PILOT TRIAL PROTOCOL

Boxing-based mentoring

Manchester Metropolitan University

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YOUTH ENDOWMENT FUND

Pilot trial protocol template (includes a control group)

Evaluating institution: Manchester Metropolitan University

Principal investigator(s): Kevin Wong, Paul Gray and Stephen Morris

Project title[1]	*Boxing based mentoring*
Developer (Institution)	*Empire Fighting Chance (EFC)*
Evaluator (Institution)	*Manchester Metropolitan University*
Principal investigator(s)	*Kevin Wong, Dr Paul Gray, Professor Stephen Morris*
Evaluation plan author(s)	*Stephen Morris, Kevin Wong, Paul Gray and Stephanie Wallace*
Evaluation setting	*Schools*
Target group	*School pupils from Years 8 and 9 in November 2021*
Number of participants	*12 schools, 144 pupils*

Protocol version history

Version	Date	Reason for revision
1.2 [*latest*]		
1.1		
1.0 [*original*]		*[leave blank for the original version]*

[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).

1.Intervention

The description of the intervention below ***has been summarised from information provided by the developer***.

The Empire Fighting Chance (EFC), boxing based mentoring programme is intended to run for 12 weekly sessions, combining non-contact boxing physical activites with personal development This programme is an amalgam of two programmes which EFC have previously developed and run Training with the champions; and Therapeutic Boxing.

The physical activities are delivered by EFC coaches and include: skipping, circuit training, punch pads and boxing techniques. The activities are intended to engage the young people and to be used as opportunities for the coaches to speak with them in relation to Personal Development Points.

The most common Personal Development Points which make up the 12 week programme are described by EFC as follows:

Week 1 – The magic of moods

Week 2 – Awesome exercise

Week 3 – Positive reactions

Week 4 – Going with the flow

Week 5 – Remove the victim

Week 6 – You are what you eat

Week 7 – Relaxed excellence

Week 8 – Focus on action not outcome

Week 9 – The magic of mini-goals

Week 10 – Feel the fear

Week 11 – The growth mindset

Week 12 – The happiness myth

Further details about the intended content of these sessions is provided in Appendix 1 based on information provided by EFC

The boxing based mentoring programme is not intended to be a prescriptive programme. The coaches have been trained on how to weave the Personal Development Points into their sessions with the young people. It is anticipated that the coaches will work with the young people in response the needs identified at each session. Therefore it is expected that no 12-week programme will look the same.

Information from EFC to support the rationale for the programme has also been included in Appendix 1.

Intended Social and Psychological Outcomes

EFC have stated that the boxing based mentoring programme is intended to achieve the following outcomes.

OUTCOME 1» Young people will report experiencing positive changes in how they see, and feel about themselves as a result of their participation in Empire's programme. » Young people will report increased aspiration, desire to achieve and are not afraid to try, fail and try again. » Young people will report making new positive friendships and are unafraid to mix with different people.

OUTCOME 2» Young people will report they're more likely to persist with and focus on achieving objectives even in difficult circumstances and are able to reject negative influences. » Young people will report remaining positive and optimistic despite suffering criticism and setbacks, and make their own decisions. » Young people will report being able to regulate inappropriate behaviour and outbursts when under pressure.

OUTCOME 3» Young people, who we support, report being more able to return to school, stay in school or start new education/training courses. »Young people will report they are more able to take advantage of the opportunities available to them. » Young people will report that they're less afraid of failing.

These outcomes will be measured through the validated survey tools as determined by the YEF and detailed in Section 4.

2.Research questions and/or objectives

The aim of this pilot study is to:

1. Assess the extent to which an efficacy study evaluating the effectiveness of Empire Figting Chance's programme *Boxing based mentoring* might be feasible

2. To acquire detailed information to inform the design of such an efficacy study

3. To provide preliminary evidence of promise

In order to meet the aims of this pilot study a programme of mixed methods research has been designed to address a number of research questions. These research questions fall under three broad headings: 1) trial implementation questions, 2) trial statistical design questions, 3) intervention implementation questions.

Before outlining these questions in detail, we first discuss the assumptions that form the basis for this pilot study and which underpin the choice of questions. These assumptions draw on findings from a feasibility assessment of the intervention that is the focus on this pilot. These starting assumptions are as follows:

- The intervention will be delivered through schools
- It will target pupils that meet specified inclusion criteria discussed further below
- EFC will work with schools to recruit in the first instance a minimum of 20 students from Years 8 and 9 per school who meet their referral criteria. This is in order to achieve the target of 12 pupils per school after attrition.
- The trial under consideration is a cluster or group randomised trial, whereby students participating in the intervention will be randomised to intervention and control groups on the basis of the school in which they are located – thus randomisation takes place at the level of the school.
- The effects of the intervention will be measured at the level of the student – thus the study sample will have a nested or multi-level structure consisting of students grouped or clustered within schools

The justification for a group or cluster randomised controlled trial design (cRCT) is that evidence from the feasibility work suggests that schools form a promising channel through which to recruit and work with children, particularly in the case of sports based interventions, such as that studied in this pilot trial. Where interventions are delivered to pupils in school settings, concerns emerge around the potential for interference between experimental units, in this case between pupils. Put differently, we expect spillover effects between intervention and control units within the same settings, thus we randomise settings. The stable unit treatment value assmptions or SUTVA (Gerber, Alan & Green, Donald, 2012; Rubin, 1990) is called into question and the assumptions that underpin identification of unbiased causal effects through randomisation (see Holland, 1986, for a discussion of statistical interference and the implications for randomisation). In order to negate this potential violation of the causal model that justifies randomisation, it is common practice to randomise experimental units at higher levels of aggregation; that is at levels where such interference is judged to be absent. So in the case of school-based

interventions, this typically means randomisation of whole schools such that all eligible pupils in a school are either assigned to intervention, or to control; in some cases, randomisation of classes is undertaken. In the case of this intervention, it would appear that randomisation of whole schools is the most viable option. This pilot trial is designed to provide crucial information that can be used to design an efficacy cRCT of EFC's *Boxing based mentoring*. Although such a cRCT design avoids the problem of statistical dependence between units, this solution comes at a price; namely, larger sample sizes are required than would be the case for an individual pupil level RCT. Thus the costs of such trials can rise appreciably, particularly where primary data collection is required.

3.Trial implementation questions

The proposed pilot is designed to address a number of questions relating to the practical requirements of an efficiacy cRCT. An indication of the source of data (quantitative or qualitative) required to address the relevant question are provided in brackets:

Recruitment and eligibility

1. Can EFC identify and gain the agreement of schools to participate in the trial in the numbers required [QUANT]?
2. Do the developers feel confident explaining the trial to the schools [QUAL]? Are they sufficiently clear in their description of randomisation and its consequences [QUAL]? Do schools understand the messages about randomisation that they receive [QUAL]?
3. How acceptable is the experimental design to the various stakeholders (the developer and to schools)? Does it lead to difficulties in recruitment [QUAL]?
4. What reasons are given for schools not wanting to participate [QUAL]?
5. Can schools recruit students to the programme (in accordance with the timeline) in advance of randomisation in sufficient numbers and consistent with the inclusion criteria [QUANT and QUAL]?
6. Can the team successfully access baseline information from schools for those pupils deemed as meeting the inclusion criteria? (e.g. full name, date of birth DoB, unique pupil reference number UPN, URN, gender, exclusions in last school year, absences, ever-FSM/PP – discussed in greater detail below) [QUANT]

7. Can the study meet the legal/GDPR requirements for linking trial data to the National Pupil Database via the Office for National Statistics (ONS) Secure Research Service (SRS)? [QUAL]

8. How many parents withdraw their child from the study? What were the reasons given for withdrawing? [QUANT/QUAL]

Randomisation

9. Subsequent to recruitment of the target sample, can randomisation procedures be successfully initiated – what is the reaction of schools to the outcome of randomisation? [QUAL]

10. How many schools/pupils withdraw from the study post-randomisation and what were the reasons given for withdrawl? [QUANT/QUAL]

Data collection – primary and secondary data

11. Can baseline data in the form of questionnaires be successfully collected from identified eligible pupils in all participating schools prior to randomisation? What response rate is achieved? Can any barriers to successful completion of questionnaires be identified? [QUANT/QUAL]

12. Can follow-up data at five months post randomisation, in the form of questionnaires, be collected successfully from all pupils in both schools randomised to intervention and to control? What is the overall response rate? And the response rates in intervention and control schools? What factors act as barriers to completion of questionnaires and do these differ in intervention and control schools? [QUANT/QUAL]

4.Statistical design questions

The statistical data collected through the pilot trial can be used to provide information to perform sample size calculations for a larger efficacy cRCT. Sample size determination will proceed on the basis of calculating the number of schools required using the following equation (Dong & Maynard, 2013):

$$J=\left(\frac{M_{Jr_2-g^{\zeta}-2}}{MDES}\right)^2\left(\frac{\rho}{P(1-P)r_2}+\frac{(1-\rho)(1-\bar{R}^2)}{P(1-P)nr_1r_2}\right)....[1]$$

Where J is the number of schools, $MDES$ the effect size the main trial is powered to detect, r_2 and $r_1$the response rates at the school and pupil levels, 'n' the average number of pupils per school recruited to the trial, 'ρ' the intra class correlation coefficient, 'P' the proportion

of all participating schools assigned to the intervention, and R^2 the proportion of the outcome response variance explained through the inclusion of a baseline measure on the response in the form of a covariate in a treatment effects regression model.

Given this set up, this pilot will seek to answer the following questions that relate to the statistical design of the proposed efficacy study:

1. What is the point estimate of ρ obtained from the pilot sample, and the upper limit of the 80 per cent confidence interval for ρ?
2. What is the point estimate of r_1 obtained from the pilot sample, and the lower limit of the 80 per cent confidence interval?
3. What is the point estimate of r_2 obtained from the pilot sample, and the lower limit of the 80 per cent confidence interval?
4. What is the point estimate of R^2 obtained from the pilot sample?
5. What are a range of possible sample sizes required for an efficacy study based on estimates of the quantities above?

In addressing question 5, we will assume $P=0.5$, $n=12$ and MDEs for 0.3, 0.2 and 0.1 respectivel,y and that for the proposed efficacy study Type I and II error rates will be set at 5 and 20 per cent respectively. For a justification for the choice of the given limit to the 80 per cent confidence interval for sensitivity tests on sample size, see Bell et al. (2018), King (2011), Norman et al.(2004) and Browne (1995).

Finally, we will provide some indication of likely treatment effects and evidence of promise. But before setting out the questions to be addressed in relation to 'evidence of promise', we first discuss the content of the two main measures that will be the focus of the research and provide details of their administration.

In accordance with guidance from the YEF we will be deploying two validated scales. The Strengths and Difficulties Questionnaire (SDQ) and the Problem Behaviour Frequency Scale (PBFS).

Details of the outcomes they measure and how they are scored are below.

SDQ

The Youth in Mind Strengths and Difficulties Questionnaire (SDQ) is a 25-item questionnaire measuring behaviours, emotions, and relationships. Given the age of the participants in the study, the self-report version will be utilised and administered electronically pre- and post-intervention/follow-up. The pre-survey asks about the young person's behaviour over the

last 6 months and provides the baseline measure. The post survey or follow-up asks about their behaviour in the last month.

The questionnaire includes five subscales that measure:

1. Emotional symptoms;
2. Conduct problems;
3. Hyperactivity/inattention;
4. Peer problems;
5. Prosocial behaviour.

Each item is scored on a 3-point Likert scale (0, 1, 2) with scores ranging from 0-10 for each subscale. For emotional symptoms, conduct problems, hyperactivity/inattention, and peer problems a higher score indicates more difficulty. Whereas for the prosocial subscale, a lower score indicates less prosocial behaviour and thus more difficulty.

The SDQ can be aggregated to produce a total difficulties score by summing the scores for emotional symptoms, conduct problems, hyperactivity/inattention, and peer problems, excluding the prosocial subscale. The total difficulties score then ranges from 0-40.

In addition to the 25-item SDQ, an impact supplement is also available for those respondents that recognise their behaviour as problematic. These items can also be aggregated to create an impact score ranging from 0-10.

PBFS

The Self-Reported Delinquency - Problem Behaviour Frequency Scale (PBFS) measures the frequency of delinquent behaviour within the previous two months. The timeframe remains the same for the pre- and post-intervention/follow-up survey. The PBFS comprises of 8 items/behaviours, and the frequency of engagement for each is assigned the following values:

- Never = 1
- 1-2 times = 2
- 3-5 times = 3
- ó-9 times = 4
- 10-19 times = 5

- 20 or more times = 6

The values are then summed, with higher scores indicating higher levels of delinquency. Bearing in mind the content of these two measures, the two questions to be addressed in relation to evidence of promise are:

6. What is the adjusted difference in mean scores on the total difficulties score, and emotion, conduct, hyperactivity/inattention and peer subscales separately derived from the SDQ between intervention and control group pupils at follow-up with 75%, 85% and 95% confidence intervals?
7. What is the adjusted difference in mean score on the problem behaviour scale between intervention and control group pupils at follow-up with 75%, 85% and 95% confidence intervals?

Details of the proposed statistical models to be used to obtain estimates consistent with questions 1-5 and 6-7 are discussed further below. 75%, 85% and 95% confidence intervals are obtained in order to take account of the uncertainty associated with the small pilot-sample-size and provide for sensitivity testing the results.

5.Intervention implementation questions

Some aspects of the intervention will necessarily change due to reasons such as (1) the experimental study design and its implications for the delivery of the intervention; and (2) due to the scale of the activities required. Thus the pilot study will address the following questions primarily through qualitative research, although Question 3 below will also be addressed through analysis of monitoring data collected by EFC:

1. To what extent has the intervention as described in the feasibility study been adapted?

2. Where there any challenges in delivery? What were the nature of these? What adaptations were deemed necessary and did these adaptations address the perceived challenges successfully?

3. How did students respond to the intervention? To what extent did they engage? Did students complete the programme? What proportion dropped out?

4. Were there any unintended consequences for the students to attending the intervention instead of their usual activity at school?

5. How do the students feel about being brought together in groups with other students for this intervention?

6.Success criteria and/or targets

The following success criteria are defined for this pilot study. These critieria are assumed to be reasonable based on experience of previous studies and the best judgements of the researchers that carried a feasibility test of EFC's Boxing based mentoring programme:

- EFC can recruit 12 schools to the pilot and that at least 10 of these schools remain in the study until the follow-up data are collected from pupils
- Schools can recruit at a minimum 80 per of the target for pupil recruitment – that is around 10 pupils per school at a minimum
- That a baseline response rate to the questionnaire reaches at least 80 per cent and that loss to follow-up does not exceed 70 per cent.
- There is some evidence of promise from the outcome measure(s) and the implementation evaluation

7.Methods

An overview of the methods deployed in this study is provide in Table 7.1 below.

Table 7.1 Methods overview

Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed
Quantitative – school records	Data on 144 pupils including: demographics, school attendance free school meals, pupil premium, educational attainment	Simple descriptive summary statistics and comparisons between intervention and control groups	Trial implementation questions
Quantitative – questionnaire data using validated tools	Pre and follow-up surveys administered to 144 pupils	Descriptive analysis reporting response rates at baseline and follow-up	Trial implementation questions

Quantitative – monitoring data on intervention take-up	Data on 144 pupils recorded by EFC	Descriptive analysis	Intervention implementation questions
Qualitative interviews with pupils, project staff, teachers	Pupils n=10 Project staff n=5 Teachers n=3	Thematic analysis related to the study implementation questions and intervention implementation questions	Trial implementation questions Intervention implementation questions

7.1 Pilot trial design

This pilot trial will be a two-arm, parallel, pragmatic, cluster randomised controlled trial (cRCT). Schools recruited to the trial will be allocated at random to intervention and control groups on a 1:1 basis. Pupils identified in range of the trial in schools allocated to the intervention group will be invited to take part in the intervention. Outcomes will be measured at the pupil level through the administration of questionnaires, with measures obtained both prior to randomisation, that is at the baseline, and at five months subsequent to randomisation at follow-up. Schools are also asked to provide a range of specified data items from their data systems prior to randomisation for each participating pupil, thus forming part of the pupil baseline record, along with measures from the baseline questionnaire.

7.2 Randomisation

Participating schools, enrolled in the study by EFC, will be divided into strata based on their geographical proximity (not which local authority they are sited in). At time of writing, the pairs of schools that EFC have selected and grouped together, including their local authorities (LAs) are:

1. Cotham School

   LA – Bristol

   City Academy

   LA – Bristol

2. Patchway Community School

   LA - South Gloucestershire

   Bradley Stoke Community School
   LA - South Gloucestershire

3. Fairfield High School

   LA – Bristol

   Abbeywood Community School
   LA - South Gloucestershire

4. St Peters Catholic High School

   LA - Gloucestershire

   Tudor Grange Academy
   LA - Worcestershire

5. Mountain Ash Comprehensive School

   LA - Rhondda Cynon Taf County Borough Council

   Cyfartha High School
   LA - Merthyr Tydfil County Borough Council

6. St Albans R.C High School

   LA - Torfaen County Borough Council
   Breacon High School
   LA - Powys County Council

In order to facilitate the trial and particularly the implementation of the intervention, it is proposed that randomisation is performed in pairs, where schools are paired on the basis of locality. Once a pair is formed each school within the pair will be allocated a random number from a zero/one uniform distribution to four decimal places. Within each pair, the school assigned the highest random number will be allocated to the intervention, with the

remaining school allocated to control. The randomisation will be performed in STATA v17 statistical software.

Randomisation will be performed in a single batch. The random number sequence will be generated by a researcher blind to the identities of the schools concerned, who will also conduct the randomisation.

The outcome of randomisation will be stored in the designated trial data file. The outcome of the randomisation process will then be communicated to EFC.

7.3 Participants

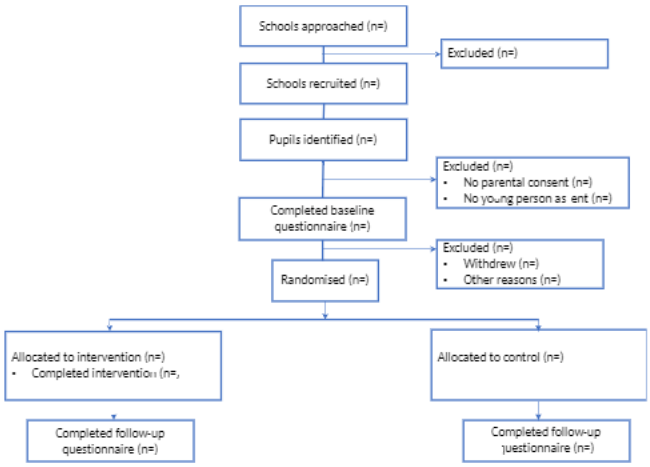
Within each participating school, EFC and school representatives will identify a minimum of 20 pupils who they will encourage to take part in the intervention. Prior to randomisation, the parents of pupils identified in this manner are asked to consent to their child taking part in the study. Pupils will also have to assent. For those pupils that assent and where parental consent is received, they are are asked to complete a baseline questionnaire and the school is asked to provide pre-agreed data items from their systems for each pupil (see below).

The following criteria will be applied to identify pupils who will be invited to take part in the intervention.

The pupils are from years 8 and 9 in November 2021 that meet the following criteria;

- incidences of the young person's behaviour have been recorded within the SIMS log (or alternative systems). At least 1 incident but no more than 5 incidences recorded prior to the point in November 2021 when they were recruited to the pilot RCT.
- attendance is becoming an area for concern. At least 1 unauthorised absence but no more than 5 unauthorised absences prior to point in November 2021 when they were recruited to the pilot RCT.
- the young person should exhibit some level of interest in sport/movement - to be assessed by PE teacher.

Figure 7.1: Outline participant flow chart



7.4 Sample size

Sample size determination in the case of pilot studies is generally a matter of judgement.

A number of contributions to the literature have suggested rules of thumb in determining pilot sample sizes. Those discussed by Bell et al. (2018) relate to prior expectations around the effect size (minimally important difference – MID) an efficacy study should be powered to detect. The Table below, reproduced from Bell et al. (2018, page 155), shows the relationship between pilot and efficacy study sample sizes based on expectations around relevant MIDs.

Table 7.2 Stepped rules of thumb for pilot study sample size per arm (adapted from Bell et al. (2018)

Standardised effect size 'd' a proposed efficacy study might be powered to detect (MIDs)	80 per cent powered main trial (assuming individual pupil randomisation)	
	Pilot 'n' per arm	Main trial 'n' per arm
Extra small ($d < 0.1$)	50	>1571
Small ($0.1 \leq d < 0.3$)	20	176-1571
Medium ($0.3 \leq d < 0.7$)	10	34-176
Large (≥ 0.7)	10	≤ 34
Source: adapted from Bell et al. (2018), Table 1		

The question becomes what might be a reasonable MID for an efficacy trial in our circumstances? To answer this question, we consider an outcome derived from the SDQ and turn to the British normed SDQ data provided on the Youth in Mind website[2]. We

[2] https://www.sdqinfo.org/norms/UKNorm3.pdf

assume that an efficacy trial is designed such that a total difficulties score is the primary outcome and that this measure is derived from self-completion questionnaires completed by students aged 11-15 years old. The mean score according to the normed data is 10 (SD 6). If we assume that most of our participants will have scores in the borderline range or slightly raised range, it might be reasonable to assume a mean score for our sample of 16 points. Further, let us assume that the intervention might lower the mean score by 1.5 points. Very crudely this would translate to an effect size of 0.25. According to the table above, this would categorise an effect size of this magnitude as small ($0.1 \leq d \leq 0.3$). Consistent with this, a trial sample size of 40 participants in total would be required. However, this calculation is based on an individual level trial and our pilot would be a cluster trial. Eldridge & Kerry (2012) recommend adjusting sample sizes up for pilot cluster trials. One way in which we can adjust the sample size to take account of clustering is to determine its 'design effect' and use the following equation to obtain a rough estimate of the sample size required in terms of the number of schools (Eldridge & Kerry, 2012):

$$k = N(1 + \rho(m-1))/m$$

Where k is the number of schools required, N the size of the sample in terms of the number of pupils in the case of an individual level randomised design, ρ the proportion of the total variance in the SDQ score that is between rather than within schools (effectively how different pupil samples are across schools or the intraclass correlation coefficient) and m the average number of pupils recruited per school. We have a provisional estimate of N, i.e. 40 pupils (based on Table 1 above) and we have set a target for the number of pupils recruited in each school such that m = 12. The unknown is ρ but we might take a conservative value for ρ, one used typically in planning education trial of 0.20. Based on these values the equation above will yield k = 11. As such the chosen number of schools which we round-up to the nearest even number is 12.

It is important to note that pupils in schools randomised to control will be offered the intervention **after** follow-up data have been collected from control and intervention samples. This means that in total, providers should be resourced to deliver the intervention in 12 schools for 144 pupils, as well as funded to manage data collection, GDPR/data protection issues and other aspects of the relationships with the schools.

8.Data collection

This is a mixed methods pilot trial comprising both quantitative and qualitative data collection.

8.1 Quantitative data collection methods

Quantitative data will be collected from pupils participating in the trial at two stages: 1) prior to randomisation in the Autumn of 2021; and 2) at follow-up five months later. Baseline data records for each participating pupil will be compiled from two sources. First, for each pupil for whom consent is being sought we will ask schools to provide the following information from their data systems for each pupil:

- Unique Pupil Number (UPN)
- School unique reference number (URN)
- School postcode (back-up in case of URN change)
- Full name of pupil
- Date of birth
- Sex
- Racial or ethnic group
- Year group
- Free School Meal (FSM) status
- Pupil Premum (PP) status
- Special Educational Needs and Disability (SEND)
- Educational Health Care Plan (ECHP or support)
- English as Additional Language (EAL) status
- Number of temporary exclusions in the previous school year
- Number of authorised absences in the previous school year
- Number of unauthorised absences in the previous school year
- Scaled score and test score for KS2 Reading
- Teacher assessment for KS2 Writing
- Scaled score and test score for KS2 Maths[3]

These records will be appended to the pupil level record that will be generated in a trial database held as a STATA v17 data file.

Second, and also prior to randomisation, each pupil invited to take part in the intervention in both control and intervention groups will be asked to complete a baseline questionnaire. Administration of the survey will be overseen by EFC and implemented by the schools. The baseline questionnaire will be administered online and will include items from the *Strengths and Difficulties Questionnaire* (SDQ) and *Problem Behaviour Frequency Scale* (PBFS), details of which have been provided above. To ensure linkage between the surveys and other records the

[3] Schools do receive a raw score – see https://www.gov.uk/guidance/understanding-scaled-scores-at-key-stage-2. Scaled scores run from 80 to 120. Raw scores can be obtained using a conversion: https://www.gov.uk/government/publications/2019-scaled-scores-at-key-stage-2

baseline questionnaire will collect the pupils' full names and date of birth. Other data collected will include:

- Informed asssent of the pupil to complete the questionnaire; and
- Questionnaire completion date.

Records from the baseline survey questionnaires will be appended to the trial database by linking each survey form to the existing trial record using the pupil's full name and date of birth.

Using a procedure similar to those described above, pupils in the trial sample will be surveyed again five months post randomisation. The follow-up questionnaire will contain the same survey items with the inclusion of:

- Duration of time spent on the programme

Using the same procedures described above, follow-up survey questionnaire data will be appended to the pupil records held in the trial data base.

In addition to these data sources, EFC will collect data on dosage, intensity and duration of the intervention:

- Number of sessions attended by pupils undertaking the intervention;
- Nature of the sessions;
- Duration of the sessions;
- Dates of the sessions;
- Who the sessions were delivered by;
- Completion/non completion of the full programme

8.2 Qualitative data collection

To qualitatively evaluate the implementation of the pilot, a series of qualitative interviews will be undertaken with EFC project staff (n=5), a sample of young people from the intervention and control schools (n= total of 10), and teachers and other professionals (n=3) involved in the process.

The interviews will be undertaken following informed consent from the participants applying the information and consent process approved through the university's ethics application process. At this stage, it is envisaged that interviews with project staff, teachers

and other professionals will be undertaken by telephone/virtually. Interviews with young people will be undertaken face to face. However, this will be dependant on any potential public health restrictions and university guidance arising in response to COVID-19.

9.Data analysis

9.1 Quantitative data analysis

Quantitative data analysis will involve a range of simple descriptive statistics as well as fitting a series of multiple regression models to the trial data set.

Simple counts and percentages of the following will be provided:

- The total number of pupils recruited to the trial, including numbers by school, numbers by sex and school
- The total number of pupils recruited to the trial for whom any baseline data from school records was received, and the percentage of records complete by school and in total
- The total number of pupils in intervention schools that withdrew from the intervention before its end, by school and in total
- The total number of pupils that withdraw from the trial, in total, in total by intervention and control group, and in total by school.
- Total number of schools that withdraw from the trial, and totals by intervention and control groups

Estimation of required parameters to inform sample size determination for an efficacy trial will the take the following forms:

First, point estimates of the intraclass correlation coefficient, with 80 per cent and 95 per cent confidence intervals will be obtained from two regression equations of the following form:

$$Y_{ij} = \beta_0 + \delta_i + \varepsilon_{it} \text{ .. ..[2]}$$

$$Y_{ij} = \beta_0 + \beta_1 T_i + \beta_2 X_{ij} + \delta_i + \varepsilon_{it} \text{.....[3]}$$

Where Y_{ij} is continuous response for pupil j in school i; T_i a binary indicator variable coded '1' if school i is allocated to the intervention, zero otherwise; β_0 is an intercept and the sample estimate of β_1 represents the estimated average causal effect of the intervention; X_{ij} is covariate capturing pupil j in school $i's$ baseline response; δ_i and ε_{it} are random effects at the school and pupil levels respectively. The random effects are assumed to be normally distributed in the population with mean zero and variances σ^2 between cluster variance and τ^2 within cluster variance respectively; thus the intraclass correlation

coefficient or ρ is equal to σ^2/σ^2+¿τ^2¿. In order to inform sensitivity tests, sample estimates of ρ will be obtained from both model [2] the unconstrained or variance components model and model [3] the adjusted treatment effects regression. 95 and 80 per cent confidence intervals will be reported.

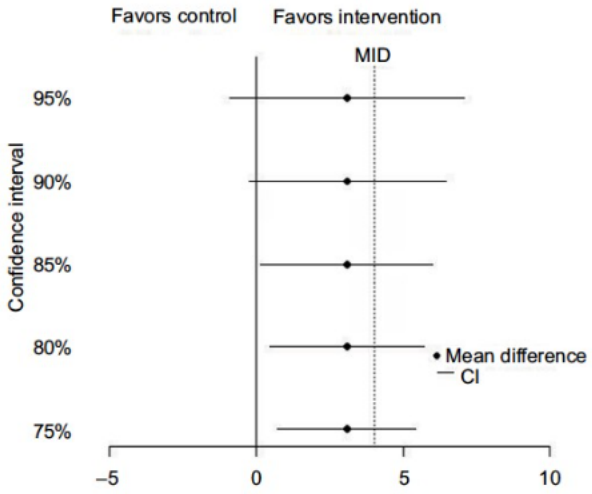
Second, simple univariate sample estimates of the proportions of all randomised pupils completing questionnaires at the baseline and the follow-up will be presented, for the sample as a whole, then for intervention and control groups separately. Each univariate estimate will be accompanied by 95 per cent and 80 percent confidence intervals to provide for sensitivity analysis in sample size determination for the efficacy study.

Third, to obtain an estimate of the proportion of variance in the response explained by the inclusion of a covariate at the pupil level capturing a baseline measure of the response, we will regress the follow-up response on the baseline response for the full sample and report the r-squared from this regression.

Using equation [1] we will plug in the sample estimates discussed to provide a range of estimated sample sizes for an efficacy trial.

Finally, to obtain sample estimates of the differences in means by intervention and control group, for two continuous response outcomes, we will estimate model [2], obtaining sample estimates of β_1 from all two models. Each of these estimates will be accompanied by 75%, 85% and 95% confidence intervals and plotted in a chart similar to that proposed by Bell et al. (2018) and presented below in Figure 2 below. To facilitate this we will convert sample estimates of β_1 to standardised mean differences according to Hedges by dividing the regression estimates through by the pool unconstrained standard deviation for the relevant response. The function `esize` in STATA v17 will be use to obtain confidence intervals. In Figure 2, MID represents the minimally important difference, which for this pilot is set at 0.25 standard deviations. Figures such as that presented at Figure 9.1 provide an indicator as to whether an 'intervention' can be deemed 'promising' or not; that is whether confidence intervals at various levels of statistical significance (presented in order to account for the diminished pilot sample size) contain the MID, which in our case we are proposing is set at 0.25.

Figure 9.1: Figure 1 from Bell et al. (2018) to illustrate proposed approach to presenting results from multiple regression models of estimated treatment effects



These estimates will not be interpretable as estimated causal effects but merely evidence of promise, or otherwise. If the confidence intervals at each level of statistical significance contain the MID of 0.25, this will be taken as providing such evidence, regardless of whether confidence intervals contains zero.

9.2 Qualitative data analysis

The interviews will be recorded and transcribed to ensure an accurate record. We will adopt a thematic approach to the analysis. We will work through a series of interconnected phases, familiarising ourselves with each interview, identifying a thematic framework (initially shaped by the interview schedule) and systematically working through each of the interviews to identify key themes that emerge from the data related to the: trial implementation questions; and intervention implementation questions (Ritchie et al, 2014, Braun & Clarke, 2006). Adopting this approach will allow us to understand the experiences of young people, project and school staff, exploring their perceptions of the processes undertaken and the chronology of events, why activities/processes worked well/less well and their reactions (positive and negative) to these.

10.Outputs

The research team will produce the following outputs:

- A revised theory of change logic model for the Empire Fighting Chance YEF programme with a focus on the Boxing based mentoring Programme.
- A report which will set out the findings in answers to the research questions posed by this pilot study – see above Trial implementation questions and Intervention implementation questions.
- This will include an assessment of the feasibility of undertaking an efficacy study with recommendations for the design of an efficacy study based on the findings from this research project.

11.Ethics and registration

The research team have sought *and received* ethical approval from the University's Arts & Humanities Committee for the research activities specified in this protocol. It should be noted that this required the submission of a lengthy and detailed application which was subject to review by two independent (and anonymous) peer reviewers and scrutiny by the Arts and Humanities Head of Ethics. It is a requirement that no fieldwork/research is undertaken until ethical approval has been granted.

The ethical approval for this study was registered on the University's Ethos Ethics application and approval system on 21st June 2021.

12.Data protection

A data sharing agreement is in place between MMU and Empire Fighting Chance as the developer of the Boxing based Mentoring Programme. A data sharing agreement and an accompanying memorandum of understanding for schools participating in the pilot study has been developed by MMU through the legal team, the university's Deputy Data Proection Office and the research team.

A full Data Protection Impact Assessment (DPIA) has been undertaken for this project by the research team supported by the university's Deputy Data Protection Officer and colleagues from Records Management and Information Security. It has incorporated relevant elements from the YEF's DPIA in particular in relation to the YEF archive where data from this pilot study will be eventually be stored after the completion of the study. The MMU DPIA has been signed off by a senior manager withing the university - the designated Data Owner. This DPIA has been shared with the YEF.

The DPIA stipulates and relies on the following legislation.

GDPR art. 6 Lawful basis for processing personal data

Both MMU and the YEF will process personal data under Article 6(1)(e) of the GDPR: processing necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

Per Article 6(3) of the GDPR and section 8 of the Data Protection Act 2018 (DPA), MMU's study is in line with the university's powers under the Education Reform Act 1988, in particular section 123A and 123B:

123A higher education corporation in England has power—

(f) to carry out research and to publish the results of the research or any other material arising out of or connected with it in such manner as the corporation think fit.

123B Supplementary powers of a higher education corporation in England

(1) A higher education corporation in England has power to do anything which appears to the corporation to be necessary or expedient for the purpose of, or in connection with, the exercise of any of their principal powers.

In addition, YEF's work performs a public task as it is funded by the Home Office in furtherance of their statutory powers to assist victims, witnesses or other persons affected by offences.

GDPR art. 9 Lawful basis for processing 'special category' data

Any special categories of personal data used by both MMU and the YEF will be processed under Article 9(2)(j) of the GDPR: processing necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes and Section 10 of the DPA, which provides that processing meets the requirement in Article 9(2)(j) of the GDPR if it meets a condition in Part 1 of Schedule 1 to the DPA. Specifically Paragraph 4 of Part 1 of Schedule 1 provides that this condition can be used for processing which is:

Schedule 1(1)(4) This condition is met if the processing—

(a) is necessary for archiving purposes, scientific or historical research purposes or statistical purposes,

(b) is carried out in accordance with Article 89(1) of the GDPR (as supplemented by section 19), and

(c) is in the public interest

In accordance with the processes set out in the DPIA. The ManMet research team will be the only persons with access to the data during and after the research period. While authorised

personnel from the University might be given limited access to the data in the event of an audit of the research project, no third parties will have access to any of the data. As previously mentioned, all digital data will be stored on the University's Research Data Storage (RDS) system. All interview transcripts will be redacted and anonymised. No digital data will be stored on the personal computers of any of the research team. Any hard copies of documents will be stored in a locked filing cabinet in the PERU office at MMU.

13.Personnel

The ManMet research team will be:

- Kevin Wong – Project Director
- Paul Gray – Project Manager/key liaison with EFC and Validated survey tool lead
- Stephen Morris – Pilot RCT and Quantitative Data Lead
- Stephanie Wallace – Pilot RCT researcher
- Deborah Jump – Qualitative fieldwork researcher
- Anton Roberts – Monitoring data researcher

Other research team members will be determined as required based on capacity and availability. They will be drawn from the university's Policy Evaluation and Research Unit (PERU) and Manchester Centre for Youth Studies (MCYS).

14.Risks

We have identified risks and how to mitigate them in the Table 14.1 based on our experience of delivering comparable projects. Key to this, is being sufficiently nimble and responsive to cope with these challenges and escalating issues (where required) to the YEF for support.

Table 14.1 Risks and mitigation

	High=3 Medium=2 Low=1			
Risks	**Impact**	**Probability**	**Rating**	**Mitigation**
Ensuring the support and assistance of the developer	3	2	6	The research team has been meeting with developer twice a month since April 2021 to ensure the planning and implementation process for this pilot study is in place. Since September 2021 weekly meetings have been instituted to enable developer and research team to: jointly monitor the implementation of the pilot study; identify problems; and resolve these in a timely manner
Postponement/cancellation of fieldwork due to delivery delays	2	2	4	Regular research team and developer team meetings will continue throughout the duration of the pilot study so that any intervention delivery delays will be identified early.
Variable quality of management data collected by the developer	3	2	6	An early data extract will be scheduled for quality checking and to work with developer to improve this if required.
Variable quality of data collected by the schools and provided to the developer	3	2	6	The research team will work with the developer to ensure that quality check process is implemented and procedure to deal with incomplete and/or poor data provided by schools.
Challenges obtaining consents from CYP and from parents for CYP to be involved in the intervention and research	3	2	6	Oversampling by developer and schools Weekly engagement between research team and developer to monitor recruitment progress

				Escalation to the YEF for support/advice Although it should be noted that an element of this pilot study is to test the extent to which the projected sample size of pupils can be achieved.

15.Timeline

Table 15.1 sets out the key milestones for the delivery of this pilot study.

Table 15.1 Pilot Study Milestones

Dates	Activity	Staff responsible/ leading
September 2021	Commence pilot study	MMU research team and EFC
October 2021	Commence enumeration of young people	EFC and schools with research team support
October 2021	Commence collection of quantitative monitoring data	EFC and schools with research team support
October 2021	Implement pre-intervention survey	EFC and schools with research team support
October 2021	Randomise schools	MMU Research team
April 2022	Implement post-intervention/follow-up survey	EFC and schools with research team support

April 2022	Qualitative fieldwork commences	MMU Research team with EFC/School support
June 2022	All data collection (quantitative and qualitative) completed	MMU Research team, EFC and schools
October 2022	Final report	MMU Research team

APPENDIX 1

Personal Development Points for the Boxing Based Mentoring Programme

Below are the most commonly used Personal Development Points, so the ones most likely to make up the 12-week programme.

- WK 1 The Magic of Moods

Your mood has an impact on the way you see the world. Moods change naturally and no mood is ever constant. Trying to hold onto the feelings we like, whilst avoiding the moods we don't like, adds a level of management to our experience and interrupts our life-flow. When you're in an extreme mood, it's best not to trust your thinking, or make any decisions. Let the noise pass and then work out what to do.

Reinforced learning:

Do you think constantly trying to manage your mood will help you to perform better at your sport? Do you think constantly battling with your mood will help you to make better life decisions? Can you remember how a bad mood effects your actions and behaviour? What are some of the dangers of getting carried away when in a positive mood?

- WK2 Awesome Exercise

Exercise is good for the body and releases feel-good chemicals in the brain which create a greater sense of wellbeing. However, try not to look to exercise as a means of achieving wellbeing, as this puts unwanted pressure on the activity. The best reason to exercise is because you enjoy it. If your motivation lies here, you are more likely to stick to your exercise goals. Exercise also provides the opportunity to develop communication and social skills and helps to build confidence.

Reinforced learning:

Are you more likely to keep exercising if you enjoy it? Will you have a healthier body if you exercise regularly? Will you develop new skills if you exercise regularly? What kind of physical activity can you do in your own time?

- WK3 Positive Reactions

There are lots of things in life we cannot control. However, what we can control is our reaction to them. The boxers who react in a healthy and controlled way to taking a hard punch in the ring are the ones who become world-class. When our minds dwell on scenarios which are out of our control, we're more likely to experience stress. When something

troubling happens in life, move your focus to your reaction rather than the event. This removes victim mentality and encourages positive action. Remember, it's the boxers who are able to react well and feel in control who make better decisions and win fights, the same with life.

Reinforced learning:

If you focus on things you cannot control, are you going to feel more or less stressed? If you react well to difficult situations, are you going to grow and learn? If you see life success in terms of how you react to events, are you going to feel more or less confident?

- WK4 Going with the Flow

Battling negative emotions can make you feel even more unstable. Thoughts, feelings, and emotions are unpredictable. We can't control the thoughts and feelings that pop into our heads. Learn not to fight your thoughts and feelings and you'll experience more stability, ease, and flow in your life. Remember that thoughts move on by themselves when they are left alone.

Reinforced learning:

What happens to negative thoughts when we leave them alone? Will they hang around or will they move on? Will getting annoyed at ourselves when we're upset make us feel better or worse? Will leaving angry feelings alone and allowing them to pass through us help to clear our heads?

- WK5 Remove the Victim

It is easy to blame life events and those around us when things aren't going to plan. The most empowering way to get what we want from life is to bring our focus back to what is within our control. If we believe we are helpless, then life will always feel like it is happening to us, and there will always be a tendency to blame circumstance. Put your energy into taking positive action in the things you can control, rather than blaming the things you can't.

Reinforced learning:

When things aren't going your way, will blaming life circumstances help your personal development? Will you feel more or less confident if you focus on what you can control instead of what you can't control? Are you more likely to feel confident if you are proactive instead of hoping for the best?

- WK6 You are what you eat

All successful athletes, especially boxers, have strict healthy eating and drinking routines. Without providing your body with the right fuel, it becomes hard to perform and function. Unhealthy food can also cause fatigue and mood swings. Therefore, how you look after your body has an impact on how you think about life, too.

Reinforced learning:

Does eating unhealthy food have an impact on your mood? Will we experience life in a healthier way if we eat and drink nutritious food? If boxers look after their bodies, do you think they will find it easier to approach boxing in a healthier way?

- WK7 Relaxed Excellence

A relaxed and calm boxer is more effective in the ring-they make better decisions and react well to challenges. In boxing, as in life, trying too hard creates stress, and being too unfocused breeds laziness. Finding the balance between the two will help you find relaxed excellence

Reinforced learning:

Do boxers perform better or worse when they're desperate to win, or when they are calm and collected? Will trying too hard to get what you want damage or support your efforts? Will being too relaxed damage or support your efforts in achieving your goals?

- WK8 Focus on Action, not Outcome

Focus on the actions within your control and you will increase the chances of success in all walks of life. Thinking about winning doesn't help you to win but thinking about what actions you need to take in order to succeed will increase your chances of winning. Often getting too focused on the outcomes of what you want to achieve can create unwanted stress and lower confidence. Keep your mind on actions and the outcomes will Look after themselves

Reinforced learning:

Will measuring success in terms of actions and not outcomes help to bring you confidence? Are you more in control of actions or outcomes? Which statement is more helpful: go out and do your best, or go out and keep your guard up?

- WK9 The Magic of Mini Goals

When we complete goals, we feel a sense of achievement and progress. Achieving small and regular goals helps us to build momentum and progress in life. The size of the goal doesn't matter. Completing regular mini goals is more important. It is helpful to make a list of the

small goals you wish to accomplish during the day and tick them off as you work through your list.

Reinforced learning:

Do you think your confidence will improve if each day you set and complete some small, achievable goals? Do you think completing small goals each day will help you to feel positive?

- WK10 Feel the Fear

When we get angry and feel negative, we look for quick fixes that can often get us into trouble. Smoking and taking drugs are two examples of ways to escape unwanted feelings. Learning not to be afraid of your experience, especially when you feel fear, creates stability. When you feel scared or unsettled, hold and experience the feelings instead of moving away from them. For example, when you feel anxious, you may play a computer game in order to escape from the feeling. Next time, try to hang out with the feelings without distracting yourself for as long as possible. If you face up to your fears, they lose their power to influence you

Reinforced learning:

If you are able to experience uncomfortable feelings without distracting yourself, will you become more or less stable? Overtime, if we keep distracting ourselves from our feelings, will we become more or less fearful of them? If we don't mind what we are experiencing, will we be more or less stable?

- WK11 The Growth Mindset

We can always improve and develop new skills. Just because we're not currently very good at something, it doesn't mean we can't become good. There is always opportunity for growth and betterment. Change is always possible. Your feelings and behaviour is not set in stone. You can choose how you write your own future.

Reinforced learning:

If you're aware that you have a choice in the way you act in the future, will this increase or lower your confidence? Do you think boxers who think they can't get better or develop new skills become world-champions? Do you think it will help boxers if they have a mindset of continuous improvement? Do you think you will feel more or less motivated if you believe it is possible to improve in all areas of life?

- WK12 The Happiness Myth

Society makes us believe that our happiness lies in what we achieve in life. Money, fame and power are some of the main culprits. If money was a true source of happiness, why do the wealthy and the fortunate talk so often about their misery and their constant search for more? The relationship is not clear-cut. If you think your happiness is in what you earn, accomplish, and achieve, you will spend your whole life searching. Knowing that true happiness is not found in this way, is helpful. It will help you to enjoy what you're doing right now without any other agendas

Reinforced learning:

Will you enjoy life more or less if you believe you can only be happy once you've achieved certain things? Are you more likely to feel happy if you accept negative experiences? Is happiness something that can be acquired?

Evidence provided by the developer to the support the rationale for the programme

There are several sources that this programme has drawn credence from within the world of academic psychology. Although there are no academic papers that directly mirror our approach, it has been influenced and informed by some of the following references.

1. *HEALTH REALISATION AND UNDERSTANDING THE NATURE OF THE MIND*

Creating space for clear thinking

Understanding that feelings, 100% of the time, are a reflection of our thinking in the present moment (conscious or unconscious). Our feelings/thoughts do not directly come from external events, but from our own construction and perception of external events. If external events were directly controlling our feelings we'd all have the same response to the same stimuli. We live in a physical world and experience events, but our mental activity / thinking is what brings the event to life. For example: "Event A" can be seen in different ways depending on our baseline mood (feelings and thoughts). This is supported by direct studies of the human brain and by scientists in other fields. By understanding the nature of the mind before we get lost in thinking and feelings, we unburden the mind. Instead of putting more into the young person's mind (in terms of thinking techniques and strategies to escape their current feelings) we create the space and the guidance to reduce the cognitive load. This gives the young person the opportunity to think clearly and develop their own healthier thinking patterns naturally. "Most therapeutic work focuses on the specific content of people's thinking as though it were absolute, with no acknowledgement of the subtle variations in thinking that arise from an ever-changing state of mind or feeling state. Once the process of thinking is realised, once people understand how their thinking

works to create reality and how powerful the transitory and illusory images of thinking appear to be, they're set free from living at the mercy of any thoughts they think. They can see that the experience of stress and distress is actually their own thought-consciousness manifesting negative, worrisome, distressing thoughts in the form of negative, worrisome, distressing experience, and that those thoughts have no life beyond the moment they're created and held in their minds. They see the illusory, kaleidoscopic nature of all formed thoughts. In every moment, when the individual mind is spontaneously or intentionally aligned with Mind (an undiluted understanding of the nature of how we create our experience), and focused away from its intensely personal memory-based world, innate mental health bubbles up, and is characterized by a natural and effortless flow of thought . . . as the experience of peace, contentment, larger perspective on immediate reality, detachment, and a general generous, loving, and deeply moral view of life."(p. 11) - Kelly (2000)

2. *PSYCHOLOGICAL HOMEOSTASIS*

The mind has an in-built ability to find balance

When we leave our thoughts / feelings alone without indulging them and /or deliberately avoiding them they naturally subside, and new healthier thinking is more likely to arise. It is argued that the natural state of the mind is one of clarity. In a space of clarity, we experience thoughts / feelings without getting lost in the detail of them. "The natural tendency of the human mind at peace is towards wisdom and insight, which might be called psychological homeostasis. Chronic stress is not an actual enemy of human well-being with which one must do battle; chronic stress is an artifact of the human imagination in a negative state of mind. According to Health Realisation, whenever the personal mind is quiet or clear, it automatically aligns with Impersonal Mind (a default space of clarity) and receives an effortless stream of free-flowing intelligent thought that is unfailingly responsive to the moment".

-Sedgeman (2005)

Feeling / mood is a guide to the quality of the young person's thinking. Understanding that all thinking is illusory and fleeting and passes when left alone will help them return to a calm state of mind.

3. *LEARNING GOALS AND THE MOTIVATIONAL CLIMATE*

We're in control of actions and not outcomes

Empire emphasises setting goals in terms of getting better and improving rather than achievement. By being intrinsically motivated, the young person responds better under

pressure, is more confident and improves their task performance (as goals are framed within their control). Their efforts are not consumed by achieving favourable outcomes and they are more present to the task at hand. The motivational climate is reinforced by the coach using process language/instructions (actions that the young person is in control of) and reinforcing effort and participation rather than achievement. This helps boost the young person's overall autonomy and engagement with the task.

Learning states

Inducing learning states to accelerate understanding and learning. The personal development messages are delivered when serotonin levels are high as the young person experiences the buzz of physical activity. The coach shares and reinforces the personal development learning during the breaks when serotonin and endorphin levels are high. This improves the learning and memory of the lessons over the course of the programme. Most of the young people who attend Empire are kinaesthetic learners and have a greater desire to be physical and learn by doing compared to traditional academic settings. By engaging in boxing routines during learning the young person is far more likely to engage in and retain the knowledge/teaching that is being shared.

4. *THE GROWTH MINDSET*

Change is always possible

"The map is not the territory" - Alfred Korzybski

Caroline Dweck's research has led the way to empowering organisations by building cultures that encourage positive change. What we think we can do, is not necessarily a clear picture of what we can actually do. Knowing that new skills can be learned, and bad behaviours and traits can be unlearned is helpful. Personality traits are not fixed entities within us and whatever we think we are all founded upon mental and neuronal activity and can therefore change. Developments in neuroscience show us that the brain is far more malleable than we ever knew. Research on brain plasticity has shown how connectivity between neurons can change with experience. These neuroscientific discoveries have shown us that we can increase our neural growth by the actions we take, such as using good strategies, asking questions, practicing, and following good nutrition and sleep habits.

5. *SELF-DETERMINATION THEORY*

Self-Determination Theory examines the conditions that support positive engagement with healthy behaviours. When we arrive at our own healthy ideas about life, we're much more likely to act upon them, compared to when someone else gives us the idea / intervention. EFC regularly encourages creativity and independent thinking to increase the chances of the

young person taking healthy action beyond the programme's provision. "Deci, Lens and Vansteenkiste (2006) conducted a study that demonstrated intrinsic goal framing (compared to extrinsic goal framing and no-goal framing) produced deeper engagement in learning activities, better conceptual learning, and higher persistence at learning activities."-Learning Theories 2017

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