Evaluation of DARE 25: A clustered randomised controlled trial

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YOUTH ENDOWMENT FUND

Evaluation of DARE 25: A clustered randomised controlled trial Statistical Analysis Plan

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PROJECT TITLE	Evaluation of DARE 25: A clustered randomised controlled trial
DEVELOPER (INSTITUTION)	Life Skills Education
EVALUATOR (INSTITUTION)	Sheffield Institute of Education, Sheffield Hallam University
PRINCIPAL INVESTIGATOR(S)	Eleanor Formby, Ben Willis, Martin Culliney
SAP AUTHOR(S)	Martin Culliney
TRIAL DESIGN	Two-armed, cluster randomised controlled trial with random allocation at the school level
TRIAL TYPE	Efficacy
EVALUATION SETTING	School-based
TARGET GROUP	Y6 Pupils
NUMBER OF PARTICIPANTS	121 schools, 3881 pupils
PRIMARY OUTCOME MEASURE AND SOURCE	Strengths and Difficulties Questionnaire (online survey)
SECONDARY OUTCOME MEASURE AND SOURCE	Problem Behaviour Frequency Scale (online survey)

SAP version history

VERSION	DATE	CHANGES MADE AND REASON FOR REVISION
1.2 [*latest*]		
1.1	19.1.22	Amendments to align with final protocol and report (SDQ measurement, missing data treatment, minor drafting edits).
1.0 [*original*]		*[leave blank for the original version]*

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Introduction

DARE 25 is a programme designed to help young people take safer and healthier choices and reduce offending behaviours including hate, knife, drug and alcohol related crime. Year 6 pupils will participate in ten one-hour lessons delivered by a trained DARE officer in the child's regular classroom. The class teacher and classroom assistants will be present, although the session is led by the DARE officer. The lessons will involve role play, age-related scenarios, group skills sessions, discussion groups, reading and writing exercises and other interactive methods.

Further information about the intervention can be found here:
https://lifeskillseducation.co.uk/resources/the-dare-primary-programme/

Design overview

This efficacy trial uses a two-arm, two-level design, with pupils clustered into schools. The unit of randomisation is the school. All Y6 pupils at participating schools undertake baseline and outcome tests during the 2020/21 school year. Intervention schools receive the intervention during the 2020/21 school year. Control schools operate under business as usual during 2020/21 (insofar as this was possible given pandemic disruption) and received DARE25 during the 2021/22 school year. The 2020/21 Y5 cohort in control schools receive the intervention during the 2021/22 academic year, when they are in Y6, and do not contribute any data to the trial. This was mainly intended to incentivise recruitment through a guarantee that all schools would receive the intervention either during 2020/21 or 2021/22. No evaluation activity is scheduled for 2021/22. By this point, pupils participating in the baseline and outcome tests as Y6 pupils in 2020/21 will have left their primary school.

Control group data stored in the YEF data archive therefore relates to pupils in Y6 during 2020/21, who do not receive the intervention at any stage as part of this trial, allowing meaningful comparisons with the intervention group in future research. This feature of the design has been introduced to facilitate longitudinal analysis of data from the trial, with a view to understanding the longer-term effects of participating in DARE 25.

Randomisation was blocked by geographical area, with schools split into six groups: Derbyshire North, Derbyshire South and West Midlands, Leicestershire and Northamptonshire, Nottinghamshire and Lincolnshire, South Yorkshire, and West Yorkshire. A variable representing 'area' will therefore be included as a covariate in the analysis.

Randomisation was undertaken by the evaluation team at two separate times, early December 2020 for Cohort A, and March 2021 for Cohort B. Randomisation was blocked by geographical area to help manage the workload of the delivery team. The original plan was for intervention schools in Cohorts A and B to receive the intervention in Spring and Summer 2021 respectively. However, as a result of schools closures from January to March 2021, all intervention schools will receive the intervention in Summer 2021 (April to July), with outcome data collected after the ten in-class sessions have been delivered.

The primary outcome measure is the Strengths and Difficulties Questionnaire. The secondary outcome measure is the Problem Behaviour Frequency Scale, to be analysed as seven separate subscales. Data for both of these measures was collected directly from participating pupils using an online survey administered in class at pre- and post-intervention.

Table 1: Trial design overview

Trial design, including number of arms		Two-arm, cluster randomised controlled trial
Unit of randomisation		School
Stratification variables (if applicable)		Geographic area
Primary outcome	variable	Behavioural and emotional problems
	measure (instrument, scale, source)	Strengths and Difficulties Questionnaire Total Difficulties score, pupil self-report version (online), 0-40 scale
Secondary outcome(s)	variable(s)	Problem Behaviour Frequency
	measure(s) (instrument, scale, source)	Problem Behaviour Frequency Scale (online survey, pupil self-report), analysed as seven separate subscales: Physical Aggression Verbal Aggression Relational Aggression Overt Victimisation Relational Victimisation Delinquent Behaviour Substance Use
Baseline for primary outcome	variable	Strengths and Difficulties Questionnaire Total Difficulties score, pupil self-report version (online), 0-40 scale
	measure (instrument, scale, source)	Strengths and Difficulties Questionnaire (online survey)
Baseline for secondary outcome	variable	Problem Behaviour Frequency
	measure (instrument, scale, source)	Problem Behaviour Frequency Scale (online survey, pupil self-report) Analysed as seven separate subscales as above

Sample size calculations overview

Table 2 presents minimum detectable effect size (MDES) estimates and sample sizes for the DARE25 impact evaluation. Sample size figures for the randomisation and protocol stages are the same for this trial as the protocol template was only made available after the first phase of randomisation had been completed. Two scenarios are presented below to show the MDES associated with different estimates of participant-level pre/post-test correlations.

The sample size for this trial was determined primarily by the capacity of the developer to recruit and deliver within the study timeframe. Figures presented here reflect the achieved sample size at baseline. In calculating the MDES, our estimates are based on the following assumptions:

R_i^2 - Participant (pupil) level pre/post-test correlation of 0.5 (Scenario 1) or 0.7 (Scenario 2).

R_c^2 - Cluster (school) level pre/post-test correlation of 0.25
ρ - Intracluster correlation (ICC) between 0.168 and 0.217
j - 121 schools
m - 32 pupils per school

Estimates of the ICC and pre/post-test correlations are based on previous research using the primary outcome measure (SDQ)[1]. As these calculations were not based on any prior evidence relating to the secondary outcome measures, analysis using those scales will be treated as exploratory.

Table 2: Sample size calculations

		Scenario 1	Scenario 2
Minimum Detectable Effect Size (MDES)		0.22-0.24	0.21-0.24
Pre-test/ post-test correlations	level 1 (participant)	0.5	0.7
	level 2 (school)	0.25	0.25
Intracluster correlations (ICCs)	level 1 (participant)	-	-
	level 2 (school)	LOW=0.168, HIGH=0.217	LOW=0.168, HIGH=0.217
Alpha		0.05	0.05
Power		0.8	0.8
One-sided or two-sided?		2	2
Average cluster size		32	32
Number of clusters (schools)	intervention	63	63
	control	58	58
	total	121	121
Number of participants	intervention	1979	1979
	control	1902	1902
	total	3881	3881

[1] Findon, J., Cadman, T., Stewart, C. S., Woodhouse, E., Eklund, H., Hayward, H., Le Harpe Golden, D.D., Chaplin, E., Glaser, K., Simonoff, E., Murphy, D., Bolton, P., McEwen, F. (2016). Screening for co-occurring conditions in adults with autism spectrum disorder using the strengths and difficulties questionnaire: A pilot study. Autism Research, 9(12), 1353-1363.
Yao, S., Zhang, C., Zhu, X., Jing, X., McWhinnie, C. M., & Abela, J. R. (2009). Measuring adolescent psychopathology: psychometric properties of the self-report strengths and difficulties questionnaire in a sample of Chinese adolescents. Journal of Adolescent Health, 45(1), 55-62.

MDES calculations were performed in Excel using the formula set out in Bloom et al (2007)[2], which relates to two-level clustered randomised controlled trials:

$$MDES = M_{n-k*-2} \sqrt{\left(\frac{\rho(1-R_C^2)}{P(1-P)J}\right) + \left(\frac{(1-\rho)(1-R_i^2)}{P(1-P)Jm}\right)}$$

Using the Bloom et al formula allows baseline covariates to be added at the cluster (school) level, pupil level or both. Our analysis plan involves using mean-centred baseline scores at both pupil and school level in the multilevel models. Having a covariate at both school and pupil levels maximises the precision of the trial, leading to a smaller MDES estimate than approaches that use only one covariate or none. This is indicated in the formula, where ρ = School level intra-cluster correlation; R_c^2 = R^2 for cluster level covariate; R_i^2 = R^2 for pupil level covariate; j = number of schools; m = number of participants per school; M_{n-k*-2} = z-score multiplier; P = proportion of schools assigned to intervention. Using this formula produces MDES estimates of 0.22-0.24 standard deviations for Scenario 1 and 0.21-0.24 standard deviations for Scenario 2.

It was decided that adopting a three level design with pupils clustered into classes would not be viable owing to a lack of information on how strictly the separation of these clusters would be maintained by schools. Furthermore, the decision was taken not to treat the trial as a multi-site clustered design due to the assumption that the programme would be delivered the same way across geographical areas and any differences would arise from factors unrelated to these, which were drawn together in attempt to aid recruitment and do not correspond neatly with official administrative boundaries that may have distinct educational policies. However, as stated above, these areas were used to block the randomisation and will still be included in the analysis as covariates.

Analysis

Analysis will be conducted through multilevel linear regression models, with pupils clustered into schools. The intention treat sample is to be used in all models unless otherwise stated. The following research questions will be addressed:

1. *What is the impact of DARE 25 on behavioural and emotional problems among Y6 pupils as measured by the Strengths and Difficulties Questionnaire?*
2. *What is the impact of DARE 25 on problem behaviour frequency among Y6 pupils as measured by the seven dimensions of the Problem Behaviour Frequency Scale?*

For both the primary and secondary outcomes, the same measure is being used at pre- and post-intervention. The simple model will include the baseline (school centred) as a covariate at both the pupil and school level. The full model will include both the pupil-level, school-centred baseline and school-level mean baseline scores as covariates. Including baseline covariates at both school and pupil levels results in lower MDES estimates than would be obtained with a single covariate at one of these levels. In other words, for the same level of statistical significance (p<0.05) and statistical power (80%), a model that includes both school and pupil level covariates can detect a smaller effect size as statistically significant compared to a model that only includes one covariate at either school or pupil levels. Post-intervention test scores will be used as outcome variables in the analysis. The full model will

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[2] Bloom, H.S., Richburg-Hayes, L. and Black, A.R. (2007) Educational Evaluation and Policy Analysis, Vol. 29, No. 1, pp. 30–59

also contain a covariate representing geographical areas, and whether the school was in cohort A or B.

The purpose of these analyses is to address the research questions by estimating the difference between the intervention and control groups on the trial outcomes and controlling for the variables specified in Table 3. Only pupils providing both baseline and outcome data will be included in the analysis for each of the outcome measures. In the event of item non-response, cases will be excluded from the analysis. Further detail is provided below in relation to the specific measures to be used.

Table 3: Analysis models

Analysis and Sample	Level 1 (pupil) Variables	Level 2 (school) Variables
ITT sample (empty)	SDQ score (school centred)	
ITT sample (simple)	SDQ score (school centred)	• Group (1=intervention; 0=control); • Mean SDQ score (Grand mean centred)
Full (headline) Analysis ITT sample	SDQ score (school centred)	• Group (1=intervention; 0=control); • Mean SDQ score (Grand mean centred) Stratification variables: • Geographical hub area • Trial cohort

Analysis will be conducted using the 'mixed' command in Stata. Example code:

Empty model: mixed SDQ_post || School_ID:

Simple model: mixed SDQ_post Allocation SDQ_pre SDQ_pre_school || School_ID:

Full model: mixed SDQ_post Allocation SDQ_pre_pupil SDQ_pre_school b1.Area Cohort || School_ID:

Primary outcome analysis

The primary outcome measure is the Strengths and Difficulties Questionnaire (SDQ). All participating pupils will complete questionnaires electronically in school at both pre- and post-intervention. Data is being collected using the website Qualtrics. The SDQ is a brief behavioural screening questionnaire for 3-16 year olds. It contains 25 items on psychological attributes, some positive and others negative, 20 of which combine to provide the Total Difficulties Score. The Strengths and Difficulties Questionnaire is being used by YEF across its projects to create consistency and comparability between different evaluations. Further information about the SDQ is available here: https://www.sdqinfo.org/

The SDQ Total Difficulties score is measured on a scale of 0 to 40[3], with 0 indicating the lowest level of behavioural and emotional problems, and 40 the lowest. A listwise approach

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[3] The SDQ contains 25 items but five of these relate to prosocial behaviour and are omitted from the analysis, which focusses on the 'total difficulties score' as defined in the YEF SDQ guidance document

to item non-response was used for baseline and outcome data. Any respondents with missing data for any of the 20 SDQ items were treated as having missing data for the primary outcome measure. Of the 3881 cases collected at baseline, 328 (9%) had at least one missing value across the 20 SDQ questions. If the intervention is associated with improving behavioural and emotional problems among participating pupils, lower scores on the SDQ would be expected.

To formally specify the ITT model, let Y_{ik} represent the outcome score for pupil i in school k.

The level 1 (pupil-level) model is:
$$Y_{ik} = \pi_{0k} + \pi_{1k}(Baseline_{ik}) + e_{ik} \sim N(0, \sigma^2)$$

Where:
$i = 1, \ldots, n$ pupils per school; $k = 1, \ldots, k$ schools

- π_{0k} is the mean score for school k
- $Baseline_{ik}$ is the pupil-level (school-centred) pre-test covariate for pupil i in school k. π_{1k} is the coefficient for the pupil-level baseline covariate for school k
- e_{ik} is the pupil-level error/residual
- σ^2 is the within-school variance

The level 2 (School-level) model is:
$$\pi_{0k} = \gamma_{00} + \gamma_{01}Group_k + \gamma_{02}BaseS_k + \gamma_{03}Cohort_k + \gamma_{04}Hub_k + u_{0k};$$

$$u_{0k} \sim N(0, \tau_{\beta_0})$$

Where:
- γ_{00} is the estimated adjusted school-level grand mean
- $Group_k$ is '1'for treatment and '0' for control schools, γ_{01} is the treatment effect coefficient.
- $BaseS_k$ is the school level mean baseline covariate (centred around the school level grand mean), γ_{02} is the coefficient for the school-level baseline covariate.
- $Cohort_k$ represents a binary variable identifying the pupil cohort (cohort 1=0; cohort 2=1), γ_{03} is the coefficient for cohort 2 schools.
- Hub_k represents a vector for the geographical hub area dummy variables, γ_{04} is a coefficient vector for the geographical hub covariates. In total, for the six hub areas, five binary dummy variables will be included, γ_{04} is a coefficient vector for the hub area covariates.
- u_{0k} is the random effect associated with each school mean
- τ_{β_0} is the residual/error variance between schools

This approach is set up to capture differences between intervention and control groups overall. To estimate the impact of the intervention on each cohort, an interaction between group and cohort and/or running analyses on each separate cohort will be needed. We will conduct separate subgroup analyses only if the cohort*allocation interaction is significant.

Secondary outcome analysis

The secondary outcome measure is the Problem Behaviour Frequency Scale (PBFS). This contains 35 items asking about the frequency with which a young person has engaged in

problem behaviour. It will be analysed as seven separate sections: physical aggression, verbal aggression, relational aggression, overt victimisation, relational victimisation, delinquent behaviour, and drug use. The analysis of PBFS as seven dimensions follows Farrell et al (2016)[4], who used confirmatory factor analysis and found that grouping the items in other configurations resulted in weaker model fit. PBFS was selected as an outcome measure due to alignment with the aims of the intervention, and will be analysed in seven sections in order to generate more precise insights into the areas where the intervention is associated with change in pupil behaviour. All analyses on these secondary outcome measures will be conducted according to the same analysis plan as specified for the primary outcome. Descriptive statistics for the PBFS seven subscales are presented in Table 4.

Table 4: Descriptive statistics for the outcome variables at baseline

Variable	N items	Control			Intervention		
		N	Mean	Std. Deviation	N	Mean	Std. Deviation
SDQ (primary)	25	1712	13.97	3.92	1812	13.96	3.92
PBFS (secondary)							
1. Physical Aggression	5	1869	7.25	3.70	1947	7.23	3.54
2. Verbal Aggression	4	1867	5.41	2.74	1940	5.47	2.70
3. Relational Aggression	5	1857	6.03	2.67	1940	6.04	2.45
4. Overt Victimization	5	1841	8.79	4.66	1914	8.80	4.68
5. Relational Victimization	5	1840	7.54	4.30	1931	7.52	4.24
6. Delinquent Behaviour	5	1856	5.45	1.96	1935	5.45	1.86
7. Drug Use	6	1846	6.49	2.34	1923	6.54	2.35

In instances of item non-response, the entire subscale is treated as missing for that case. All cases with valid data will be entered into the analysis irrespective of whether data is missing on other outcomes. PBFS questions are listed at the end of this document.

Subgroup analyses

Subgroup analysis on both delivery Cohorts A and B will be carried out. This is necessary as baseline data for Cohort A was collected in November and December 2020, whereas baseline data for Cohort B was collected in March 2021. It is possible that the difference in time elapsed between pre- and post-test data collection for the two cohorts will affect analysis results. Conducting subgroup analysis, in addition to using trial cohort as a covariate in the headline analysis modelling, will determine whether this has happened.

Further analyses

For delivery purposes, there are two instances where more than one school is being treated as a single cluster in this trial, involving rural schools with small pupil numbers that form part of the same federation. These have been randomised as single schools and will be analysed as such. Pupils in these amalgamated schools will receive the delivery at the same time, so

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[4] Farrell AD, Sullivan TN, Goncy EA, Le AH (2016) Assessment of adolescents' victimization, aggression, and problem behaviors: Evaluation of the Problem Behavior Frequency Scale. Psychological Assessment. 28(6):702-714

that they are all essentially treated as the same school. To examine the implications of this approach, adopted for practical reasons, exploratory analysis will be undertaken with these schools separated into distinct clusters to check for any important differences in results.

Imbalance at baseline

Table 5 displays descriptive statistics about the study sample at baseline. The six geographical areas are well balanced between the intervention and control groups owing to the blocked randomisation approach. There is also very good balance between the two groups in terms of primary outcome scores at baseline.

Table 5: Baseline sample balance

School-level (categorical)	Control group		Intervention group		
	n/N (missing)	Count (%)	n/N (missing)	Count (%)	
Hub area					
Derbyshire North	6/58	6 (10.3%)	7/63	7(11.1%)	
Derbyshire South + West Midlands	13/58	13(22.4%)	10/63	10(15.9%)	
Leicestershire and Northamptonshire	9/58	9(15.5%)	9/63	9(14.3%)	
Nottingham + Lincolnshire	8/58	8(13.8%)	12/63	12(19%)	
South Yorkshire	12/58	12(20.7%)	13/63	13(20.6%)	
West Yorkshire	10/58	10(17.2%)	12/63	12(19%)	
Cohort					
A	30/58	30(51.7%)	31/63	31(49.2%)	
B	28/58	28(48.3%)	32/63	32(50.8%)	
Pupil-level (continuous)	n/N (missing)	Mean (SD)	n/N (missing)	Mean (SD)	Effect size
SDQ	1712(190)	13.97 (3.918)	1812(167)	13.96 (3.922)	0.00

Missing data

Extent of and reasons for any missing data (such as school/pupil withdrawal) will be summarised in the final report. If more than 5% of outcome data is missing, as part of the follow-on analyses a multilevel logistic regression model with a binary outcome identifying when outcome data is missing (=1) or not (=0) will be constructed. The ITT variables and additional school level variables shown in Table 4 will be used to identify whether the missing outcome data can be assumed to be missing at random. If any of the explanatory variables account for a statistically significant amount of variation in the missing data outcome, we would cautiously conclude that the data is missing at random.

If one or more explanatory variables are found to account for a statistically significant amount of variation in the missing data outcome we would undertake a sensitivity analysis to repeat the ITT analysis with these variables included. The potential bias introduced by missing outcome data on the ITT estimate will be illustrated by comparing the estimated ITT effect size with the effect size estimated from the ITT model including the additional variables. Multiple imputation was not considered due to the lack of data on pupil characteristics or other individual level information.

Compliance

Compliance is being measured at the school level. The intervention is delivered over ten in-class sessions, ideally scheduled weekly over ten weeks. However, the current trial is taking place against the backdrop of continuing disruption due to the Covid-19 pandemic. At the time of writing, there are instances of school pupils, staff and personnel from the delivery team undergoing periods of isolation as a result of exposure to the virus. This increases the risk that the intervention will not be delivered as intended. As such, at the end of the trial, participating schools will be categorised into the following groups:

1) Fully compliant (ten in-class lessons over ten weeks, plus graduation ceremony)

2) Intervention completed, but over condensed period or with remote sessions

3) Intervention not completed (school does not finish ten lessons plus graduation)

Analysis models will be conducted to compare each of these groups to the control group. This will be limited to the primary outcome measure in the first instance, but in the event that any significant effects are discovered, analysis for the relevant subgroup will be extended to include the secondary outcome measures. The delivery team will provide detail on the number of sessions completed in each school, including the graduation ceremony, and the number of these sessions that were delivered remotely or in the same week, as a measure of how closely it has been possible to adhere to the intended schedule. The final report will present this data in full using descriptive statistics.

If possible, pupil level compliance will be measured through a simple binary indicator of whether a pupil has completed the programme and been awarded a graduation certificate. It was agreed that collecting pupil level data to monitor attendance at each DARE 25 session would not be feasible.

Complier Average Causal Effect (CACE) will be used to examine the effect of compliance on the trial results. This will be estimated using two stage least squares (2SLS) regression (Gerber and Green, 2012). The first stage will model the compliance variable using the same explanatory variables used for the headline ITT analyses. This will be a multilevel logistic regression model used to generate predicted compliance for use in the second stage model. The second stage models will use predicted compliance in place of the group identifier variable in the ITT analyses specified above to generate the CACE estimates.

Intra-cluster correlations (ICCs)

Clusters in this trial are schools. ICCs are calculated using the 'estat icc' command in Stata.

Presentation of outcomes

Effect sizes will be calculated using Hedges' g, as specified in the following equation, where T is the treatment mean, C is the control mean, δ^2_{sch} is the school level variance and δ^2_{pup} is the pupil level variance:

$$ES = \frac{(T - C)_{adjusted}}{\sqrt{\delta^2_{sch} + \delta^2_{pup}}}$$

The headline effect size will be calculated from the group allocation (intervention/control) coefficient in the full analysis model (including geographical area and cohort), with the unconditional variance used as the denominator. The effect sizes will be reported along with confidence intervals and p-values to reflect statistical uncertainty.

Problem Behaviour Frequency Scale (from Farrell et al, 2016)
Possible responses (all items): 0, 1-2, 3-5, 6-9, 10-19, 20 or more
In the last 30 days, how many times have you …

1. Physical Aggression
Hit or slapped another person
Thrown something at another pupil to hurt them
Threatened to hit or physically harm another person
Shoved or pushed another person
Threatened someone with a weapon (gun, knife, stick, etc.)

2. Verbal Aggression
Put someone down to their face
Picked on someone
Teased someone to make them angry
Said things about another pupil to make other pupils laugh

3. Relational Aggression
Told another person you wouldn't like them unless they did what you wanted them to do
Spread a false rumour about someone
Tried to keep others from liking another person by saying unkind things about him/her
Left another person out on purpose when it was time to do an activity
Didn't let another pupil be in your group anymore because you were angry at them

4. Overt Victimization
Had another pupil threaten to hit or physically harm you
Been pushed or shoved by another person
Been threatened or injured by someone with a weapon (gun, knife, stick, etc.)
Been hit by another person
Been shouted at or called unkind names by another person

5. Relational Victimization
Had a person who is angry at you try to get back at you by not letting you be in their group anymore
Had a person say they won't like you unless you do what he/she wanted you to do
Been left out on purpose by other persons when it was time to do an activity
Had someone spread a false rumour about you
Had a person try to keep others from liking you by saying unkind things about you

6. Delinquent Behaviour
Stolen something from another pupil
Snuck into someplace without paying such as cinema, onto a bus or train
Written things or sprayed paint on walls, pavements or cars where you were not supposed to
Taken something from a shop without paying for it (shoplifted)
Damaged school or other property that did not belong to you

7. Drug Use
Drunk beer (more than a sip or taste)
Drunk wine (more than a sip or taste)
Smoked cigarettes
Been drunk
Drunk spirits (like whiskey or gin)
Used cannabis (weed)

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