STATISTICAL ANALYSIS PLAN

RCT evaluation of the Positive Pathways programme

Sheffield Hallam University

Principal investigator: Ben Willis and Dr Josephine Booth

YOUTH ENDOWMENT FUND

RCT-centred evaluation of the Positive Pathways programme

Statistical analysis plan

Evaluating institution: Sheffield Hallam University
Principal investigator(s): Ben Willis and Dr Josephine Booth

YEF statistical analysis plan

Any guidance notes (in italics) can be deleted on completion and replaced with the actual text which should not be in italics and instead in justified black Calibri font size 12 with 10pt spacing before and after and multiple 1.15 line spacing.

Project title[1]	***RCT evaluation of the Positive Pathways programme***
Developer (Institution)	*Ingeus*
Evaluator (Institution)	*Sheffield Hallam University*
Principal investigator(s)	*Ben Willis and Dr Josephine Booth*
SAP author(s)	*Professor John Reidy, Dr Antonia Ypsilanti, Dr Josephine Booth, Ben Willis, Sean Demack*
Trial design	*Two-armed Efficacy Trial with Internal Pilot*
Trial type	*Efficacy with internal pilot and randomisation at the individual level*

[1] Please make sure the title matches that in the header and that it is identified as a randomised trial as per the CONSORT requirements (CONSORT 1a).

Evaluation setting	*Mixed out of school – mentoring and adventure learning residential centres*
Target group	*15–17-year-olds, blended cohort of secondary (at risk of* involvement in violent crime*) and tertiary (involved in the criminal justice system) need*
Number of participants	*800 total – 120 from an internal pilot and 680 from the main stage efficacy study.*
Primary outcome and data source	*Volume of self-reported offending behaviours (SRDS, volume score)*
Secondary outcome and data source	*Number of different types of delinquent behaviours reported (SRDS Variety Score)* *Total difficulties (SDQ Total Difficulties Score)* *Prosocial behaviour (SDQ Prosocial Scale)* *Hyperactivity/inattention (SDQ Hyperactivity-Inattention Subscale)* *Behaviours considered disruptive or problematic (SDQ Conduct Problems Subscale)* *Emotional difficulties, such as anxiety or depression (SDQ Emotional Problems Subscale)* *Difficulties with forming and maintaining positive peer relationships (SDQ Peer Problems Subscale)* *Subjective well-being over time (ONS4 personal wellbeing)*

SAP version history

Version	Date	Changes made and reason for revision
1.2 [*latest*]		
1.1		
1.0 [*original*]		*[leave blank for the original version]*

Any changes to the design or methods need to be discussed with the YEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design. Please ensure that these changes are also reflected in the SAP (CONSORT 3b, 6b).

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Introduction

This statistical analysis plan outlines the key features that will be followed to analyse the data from the study designed to evaluate a program that integrates adventure/outdoor learning with mentoring. The **Positive Pathways** program is aimed at young people aged 15–17 in the East and West Midlands who are either at risk of engaging in violent crime or already involved in the Youth Justice system. The study will include an impact evaluation using a two-arm Randomised Control Trial (RCT) with primary and secondary outcome measures. Data will be collected at two points: the start of the program (during onboarding and at the program's conclusion. The analysis will determine whether the intervention produces statistically significant changes in participants compared to the control group.

A combination of linear regression analyses and group comparisons will be used. For the primary outcome, the model will use the SRDS Volume score at endpoint as the dependent variable. Independent variables will include group assignment, the baseline SRDS Volume score, and the two variables used to stratify randomization (referral route and level of need). The coefficient for group assignment will estimate the impact of the Positive Pathways program. This coefficient will be converted into a standardised effect size and the upper and lower bounds of the 95% confidence interval for the group coefficient will be reported. A comparable analytical method will be applied to secondary outcomes, with additional exploration of mediation effects to assess how secondary outcomes influence the primary outcome, thereby testing the program's theory of change.

Design overview

The impact evaluation will be implemented using a two-armed Randomised Control Trial (RCT) with both primary and secondary outcome measures. The primary outcome variable will be volume of self-reported offending behaviours (the volume sub-scale from the Self-Report Delinquency Scale, SRDS; Smith and McVie, 2003). The secondary outcome measures will include the variety of self-reported offending behaviours (Variety sub-scale of the SRDS), reported strengths and difficulties, pro-social behaviours, hyperactivity, conduct problems, emotional problems, peer problems (sub-scales from the Strength and Difficulties Questionnaire, SDQ; Goodman, 1997) and a measure of young person wellbeing (ONS Wellbeing Scale; Dolans and Metcalfe, 2012; ONS, 2018). Data for these measures will be collected at the start of the programme, at onboarding and at endpoint. These data will be analysed established whether there differences between the intervention and control group on the primary and secondary outcome measures at the endpoint. Randomisaton will be at the individual level but will involve stratification based upon referral routes (Education/Local

Authority/Police/Community & Voluntary Sector) and YEF area of need (Upper Secondary/Lower Tertiary).

Trial design, including number of arms		*Two-arm Randomised Controlled Trial with randomisation at the individual (young person) level.*
Unit of randomisation		*Individual participant*
Stratification variables (if applicable)		*Referral routes and YEF classification of area of need (Secondary Level vs Tertiary Level).*
Primary outcome	variable	*Volume of self-reported offending behaviours (Self-Report Delinquency Scale SRDS, volume score, see Smith and McVie, 2003).*
	measure (instrument, scale, source)	*Self-Report Delinquency Scale SRDS, volume score, (see Smith and McVie, 2003). [0 to 198]*
Secondary outcome(s)	variable(s)	*a) Self-reported variety of offending behaviours* *b) Total reported strengths and difficulties* *c) Pro-social behaviours* *d) Hyperactivity* *e) Conduct problems* *f) Emotional problems* *g) Peer problems* *h) Wellbeing*
	measure(s) (instrument, scale, source)	*a) SRDS, Variety Scale [0 to 19]*

		b) Total difficulties scale from the Strengths and Difficulties Questionnaire (SDQ; Goodman, 2005) [0 to 40] *c) SDQ pro-social scale; [0 to 10]* *d) SDQ hyperactivity subscale; [0 to 10]* *e) SDQ conduct problems subscale; [0 to 10]* *f) SDQ emotional problems subscale; [0 to 10]* *g) SDQ peer problems subscale; [0 to 10]* h) *ONS4 Personal Wellbeing Scale (Dolans & Metcalfe, 2012) [0 to 10]*
Baseline for primary outcome	**Variable**	*Pre-randomisation Self-Report Delinquency Scale SRDS, volume score*
	measure (instrument, scale, source)	*SRDS, volume scale [0 to 198]*
Baseline for secondary outcome	**Variable**	*Pre-randomisation variables listed above for secondary outcome variables*
	measure (instrument, scale, source)	*As above*

Research questions or study objectives

The study has one overarching primary research question – (OA-RQ), plus eight research questions relating to the Impact Evaluation as shown below and 10 research questions relating to the Implementation Process Evaluation as shown in section 2.2 of the original protocol.

OA-RQ: **What is the impact of the Positive Pathways programme, a residential wilderness and adventure learning programme with mentoring, on the volume of offending behaviour (as measured by the self-reported SRDS**

volume score) amongst 15–17-year-olds that have offended (or are at risk of doing so)? (primary outcome).

IE-RQ1: What is the impact of the Positive Pathways programme on the prevalence and variety of offending behaviour (as measured by the self-reported SRDS variety score)?

IE-RQ2: What is the impact of the Positive Pathways programme total difficulties (as measured by the total difficulties scale of the SDQ)?

IE-RQ3: What is the impact of the Positive Pathways programme on prosocial behaviour (as measured using the self-reported Strengths and Difficulties Questionnaire prosocial scale; SDQ prosocial)?

IE-RQ4: What is the impact of the Positive Pathways programme on hyperactive behaviour (as measured by the self-reported SDQ hyperactivity subscale)?

IE-RQ5: What is the impact of the Positive Pathways programme on problem behaviours (as measured by the self-reported SDQ conduct problems subscale)?

IE-RQ6: What is the impact of the Positive Pathways programme on emotional problems (as measured by the self-reported SDQ emotional problems subscale)?

IE-RQ7: What is the impact of the Positive Pathways programme on peer problems (as measured by the self-reported SDQ peer problems subscale)?

IE-RQ8: What is the difference in wellbeing scores as measured by the ONS4 between the intervention group and the control group? (secondary outcome)

Sample size calculations overview

Please ensure all details are in line with the latest version of the protocol.

		Protocol	SAP (based upon revised numbers possible for randomisation)
Minimum Detectable Effect Size (MDES)		0.16 SDs	0.18 SDs
Pre-test/ post-test correlations	level 1 (participant)	.45 (R^2 = .20)	.45 (R^2 = .20)
	level 2 (cluster)	N/A	N/A
Intracluster correlations (ICCs)	level 1 (participant)	N/A	N/A
	level 3 (cluster)	N/A	N/A
Alpha[2]		0.05	0.05
Power		0.8	0.8
One-sided or two-sided?		Two	Two
Average cluster size		Not clustered	Not clustered
Number of clusters[3]	Intervention	N/A	N/A
	Control	N/A	N/A
	Total	N/A	N/A
	Intervention	500	400

[2] Please adjust as necessary for trials with multiple primary outcomes, 3-arm trials etc. when a Bonferroni correction is used to account for family-wise errors.
[3] Please adjust as necessary e.g., for trials that are randomised at the setting, practitioner or participant level.

		Protocol	SAP (based upon revised numbers possible for randomisation)
Number of participants	Control	500	400
	Total	1000*	800

**A change is estimated sample size was made between the protocol and the SAP, see below for further details.*

In the original protocol the pre-test/post-test correlation was estimated on the basis of data from the pilot stage of the YEF funded Reach evaluation. Given the lack of availability of pilot data from the current Positive Pathways Project with which to provide a preliminary estimate of this parameter we have continued with the estimate from the Reach evaluation protocol.

The MDES estimates in the original protocol were based upon a total sample size of 1000 CYPs and given for 10%, 20% & 30% attrition rates. Given the experience of the pilot study, here we have provided the MDES estimates with the same attrition rates but for a total sample size of 800 CYPs as this is a more realistic target given the pilot study experience. This is the intended sample size. From the pilot study and the ongoing data collection it is likely that the 30% attrition rate scenario will be the most realistic for estimates here. Additional MDES estimates for a number of attrition rates are presented a the end of this section.

As per the protocol the internal pilot study involved 60 CYPs in each arm of the RCT (Positive Pathways vs Control). These 120 CYOs combined with a further 680 from the efficacy trial leads to a total sample size of 800 CYPs (400 in the Positive Pathways arm and 400 in the control arm). From this we estimate that this sample is sufficiently large to detect an effect size of 0.18 or larger (assuming $\alpha = .05$ and power = .80).

For a balanced design (where half of the young people are allocated to each group), the minimum effect size that could be detected as statistically significant ($p<.05$, two tailed) with a statistical power of 0.80 can be calculated using Eq. 1 (Dong and Maynard, 2013, PowerUP! sheet 1.0 IRA).

[Eq. 1] $$MDES_{RCT} \sim 2M_{n-k-2}\sqrt{\frac{(1-R^2)}{n}}$$

Where

- n = 800 (No of CYP recruited at internal pilot and stage 2 evaluation stages combined)
- R^2 = the proportion of variance accounted for by the covariates in the primary outcome measure of SRDS Volume (the assumed R^2 = 0.20, drawing on internal data for the pilot stage of the YEF funded evaluation of Reach)
- k = the number of covariates included in the impact evaluation (=5): baseline SRDS volume, level of need dummy variable (tertiary =1 or secondary =0) and three referral route dummy variables (assuming four distinct referral routes).
- M = t-distribution multiplier that specifies a statistical significance of (p<) 0.05 (two tailed) and statistical power of 0.80 with n-k-2 (793) degrees of freedom.

The MDES calculated based upon 800 CYPs included at randomisation was 0.18 SDs.

We also examined the impact on MDES of possible attrition rates of 10%, 20% and 30%. With a 10% attrition rate the MDES would be 0.19 SDs, with 20%, the MDES would be 0.20 SDs and with 30% attrition rate the MDES would be 0.21 SDs.

Analysis

Analyses were determined prior to the impact evaluation as per the study protocol. Multiple linear regression will be undertaken to examine the impact of the intervention on both the-primary and secondary outcome variables IE-RQ1 to IE-RQ6 (see above). Primary and secondary outcome analyses will be conducted using STATA version 18 (StataCorp, 2023).

Primary outcome analysis

The primary outcome analysis will be an intention to treat (ITT) analysis. All CYP who are randomised will be included in this ITT analysis. For the primary outcome analysis, an Ordinary Least Squares (OLS) regression will be undertaken in which the SRDS Volume scores collected at endpoint will be the outcome variable and baseline SRDS Volume scores, group (intervention vs control) and variables used for stratification (referral routes & YEF level of need) will be the explanatory variables. Stratification variables will be represented in the analysis through a set of dummy variables. One dummy variable will represent the level of need factor (0 = Upper Secondary, 1 = Lower Tertiary) and three dummy variables will represent the referral routes with Education as the reference referral route. The regression model is specified in Eq. 2:

Eq. 2:

$$Y_i = \beta_0 + \beta_1 T_i + \beta_2 L_i + \beta_3 R1_i + \beta_4 R2_i + \beta_5 R3_i + \beta_6 SRDS_i + \varepsilon_i$$

Where:

- Y_i is young person $i's$ SRDS score
- T_i is a binary indicator coded to 1 if young person i is assigned to the intervention, 0 otherwise
- L_i is the binary indicator coded 1 if the person i is designated as lower tertiary level of need and 0 otherwise
- $R1_i \; to \; R3_i$ are the set of three dummy variables to represent referral route of person i
- $SRDS_i$ is the baseline SRDS volume score for person i
- ε_i is the error term

The coefficient for the intervention identifier will be used to estimate the impact of Positive Pathways and this will be converted into a Hedges g effect size by dividing by the total standard deviation. The same conversion will be undertaken for the upper and lower 95% confidence intervals for the group membership coefficient.

$\beta_0 - \beta_6$ are unknown parameters estimated from the sample data. Attention focuses on the estimate for $\beta_1$which is the sample estimate of the effect on the programme on the primary outcome. Robust hc2 standard errors will be calculated using the vce(hc2) option within the regress call in Stata.

Secondary outcome analysis

The secondary outcome analysis will address IE-RQ1 to IE-RQ6 (see above). For these analyses an ITT approach will be adopted. Similar linear regression analyses will be undertaken to that for the primary outcome analyses with the same predictor variables but with the following as the outcome variables:

- SRDS variety score
- SDQ total difficulties subscale
- SDQ prosocial subscale
- SDQ hyperactivity subscale
- SDQ conduct problems subscale
- SDQ emotional problems subscale
- SDQ peer problems subscale
- ONS4 wellbeing measure

Eq. 3:

$$Y_i = \beta_0 + \beta_1 T_i + \beta_2 L_i + \beta_3 R1_i + \beta_4 R2_i + \beta_5 R3_i + \beta_6 SO_i + \varepsilon_i$$

Where:

- Y_i is young person $i's$ endpoint secondary outcome score
- T_i is a binary indicator coded to 1 if young person i is assigned to the intervention, 0 otherwise
- L_i is the binary indicator coded 1 if the person i is designated as lower tertiary level of need and 0 otherwise
- $R1_i \; to \; R3_i$ are the set of three dummy variables to represent referral route of person i
- SO_i is the relevant baseline score for person i
- ε_i is the error term
- $\beta_0 - \beta_6$ are unknown parameters estimated from the sample data. For each secondary outcome the attention focuses on the estimate for $\beta_1$which is the sample estimate of the effect on the programme on the seconday outcome.

It should be noted that the secondary analyses detailed here are exploratory in nature. We are interested in exploring the possible impact of the intervention on a range of secondary outcome variables. Given the number of analyses being undertaken in these exploratory analyses adjustment of the critrion for significant (α) will be adjusted to account for the possibility of increased type 1 errors. To strike the balance between type 1 and type 2 errors an α < .01 will be used as the criterion for significance.

Subgroup analyses

The sub-group analyses will be conducted to address the exploratory research questions. For example, for IE-RQ9 it is intended to examine whether there is differential impact of the intervention for CYPs with different (upper secondary/lower tertiary) level of need. In this analysis (for the primary and secondary outcomes variables) an interaction term which multiples the level of need term with the treatment group term will be added to the analysis. If the interaction term is statistically significant this presents evidence of differential impact of the intervention. In such a case simple slopes analyses would then be undertaken to further explore the nature of any differential impact.

Descriptive statistical analyses and chi-square analyses will be undertaken to address IE-RQ8. For these chi-square analyses frequency counts will be analysed to assess whether there was

any association between treatment allocation group and relevant sub-groups (e.g. ethnicity[4], CYPs with additional needs, CYPs from lower social economic backgrounds). In terms of ethnicity sub-group associations given the number of categories used in the data collection the chi-square analysis would involve collapsing across categories e.g. comparing, Asian vs Black vs mixed/multiple ethnic group vs White British vs White other groupings. These reflect well the make-up of most prevalent grouping across the regions.

Descriptive statistics (e.g. frequency counts) and appropriate chi-square analyses will be presented to address IE-RQ9 where the characteristics of those CYPs who were excluded at referral stage are explored in order to identify possible patterns of exclusion/attrition across participants and within specific groups (e.g. minority ethnic, SEND)

Further analyses

Additional exploratory analyses will be undertaken to examine the proposed theory of change. In the theory of change presented in Appendix 1 of the protocol the key secondary outcome variable identified was prosocial behaviour. Thus, mediation analyses will be undertaken to examine whether changes in prosocial behaviour mediate the impact of the intervention on the primary outcome of SRDS volume scores. A simple mediation analysis will be conducted using the 'mediate' command in STATA. In this analysis the categorical treatment group variable will be the predictor variable, endpoint SRDS volume score the outcome variable and endpoint prosocial subscale of the SDQ will be the mediator. We will also include baseline SRDS volume and prosocial behaviours scores in the analyses as covariates. The direct and indirect paths will be evaluated for statistical significance as well as reporting on the component paths (treatment group predicting SDQ prosocial scores & SDQ prosocial scores predicting SRDS volume scores) for the indirect effect. It is important to note that these are exploratory analyses only and we cannot suggest any causal relationships

[4] Categories used on ethnicity data collection are Asian, Asian British or Asian Welsh: Bangladeshi, Asian, Asian British or Asian Welsh: Chinese, Asian, Asian British or Asian Welsh: Indian, Asian, Asian British or Asian Welsh: Pakistan, Asian, Asian British or Asian Welsh: Other Asian, Black, Black British, Black Welsh, Caribbean or African: African, Black, Black British, Black Welsh, Caribbean or African: Caribbean, Black, Black British, Black Welsh, Caribbean or African: Other Black, Mixed or Multiple ethnic groups: White and Asian, Mixed or Multiple ethnic groups: White and Black African, Mixed or Multiple ethnic groups: White and Black Caribbean, Mixed or Multiple ethnic groups: Other Mixed or Multiple ethnic groups, White: English, Welsh, Scottish, Northern Irish or British, White: Irish, White: Gypsy or Irish Traveler, White: Roma, White: Other White, Other ethnic group: Arab, Other ethnic group: Any other ethnic group, Prefer not to say

between treatment, prosocial behaviours and volume of offending from such this analysis, particularly given that the prosocial behaviour and volume of offending scores in the analysis are both measured at endpoint.

Longitudinal follow-up analyses

No longitudinal follow-ups will be undertaken as part of the Positive Pathways evaluation.

Imbalance at baseline

The characteristics of the treatment and control groups will be compared on the variables measured at baseline (i.e. prior to randomisation). These variables will include the baseline primary and secondary outcomes as well as ethnicity, age, sex at birth, send status, whether they have been arrested and/or convicted of a crime and looked after child (LAC) status. For categorical variables, counts and percentages will be reported and for scale/continuous variables means and standard deviations will be reported. Additionally, for the scale/continuous variables Hedges *g* effect sizes will calculated by dividing the difference between the treatment and control groups by the pooled standard deviations.

Furthermore, robustness checks will be undertaken in line with the guidance provided in the YEF Analysis Guidance. Initially, assumptions underlying OLS regression will be checked and reported as appropriate. Additionally, covariates that were identified as imbalanced at baseline will be added to the primary outcome model (see Eq. 1 above). The addition of these covariates should not impact the point estimates of the impact of the intervention for robustness to be supported.

Missing data

Missing data will be dealt with by adhering to the YEF guidelines on missing data (see Table 1 of YEF Analysis Guidance). The amount of missing data for the primary outcome (SRDS volume) will be reported and reasons for missingness explored in terms of whether the data is missing completely at random (MCAR), missing at random (MAR) or not missing at random (MNAR). If there is greater than 5% of missing primary outcome data then a logistic regression analysis will be undertaken to explore the potential reasons for missingness. In this analysis there will be a binary variable representing the presence/absence of the endpoint SRDS volume as the outcome variable and baseline measure of secondary outcome variables included as the explanatory variables. If none of the explanatory variables are significant predictors of the missing data then imputation is not recommended and as recommended sensitivity analyses will be conducted in addition to the ITT analysis.

If any of the covariates in the logistic regression model are significant predictors of the missing data then this suggests that the missing data are MAR. In this case multiple imputation of the

missing values on the primary outcome variable will be conducted using the MI Impute command in STATA. The multiply imputed data will then be used to run the linear regression analysis (see equation 1 above) and the pooled estimate of the treatment effect (β_1) will be compared with that from the complete case analysis and this discussed in the final report.

Compliance

Young people must take part in two or more mentoring sessions (i.e. initial session, plus one later session) and the residential to be considered to have meaningfully experienced the core programme. Ingeus to provide 'catch up' mentoring sessions as and when necessary (e.g. due to illness etc).

Compliance is assumed to be one-sided as while those allocated to the treatment group can be non-compliers those allocated to the control (business as usual) group will not have had the opportunity to experience the various elements of the intervention. CYPs will be identified as 'compliant' 'or non-compliant' and these classifications will be used in the Compliers Average Causal Effects (CACE) analysis. For this CACE analysis an instrumental variable (IV) approach will be utilised and this implemented using a two-stage least squares approach. The first stage involves modelling the compliance outcome (C_i) by inclusion of the treatment identifier (T_i)included in the model as a covariate. The second stage then enters the predicted compliance outcome values (C_j') calculated from the first stage analysis as a covariate instead of the treatment identifier (T_i) in predicting the primary outcome variable (Y_i). These two stages are described in the equations Eq. 3 (stage 1) and Eq. 4 (stage 2) below:

Eq. 3:

$$C_i = \beta_0 + \beta_1 T_i + \beta_2 L_i + \beta_3 R1_i + \beta_4 R2_i + \beta_5 R3_i + \beta_6 SRDS_i + \varepsilon_i$$

Eq. 4:

$$Y_i = \beta_0 + \beta_1 C_j' + \beta_2 L_i + \beta_3 R1_i + \beta_4 R2_i + \beta_5 R3_i + \beta_6 SRDS_i + \varepsilon_i$$

These two stages will be undertaken using the 'ivregress' command in STATA in a single call.

Intra-cluster correlations (ICCs)

As this is not a clustered randomised control trial, ICCs will not be calculated.

Presentation of outcomes

The effect size measure to be used with be Hedge's *g*. This will be calculated as per equation 6

Eq. 6

$$\mathrm{ES} = \frac{(\bar{Y}_T - \bar{Y}_C)_{Adjusted}}{S^*}$$

Where, $(\bar{Y}_T - \bar{Y}_C)_{Adjusted}$ is the regression adjusted difference in the primary outcome (SRDS-V endpoint) between the intervention and control conditions and S^* is the pooled variances of the two conditions. 95% confidence intervals for the treatment regression coefficient along with p-values will be reported to reflect statistical significance as well as statistical uncertainty. The 95% confidence intervals for the effect size will be calculated by dividing the upper and lower bounds of the 95% confidence intervals for the β_1 coefficient for the treatment effect by the pooled variances ($S^*$from Eq. 5).

References

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YOUTH ENDOWMENT FUND

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