable. This analysis will compare the adjusted mean difference of the CDRS-R score between treatment arms at both 6- and 12-months post randomisation. A linear mixed effects regression model will be used, replacing the baseline value of RCADS-25 T-Score to that of the baseline CDRS-R T-score, with all other fixed and random covariates remaining the same as the primary model.

For the second analysis, the CDRS-R T-scores will be categorised into three groups as defined in section 5.2.3. This analysis will compare the odds of being in a higher category than the non-diagnosable depression category for each treatment arm. A mixed ordinal logistic regression model will be used, replacing the baseline value of RCADS-25 T-Score to that of the baseline CDRS-R T-score, with all other fixed and random covariates remaining the same as the primary model. This will be analysed at both 6- and 12-months post randomisation. The proportional odds assumption for ordinal regression models will be assessed using the Brant test.

5.9.2.1 Sensitivity analysis for non-visual appointments

A sensitivity analysis will be conducted including the participant's CDRS-R T-scores that were unable to complete Items 15 or 17 due to being a telephone or online (with no camera) appointment. The secondary CDRS-R analysis models (described above in section 5.9.2) will be rerun but including the participants that had these types of appointments.

5.9.3 BADS-SF

The total score of the BADS-SF questionnaire will be used as the continuous response variable for this secondary analysis. This analysis will compare the adjusted mean difference of the BADS-SF score between treatment arms at both 6- and 12-months post randomisation. A linear mixed effects regression model will be used, replacing the baseline value of RCADS-25 T-Score to that of the baseline BADS-SF score, with all other fixed and random covariates remaining the same as the primary model.

5.9.4 Adverse Events

Adverse events (AEs) and Serious Adverse Events (SAEs) will be summarised descriptively, by trial arm, and overall. The number of AEs and SAEs per participant will be presented, by treatment group and overall. The event type, expectedness, and relatedness to the study treatment of the AEs and SAEs will be summarised similarly.

5.10 Other analyses

5.10.1 Mediation analysis

Mediation analysis (using the *mediate* command in Stata) will be used to examine direct and indirect effects of treatment on the RCADS-25 at 12-months post-randomisation with the indirect effect being mediated through the BADS-SF score at 6-months post-randomisation. The model for the outcome will include trial arm, age, sex, setting and site. In order to account for hidden confounding between the mediation variable and outcome (Emsley R et al (2010)), the model for the mediator will include these terms and in addition interaction terms between trial arm and the following variables: age, sex, setting and site.

This analysis will be repeated with the CDRS-R score at 12-months post-randomisation in place of the RCADS-25 score.

5.11 Analysis Software

All analyses will be conducted in Stata Version 18 or later (StataCorp. 2023)

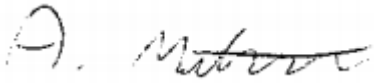
6. Signatures of Approval

6.1 Contributions

Fraser Wiggins and Alex Mitchell drafted the statistical analysis plan; however, sections of this document have been copied and adapted from the trial grant application (and protocol). This document will be reviewed by members of the PMG and PSC.

6.2 Signatures

Sign-off of the Statistical Analysis Plan by, as a minimum, the person writing the SAP, a relevant senior statistician, and the Chief Investigator.

Name	Trial Role	Signature	Date
Professor Lina Gega	Chief Investigator		20/08/2025
Dr Lucy Tindall	Programme Manager		11/07/2025
Professor Catherine Hewitt	Senior Statistician		01/07/2025
Alex Mitchell	Statistician		03/07/2025
Fraser Wiggins	Statistician		01/07/2025

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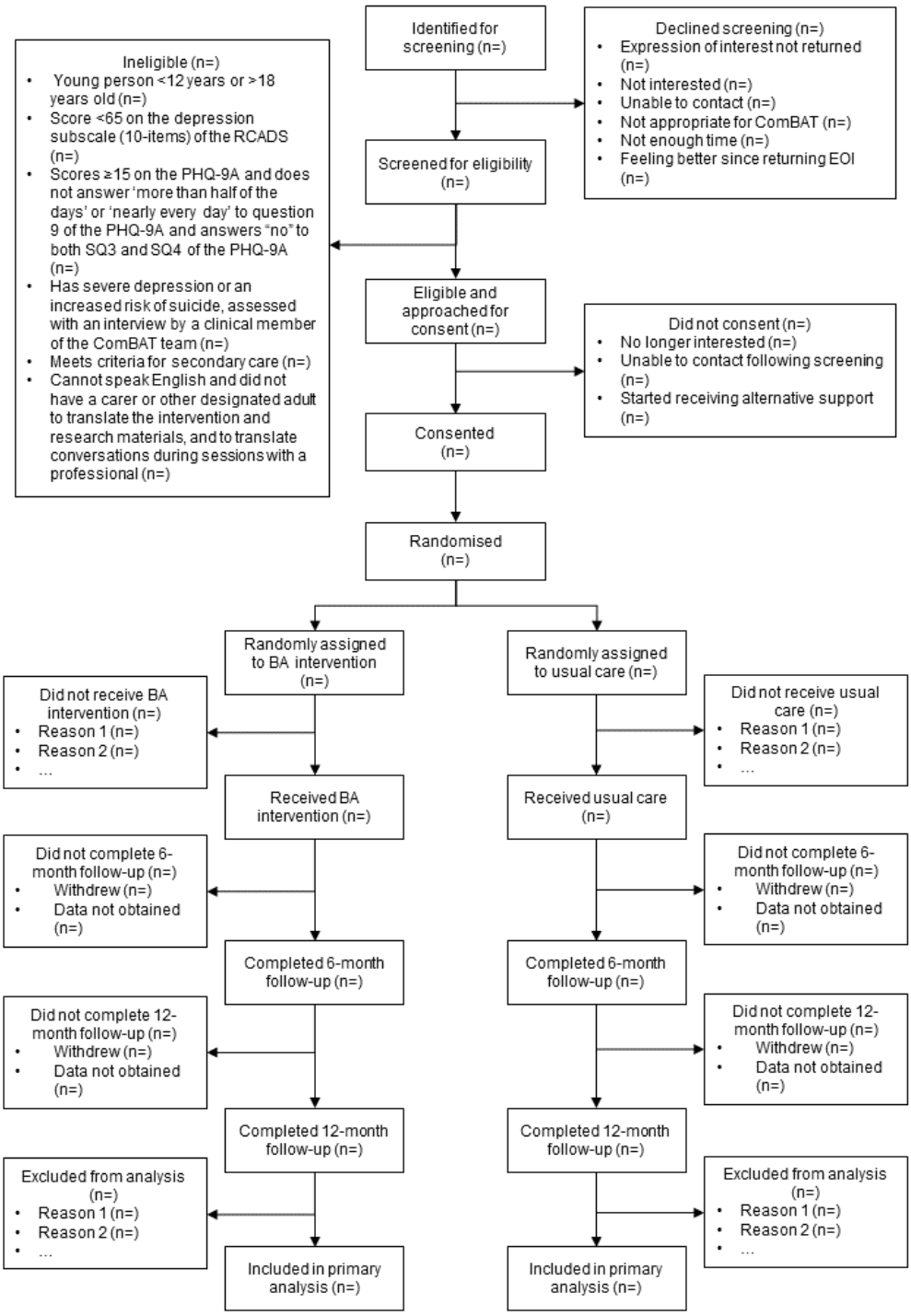
8. Appendices

8.1 Planned Tables and Figures

The following tables and figures are intended as templates for the statistical analysis report of the ComBAT trial. The final tables and figures may differ in some details from the templates proposed here.

8.1.1 Trial Progression

Figure 1: A CONSORT diagram outlining the progression of the trial.



8.1.2 Demographics and Baseline Characteristics

Table 3: Demographic and baseline characteristics presented by treatment allocation for the 'as randomised' and 'as analysed' participants

	As randomised (n=)		**As analysed (n=)**	
	Behavioural Activation (n=)	Usual Care (n=)	Behavioural Activation (n=)	Usual Care (n=)
Age, n (%) n (%) Mean (SD) Median (IQR) Min, Max				
Gender, n (%) Male Female Non-binary Prefer not to say Missing				
Ethnicity, n (%) English/Welsh/Scottish/Northern Irish/ British Irish Gypsy or Irish Traveller Any other White background Indian Pakistani Bangladeshi Chinese Any other Asian background White and Black Caribbean White and Black African White and Asian Any other mixed/multiple ethnic background African Caribbean Any other Black / African / Caribbean background Arab Any other ethnic group Prefer not to say Missing				
Religion, n (%) Protestant (Church of England) Catholic Mormon Jehovah's Witness Orthodox Other Christian Atheist Agnostic Jewish Muslim Buddhist Hindu Other World Religion Prefer not to say Other				

	As randomised (n=)		As analysed (n=)	
	Behavioural Activation (n=)	Usual Care (n=)	Behavioural Activation (n=)	Usual Care (n=)
Missing				
Currently living with, n (%) Biological Parent(s) Adoptive Parent(s) Foster Carer(s) Children's home Partner Friend Alone Other Missing				
Education, n (%) Secondary Further/Higher (University or College) Not in education Other Missing				
Employment, n (%) Employed Full-Time Employed Part-Time Self Employed Unemployed Seasonal Holiday Job Volunteering Other Missing				

8.1.3 Treatment Delivery

Table 4: Summary of session log bookings, attendance, and session length

	Behavioural Activation (n=)	Usual Care (n=)	Total
Location of session, N (%) In Person Online Telephone Missing			
Sessions booked N Mean (SD) Median (Q1, Q3) Min, Max			
Sessions attended N (% of booked) Mean (SD) Median (Q1, Q3) Min, Max			
Session length N Mean (SD) Median (Q1, Q3) Min, Max			

8.1.4 Primary Analysis

Table 5: RCADS-25 T-scores presented descriptively by treatment group. Adjusted mean differences alongside corresponding 95% confidence intervals and p-values are presented.

	Behavioural Activation (n=)	**Usual Care (n=)**	**AMD 95% CI p-value**
RCADS T-Scores			
Month 6 n (%) Mean (SD) Median (IQR) Min, Max			
Month 12 n (%) Mean (SD) Median (IQR) Min, Max			

8.1.5 Analysis of Secondary Outcomes (Excluding Adverse Events)

Table 6: Secondary (continuous) outcomes presented descriptively by treatment group. Adjusted mean differences alongside corresponding 95% confidence intervals and p-values are presented.

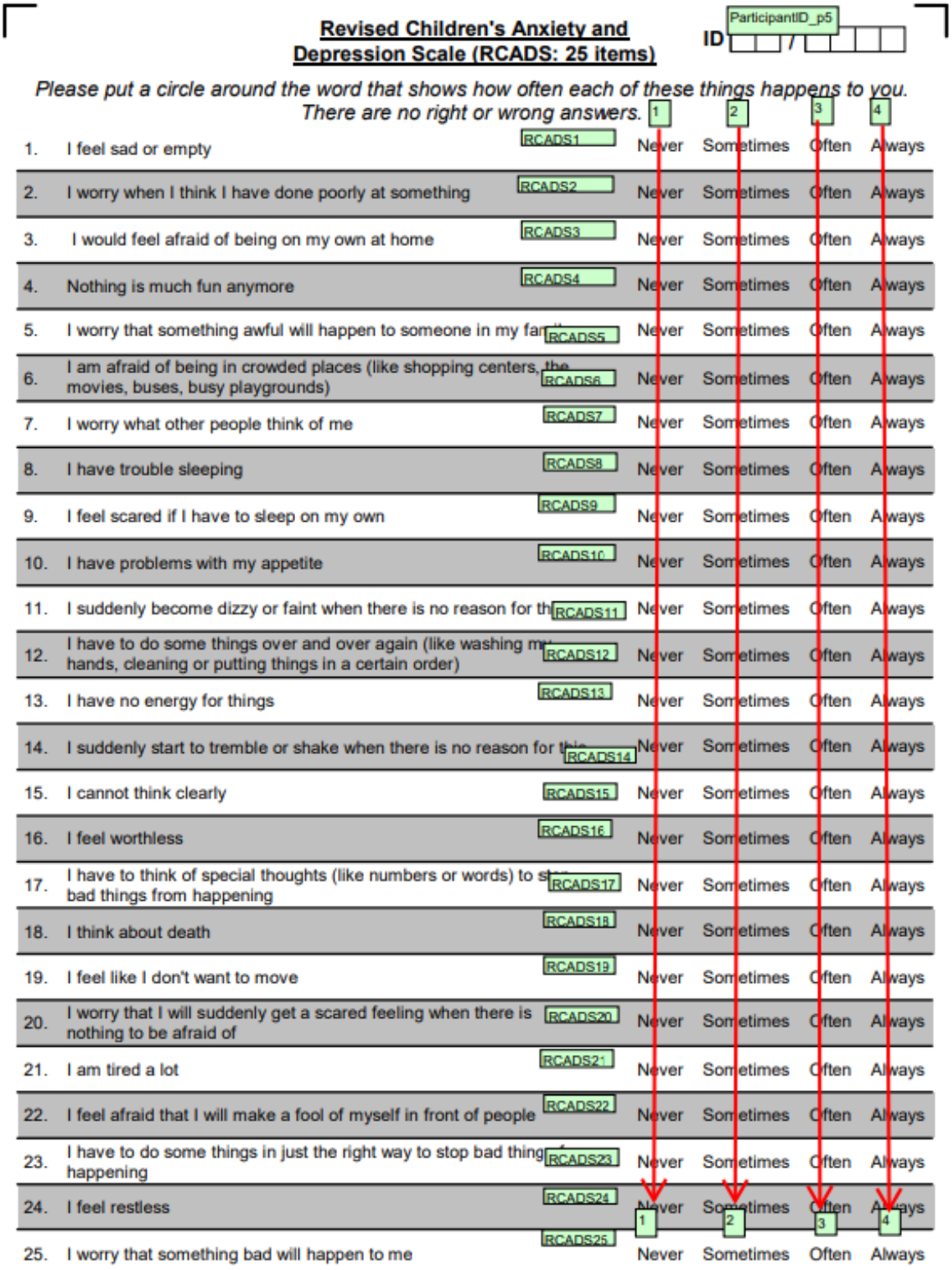
	Behavioural Activation (n=)	**Usual Care (n=)**	**AMD 95% CI p-value**
BADS-SF			
Month 6 n (%) Mean (SD) Median (IQR) Min, Max			
Month 12 n (%) Mean (SD) Median (IQR) Min, Max			
CDRS-R T-Score			
Month 6 n (%) Mean (SD) Median (IQR) Min, Max			
Month 12 n (%) Mean (SD) Median (IQR) Min, Max			

Table 7: Secondary (ordinal) outcomes presented descriptively by treatment group. Odds ratios alongside corresponding 95% confidence intervals and p-values are presented.

	Proportion		**Odds ratio (95% CI)**	**p-value**
	Behavioural Activation (n=)	**Usual Care (n=)**		
RCADS T-Score				
Month 6				
Non-clinical				
Borderline clinical				
Clinical				
Month 12				
Non-clinical				
Borderline clinical				
Clinical				
CDRS-R T-Score				
Month 6				
Unlikely depression				
Possible depression				
Likely depression				
Month 12				
Unlikely depression				
Possible depression				
Likely depression				

8.2 Questionnaires for primary/secondary outcomes

8.2.1 RCADS-25



Revised Children's Anxiety and Depression Scale (RCADS: 25 items)

ID ParticipantID_p5

Please put a circle around the word that shows how often each of these things happens to you. There are no right or wrong answers.

1.	I feel sad or empty	RCADS1	Never	Sometimes	Often	Always
2.	I worry when I think I have done poorly at something	RCADS2	Never	Sometimes	Often	Always
3.	I would feel afraid of being on my own at home	RCADS3	Never	Sometimes	Often	Always
4.	Nothing is much fun anymore	RCADS4	Never	Sometimes	Often	Always
5.	I worry that something awful will happen to someone in my fa	RCADS5	Never	Sometimes	Often	Always
6.	I am afraid of being in crowded places (like shopping centers, the movies, buses, busy playgrounds)	RCADS6	Never	Sometimes	Often	Always
7.	I worry what other people think of me	RCADS7	Never	Sometimes	Often	Always
8.	I have trouble sleeping	RCADS8	Never	Sometimes	Often	Always
9.	I feel scared if I have to sleep on my own	RCADS9	Never	Sometimes	Often	Always
10.	I have problems with my appetite	RCADS10	Never	Sometimes	Often	Always
11.	I suddenly become dizzy or faint when there is no reason for th	RCADS11	Never	Sometimes	Often	Always
12.	I have to do some things over and over again (like washing my hands, cleaning or putting things in a certain order)	RCADS12	Never	Sometimes	Often	Always
13.	I have no energy for things	RCADS13	Never	Sometimes	Often	Always
14.	I suddenly start to tremble or shake when there is no reason for this	RCADS14	Never	Sometimes	Often	Always
15.	I cannot think clearly	RCADS15	Never	Sometimes	Often	Always
16.	I feel worthless	RCADS16	Never	Sometimes	Often	Always
17.	I have to think of special thoughts (like numbers or words) to st bad things from happening	RCADS17	Never	Sometimes	Often	Always
18.	I think about death	RCADS18	Never	Sometimes	Often	Always
19.	I feel like I don't want to move	RCADS19	Never	Sometimes	Often	Always
20.	I worry that I will suddenly get a scared feeling when there is nothing to be afraid of	RCADS20	Never	Sometimes	Often	Always
21.	I am tired a lot	RCADS21	Never	Sometimes	Often	Always
22.	I feel afraid that I will make a fool of myself in front of people	RCADS22	Never	Sometimes	Often	Always
23.	I have to do some things in just the right way to stop bad thing happening	RCADS23	Never	Sometimes	Often	Always
24.	I feel restless	RCADS24	Never	Sometimes	Often	Always
25.	I worry that something bad will happen to me	RCADS25	Never	Sometimes	Often	Always

Ebesutani, C., Reise, S. P., Chorpita, B. F., Ale, C., Regan, J., Young, J., ... & Weisz, J. R. (2012). The Revised Child Anxiety and Depression Scale-Short Version: scale reduction via exploratory bifactor modeling of the broad anxiety factor. Psychological Assessment, 24(4), 833.

8.2.2 CDRS-R

ID: ParticipantID_p6 /

CHILDREN'S DEPRESSION RATING SCALE, REVISED (CDRS-R)

CDRS-R Raw Summary Score: CDRS_RScore

CDRS-R *T*-Score: CDRS_TScore

Percentile	2	10	20	30	40	50	60	70	80	90	95	99
Raw Score	17	20						30			40				50				60				70			77–113
T-Score	30	33	40	44	48	51	53	55	57	59	61	62	63	64	65	66	67	68	69	71	73	75	76	78	80	81	82	83	84	85	>85

Interpretation of the CDRS-R *T*-Score

✔	*T*-Score Range	Interpretation
	39 or lower	Scores this low are extremely rare. Seek information from others, as such uncommonly low scores may be associated with pervasive denial.
	40–54	A depressive disorder is unlikely to be confirmed in further evaluation.
	55–64	It is possible that a depressive disorder might be confirmed in a comprehensive diagnostic evaluation. Further evaluation should be pursued if any of the following conditions are applicable: • Moderate to severe ratings were made in any symptom areas • The rating for Suicidal Ideation is 3 or above • A chronic course (i.e., more than one year) is described for a clinically significant indicator of depressive mood (i.e., Difficulty Having Fun, Depressed Feelings, Depressed Facial Affect, or Irritability)
	65–74	A depressive disorder is likely to be confirmed in a comprehensive diagnostic evaluation. Further evaluation should be pursued.
	75–84	A depressive disorder is very likely to be confirmed. Further evaluation should be pursued.
	85 or higher	A depressive disorder is almost certain to be confirmed. Intervene and evaluate immediately.

Comparison of Symptom Ratings from All Sources

Evaluated Symptom Area	Rating Source: Child	Parent	Other	Best Description of Child
Impaired Schoolwork	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Difficulty Having Fun	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Social Withdrawal	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Sleep Disturbance	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Appetite Disturbance	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Excessive Fatigue	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Physical Complaints	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Irritability	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Excessive Guilt	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Low Self-Esteem	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Depressed Feelings	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Morbid Ideation	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Suicidal Ideation	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Excessive Weeping	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Ratings of Observed Nonverbal Behavior				
Depressed Facial Affect	1 2 3 4 5 6 7			1 2 3 4 5 6 7
Listless Speech	1 2 3 4 5			1 2 3 4 5
Hypoactivity	1 2 3 4 5 6 7			1 2 3 4 5 6 7

☐ = No apparent difficulties ▒ = Clinically significant difficulties ■ = Severe clinically significant difficulties

ID ParticipantID_p7 /

Instructions:
Rate each symptom area for this child by writing only one number in the box.
Write *NR* ("Not Rated") in the box if there is insufficient information to derive a rating.

1. IMPAIRED SCHOOLWORK → CDRS01

Performance is consistent with ability..... 1
2
Decrease in school performance and/or ability to concentrate 3
4
Major interference with performance in most subjects..... 5
6
No motivation to perform 7

Comment CDRS01_Info

2. DIFFICULTY HAVING FUN → CDRS02

Interest and activities realistically appropriate for age, personality, and social environment. No appreciable change from usual behavior during at least the past 2 weeks. Any feelings..... of boredom are seen as transient. 1
2
Describes some activities as enjoyable that are realistically available several times a week..... but not on a daily basis. Shows interest but not enthusiasm. 3
4
Is easily bored. Complains of "nothing to do" as characteristic of daily experience. Participates in structured activities with a "going through the motions" attitude. May express..... interest primarily in activities that are (realistically) unavailable on a daily or weekly basis. 5
6
Has no initiative to become involved in any activities. Describes himself/herself as primarily passive. Watches others play or watches TV but shows little interest. Requires coaxing and/or..... pushing to get involved in activity. Shows no enthusiasm or real interest. Has difficulty naming activities. 7

Comment CDRS02_Info

3. SOCIAL WITHDRAWAL → CDRS03

Enjoys friendships with peers at school and at home..... 1
2
Does not actively seek out friendships but waits instead for others to initiate a relationship. Occasionally rejects opportuni ties to play, without having a describable alternative..... 3
4
Frequently avoids or refuses opportunities for desirable interaction with others and/or sets up situations where rejection is inevitable..... 5
6
Does not currently relate to other children. States that he/she has "no friends" or actively rejects new or former friends..... 7

Comment CDRS03_Info

ID ParticipantID_p8

4. SLEEP DISTURBANCE → CDRS04

No difficulty or occasional difficulty that is siuationally explainable..... 1
2
Frequently has mild difficulty with sleep..... 3
4
Has difficulty with sleep nearly every night..... 5

Supplemental information (not scored)
Indicate when sleep disturbance occurs (check all applicable items):

CDRS04_1 Upon first going to bed

CDRS04_2 In the middle of the night

CDRS04_3 Early in the morning

Comment CDRS04_Info

5. APPETITE DISTURBANCE → CDRS05

No problems or changes in eating pattern..... 1
2
Mild but notable change from usual eating habits..... 3
4
Avoids eating and/or is not hungry most of the time OR describes a noteworthy increase in appetite and/or excessive food intake..... 5

Supplemental information (not scored)
If applicable, indicate type of appetite disturbance:

CDRS05_1
1 Increased appetite

2 Decreased appetite

Comment CDRS05_Info

6. EXCESSIVE FATIGUE → CDRS06

No unusual complaints of "feeling tired" during the day..... 1
2
Complaints of fatigue seem somewhat excessive and are not related to boredom or increased activity levels..... 3
4
Daily complaints of feeling tired..... 5
6
Complains of feeling tired most of the day. May voluntarily take long naps without feeling refreshed..... 7

Comment CDRS06_Info

CDRS_Sub1
Add all number in above boxes here: **(Subtotal 1)**

ID ParticipantID_p1 /

11. DEPRESSED FEELINGS → CDRS11

Occasional feelings of unhappiness that quickly disappear..... 1
2
Describes sustained periods of unhappiness that appear excessive for events described..... 3
4
Feels unhappy most of the time without a major precipitating cause..... 5
6
Feels unhappy all of the time; characterized by a sense of psychic pain (e.g., "I can't stand it")..... 7

Comment CDRS11_Info

12. MORBID IDEATION → CDRS12

No morbid thinking reported..... 1
Strongly denies..... 2
Discusses morbid thoughts that relate to a real event but seem excessive..... 3
Describes preoccupation with morbid thoughts several times a week. These morbid thoughts extend beyond external reality..... 4 5
Preoccupied on a daily basis with death themes or morbid thoughts that are elaborate, extensive, or bizarre..... 6 7

Comment CDRS12_Info

13. SUICIDAL IDEATION → CDRS13

Understands the word *suicide*, but does not apply the term to himself/herself..... 1
Sharp denial of suicidal thoughts..... 2
Has thoughts about suicide, or of hurting himself/herself (if he/she does not understand the concept of suicide), usually when angry..... 3 4
Has recurrent thoughts of suicide..... 5
Has made a suicide attempt within the last month or is actively suicidal..... 6 7

Comment CDRS13_Info

14. EXCESSIVE WEEPING → CDRS14

Report appears normal for age..... 1
Suggestive statements that he/she cries, or feels like crying, more frequently than peers..... 2
Cries more often than peers, occassionally without clear precipitant..... 3
Cries or feels like crying frequently (several times a week). Admits to crying without knowing the reason why..... 4 5
6
Cries nearly every day..... 7

Comment CDRS14_Info

Add all number in above boxes here: CDRS_Sub2 **(Subtotal 2)**

ID ParticipantID_p11

STOP if the interview was conducted with a parent (or another adult). No further scoring activity is justified or supported by empirical data. Refer to chapter 3 of the CDRS-R Manual for interpretive considerations.

CONTINUE if this interview was conducted with the child. For the three remaining symptom areas, rate the child based on his or her nonverbal characterisitics during the interview.

15. DEPRESSED FACIAL AFFECT → CDRS15

Facial expression and voice animated during the interview. No sign of depressed affect..... 1

Mild suppression of affect. Some loss of spontaneity..... 2

Overall loss of spontaneity. Looks unhappy during parts of the interview (e.g., sullen face, lowered eyes, loack of animation in face). Is capable of smiling, however, and does not avoid eye contact when discussing nonthreatening areas..... 3 4

Moderate restriction of affect throughout most of the interview. Has longer and frequent periods of looking distinctly unhappy. Nothing seems to enliven him/her..... 5

Severe restriction of affect. Looks distinctly sad and withdrawn. Minimal verbal interaction throughout the interview..... 6 7
Cries or may appear tearful.

Comment CDRS15_Info

16. LISTLESS SPEECH → CDRS16

Quality of speech seems situationally sensitive without any noteworth deviations..... 1

Slowed tempo, monotone, or overly soft speech..... 2

Slowed tempo with many pauses where he/she appears to drift. Hesitations include sighing. Voice qualitites are distinctly monotonic and unanimated, and convey a sense of distress and psychic discomfort..... 3

Extreme sense of psychic distress exhibited in voice or by a profound sense of hollowness or emptiness. Has difficulty conducting the interview..... 4 5

Comment CDRS16_Info

17. HYPOACTIVITY → CDRS17

Bodily movements are animated. (Note that a hyperactive, agitated child is not distinguished here from what would be seen as normal nondistracting behavior; hyperactivity should be noted.)..... 1 2

Bodily movements appear somewhat restrict and/or slowed..... 3 4

Definite restriction in bodily autonomy and an overall sense of motor retardation..... 5 6

Severe sense of motor retardation with catatonic-like qualities..... 7

Comment CDRS17_Info

Add all number in above boxes here: CDRS_Sub3 **(Subtotal 3)**

ID ParticipantID_p1

Sum all the page subtotals to calculate the Raw Summary Score:

CDRS_SubT1 + CDRS_SubT2 + CDRS_SubT3 = CDRS_Total

Subtotal 1 Subtotal 2 Subtotal 3 **Raw Summary Total**

First, write the Raw Summary Score in the space labeled "CDRS-R Raw Summary Score" on the summary page (page 1) of this Administration Booklet. Locate the Summary Score on the middle line of the "scoring thermometer" on the same page. The *T*-score that corresponds to the Summary Score can be found directly below it, on the bottom line. Copy the *T*-score to the space labeled "CDRS-R *T*-Score." (The percentile that corresponds to the Summary Score can be found directly above it, on the top line of the scoring thermometer.)

Next, if you suspect any fabrication, denial, or similar validity problems, see chapter 3 of the CDRS-R Manual for interpretive considerations. Otherwise, in the middle of the summary page, locate the *T*-score range in which the child's *T*-score falls. Place a check mark in the column to the left of the appropriate *T*-score range to indicate the interpretive statement applicable to this child's *T*-score. Finally, proceed to the bottom portion of the same page and summarize the interview ratings for all informants.

8.2.3 BADS-SF

ID ParticipantID_p1

Behavioural Activation for Depression Scale Short Form (BADS-SF)

Please read each statement carefully and then circle the number which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

0 = Not at all 1 2 = A little 3 4 = A lot 5 6 = Completely	0	1	2	3	4	5	6	AC	AV	T
1. There were certain things I needed to do that I didn't do. BADS01	0	1	2	3	4	5	6	—		R
2. I am content with the amount and types of things I did. BADS02	☐	☐	☐	☐	☐	☐	☐	—		—
3. I engaged in many different activities. BADS03	☐	☐	☐	☐	☐	☐	☐	—		—
4. I made good decisions about what type of activities and/or situations I put myself in BADS04	☐	☐	☐	☐	☐	☐	☐	—		—
5. I was an active person and accomplished the goals I set out to do. BADS05	☐	☐	☐	☐	☐	☐	☐	—		—
6. Most of what I did was to escape from or avoid something unpleasant. BADS06	☐	☐	☐	☐	☐	☐	☐		—	R
7. I spent a long time thinking over and over about my problems. BADS07	☐	☐	☐	☐	☐	☐	☐		—	R
8. I engaged in activities that would distract me from feeling bad. BADS08	☐	☐	☐	☐	☐	☐	☐		—	R
9. I did things that were enjoyable. BADS09	0	1	2	3	4	5	6	—		—

AC BADS_AC AV BADS_AV T BADS_T

Kanter, J. W., Mulick, P. Busch, A. M., Berlin, K. S., & Martell, C. R. (2007). The behavioral activation for depression scale (BADS): Psychometric properties and factor structure. Journal of Psychopathology and Behavioral Assessment, 29, 191-202.