

EVALUATION PROTOCOL

Re-Frame: Randomised Controlled Efficacy Trial of a Diversion Programme for Adolescents in Police Custody who Possess Controlled Drugs

University of Kent

Principal investigator: Professor Simon Coulton

Project title¹	Re-Frame: Randomised Controlled Efficacy Trial of a Diversion Programme for Adolescents in Police Custody who Possess Controlled Drugs
Developer (Institution)	With You
Evaluator (Institution)	University of Kent
Principal investigator(s)	Professor Simon Coulton
Protocol author(s)	Professor Simon Coulton, Professor Theresa Gannon, Ms Nadine Hendrie
Trial design	Two arm, prospective, individually randomised efficacy trial
Trial type	Efficacy
Evaluation setting	Community
Target group	Young people aged 10-17 years inclusive in police custody and in possession of class B or C controlled drugs
Number of participants	388 young people
Primary outcome and data source	Number of offences in the 6 months post-randomisation derived from the Local Police Database (LPD)
Secondary outcome and data source	Self-Reported Delinquency (SRDS), emotional regulation (SDQ), frequency of substance use TLFB, Situational Confidence (SCQ), Motivation to change behaviour (RR), negative and positive expectancy (SUES)

Protocol version history

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Study rationale and background

Adolescence is a critical developmental stage where young people make behavioural and lifestyle choices that have the potential to impact on their health and wellbeing into adulthood. While risk-taking is important for healthy psychological development, for many, inappropriate risk-taking is significantly associated with health and social harm during adolescence and these harms persist well into adulthood (Odgers et al., 2008). Young people are much more vulnerable than adults to the adverse effects of substance use due to a range of physical and psychological factors that often interact and the differential impact of substances on the developing brain (Battistella et al., 2014, Copeland et al., 2013, Parlar et al., 2021). In addition to an increased risk of accidents and injury (NHS., 2018), substance use in adolescence is also associated with poor educational performance and exclusion from education. Over the academic year 2015-16, almost 9% of permanent school exclusions in state secondary schools were due to alcohol and substance use (DFE., 2019). In the longer term, substance use is also associated with increased prevalence of non-communicable diseases, such as cancer, cardiovascular disease, and gastrointestinal disorders (Aldington et al., 2008, World Health Organization, 2014). Six percent of those aged 14 years and 11% aged 15 years reported having used cannabis in last month and 2% of 14-year-olds and 4% of 15-year-olds reported using class A substances at least once (NHS., 2018).

While the relationship between criminal activity and substance use is complex, there is clear evidence that the prevalence of substance use is far higher in the youth offending population than the general youth population. Approximately 25% of young people engaged in alcohol and drug treatment are referred from criminal justice (OHID., 2022) and data derived from the Youth Offending Team, ASSETPLUS, indicates that most young people in the CJS, 76%, use substances and 72% have a mental health need. The Juvenile Cohort Study indicates that 32% of young offenders score 2 or more on the ASSET tool for substance use, indicating substance use is at least in part a reason for them engaging in criminal activity, and 12% score 3+ (Wilson, 2013). Substance use is defined as alcohol, controlled drugs, novel psychoactive substances, and inappropriate use of prescribed medication. While the relationship between substance use and criminal activity is complex, it is clearly a major issue in the youth offending population.

In the CJS, substance use, and offending are related in the context of other forms of disinhibitory behaviour, such as aggression and risk-taking. Young people who offend experience a range of complex multiple risks and vulnerabilities including, neglect and abuse (Social Exclusion Unit, 2002, Moustafa et al., 2018), substance use and related problems (Coffey et al., 2003) and exclusion from school (Galahad SMS Ltd., 2004, Arnez and Condry, 2021). Research has shown that young people who offend are more likely to experience a range of inequalities in later life, for example worse physical health (Coffey et al., 2003), early pregnancy in females (Ritakallio et al., 2005) and higher rates of tobacco use and drug and

alcohol dependence (Galahad SMS Ltd., 2009, Galahad SMS Ltd., 2004, Bardone et al., 1998, Lennox, 2014), reduced employment opportunities and economic hardship (Willmott and van Olphen, 2005). Indeed, there is widespread agreement that young people who offend are at increased risk of health and social problems, making them one of the most vulnerable populations in the UK (British Medical Association, 2014). Furthermore, the UK has one of the highest youth custody populations in western Europe (Khan, 2010). Epidemiological studies highlight the fact that, in common with other vulnerable groups of young people, such as the homeless and those in care, young offenders are a hard to reach group from a health needs perspective, only accessing physical and mental health services in times of crisis and accessing these services is often associated with involvement with other agencies (Bardone et al., 1998, Anderson et al., 2004, Stallard et al., 2003). The experiences associated with criminality, police involvement, legal issues and potential detention are traumatic and stressful, and these are associated with higher levels of mental illness in this population (Lennox, 2014).

The Youth Justice System in England and Wales works to prevent offending and re-offending by those under the age of 18 years. The latest available data indicates that there were 19,000 arrests of young people in 2019, which is an 82% drop from 2009 (Youth Justice Board, 2020). Of these, boys made up 83% and the average age was 15.3 years. Over the same period there were 11,000 first time entrants, first reprimand or warning of community conviction, to the Youth Justice System which is a reduction of 84% since 2009 (Youth Justice Board, 2020). It is estimated that 38.5% of new offenders go on to re-offend after serving their initial sentence (Youth Justice Board, 2020). The Crime and Disorders Act 1998 is clear that the principle of youth justice is prevention, diverting young people away from youth justice is a critical part of achieving this goal. An international systematic review and meta-analysis (Petrosino et al., 2010) included 22 studies and 7300 young people and found formal processing within youth justice services appears to increase rather than reduce offending. In the United Kingdom similar effects have been observed, the Edinburgh Study in Youth Transitions and Crime (McAra and McVie, 2007) found those brought to court were twice as likely to commit another offence within twelve months than a matched sample not brought to court and a study in Northamptonshire (Kemp et al., 2002) found prosecution increased the likelihood of reoffending when compared with a similar match sample. Being arrested constitutes opportunistic teachable moment that can act to maximise the effect of a behaviour change intervention (Lawson and Flocke, 2009).

Systematic reviews of interventions for substance using offenders to date have not identified a clear, evidence-based intervention strategy (Perry et al., 2006, Henderson et al., 2016, D'Amico et al., 2013, Perry et al., 2019a, Perry et al., 2019b), but they have highlighted the paucity of good quality research in the area and the lack of UK based studies and no scientifically rigorous studies focusing on young offenders. A recent meta-analysis of 22 studies (Steele et al., 2020) synthesized the evidence regarding the use of motivational interventions (MI) for adolescents (age 12-20) who engage in substance use. Results showed

that compared to treatment as usual, the use of MI reduces heavy alcohol use days by 0.7 days per month (95% CI: -1.6 to -0.02), substance use days by 1.1 days per month (95% CI -2.2 to -0.3), and overall substance-related problems by a standardized net mean difference of 0.5 (95% CI: -1.0 to 0). Further, a meta-analysis addressing brief interventions for co-occurring alcohol and illicit substance use among adolescents found a significant benefit if the specific illicit substance use was addressed (Tanner-Smith et al., 2015). Brief psychosocial interventions delivered using a motivational interviewing approach within a FRAMES paradigm have shown evidence of potential effect among adolescents (Steele et al., 2020, Winters and Leitten, 2007) and offer an opportunity to allow structured reflection on substance use and identify strategies to enhance self-efficacy, manage expectancies and motivation to change. The FRAMES approach (Rollnick et al., 2008) highlights six key aspects of behaviour change interventions; providing feedback on the relationship between substance use and behaviour, identifying the individual as being responsible for change, offering advice and managing ambivalence, providing a menu of options for change, being supportive and empathetic and enhancing the individuals self-efficacy.

Drug education is widely used in drug prevention, health promotion and treatment. Darcy (2021) in a literature review of best practice (Darcy, 2021) identified key elements of effective drug education. These include multi-component programmes that include understanding drugs and drug related harm as well as skill development in how to manage risk, multiple structured sessions, age, and developmental appropriateness, understanding and communicating risk and dispelling misconceptions.

The Re-Frame intervention builds on both the FRAMES approach to behaviour change but also best practice in drug education.

A pilot evaluation of the Reframe intervention was conducted and recruited 76 participants. In the pilot evaluation we set several a priori parameters that would indicate whether an efficacy study was feasible. All these criteria were met; 93% of those referred were eligible, 80% of these consented, 92% adhered to all the intervention, 88% were followed-up at months, the primary outcome was available for 100% of participants.

The qualitative analysis found the intervention was considered acceptable to all stakeholders, young people, interventionists, and the police. The qualitative analysis found no substantial hindrances to the implementation of the Reframe intervention, but it did highlight some areas where improvements to referral processes could be made. These included raising awareness within the police and streamlining referral pathways.

The trial is a mixed methods prospective, individually randomised efficacy trial with equal probability of being allocated to one of two arms, the Reframe intervention or business as usual.

Intervention

Intervention Group

Two sessions of Brief Intervention by skilled youth workers, minimum qualifications include a NVQ level 3 in tackling substance misuse and experience of working in a similar capacity as a young person's substance misuse worker. Staff training was conducted by a senior young person's substance misuse worker and was delivered on-line over a working week, assessment of competence and ongoing supervision is provided monthly. The intervention is delivered either in person or on-line, and the young person is allowed flexibility in how both parts of the intervention are delivered, in the pilot study some for example decided to 'walk and talk', the content of the intervention remains the same irrespective of the mode of delivery. In session one the young person will use a Drug Grid, based on the work of Zinberg (Zinberg, 1984), to reflect on how their actions have affected their lives, their family and wider community. The young person will have the opportunity to recall their arrest experience and explain how this impacted them. The practitioner will assist the young person in critically reflecting on this event and offer support in relation to trauma or consequences they may feel.

The Drug Grid is a drug education exercise that enables the young person to demonstrate current understanding of substances (including medication, novel psychoactive substances, and image and performance enhancing drugs). As they go through the exercise they will learn about these substances (e.g., depressant or psychedelics), being led by their own experience and building on their knowledge base. The worker can dispel myths and provide information on the effects of each substance, including the risks of poly drug use and overdose.

Brief intervention session two is the Drug Triangle, based on an in-house psycho-education tool, delivered one week after session one. Using the Drug Triangle, the young person will focus on the substance mindset and setting that led them to the session, including the relevant legislation and how that legislation has been applied in their situation. This holistic harm reduction approach ties in with contextual safeguarding, framing the young person's situation within a wider context. They will spend time thinking about how this has affected them, their family, school (if applicable), and community. The young person will also be encouraged to reflect on the impact on those people and communities that produce drugs. At the end of the session the participant will be advised around their rights in relation to stop and search procedures should they require it in the future as well as assertion techniques and advice relating to the procedure itself.

At the end of the two sessions the young person will have greater clarity about the risks they have taken, the links between substance use, risk-taking behaviour and offending and the potential of criminal prosecution. The short-term aims are that the young person will have a greater understanding of their personal needs, increase in confidence to reduce substance

use, and a positive shift from precontemplation to action and maintenance in the cycle of change. The logic model for the intervention is presented in figure 1.

Figure 1: Logic model of the Re-Frame intervention

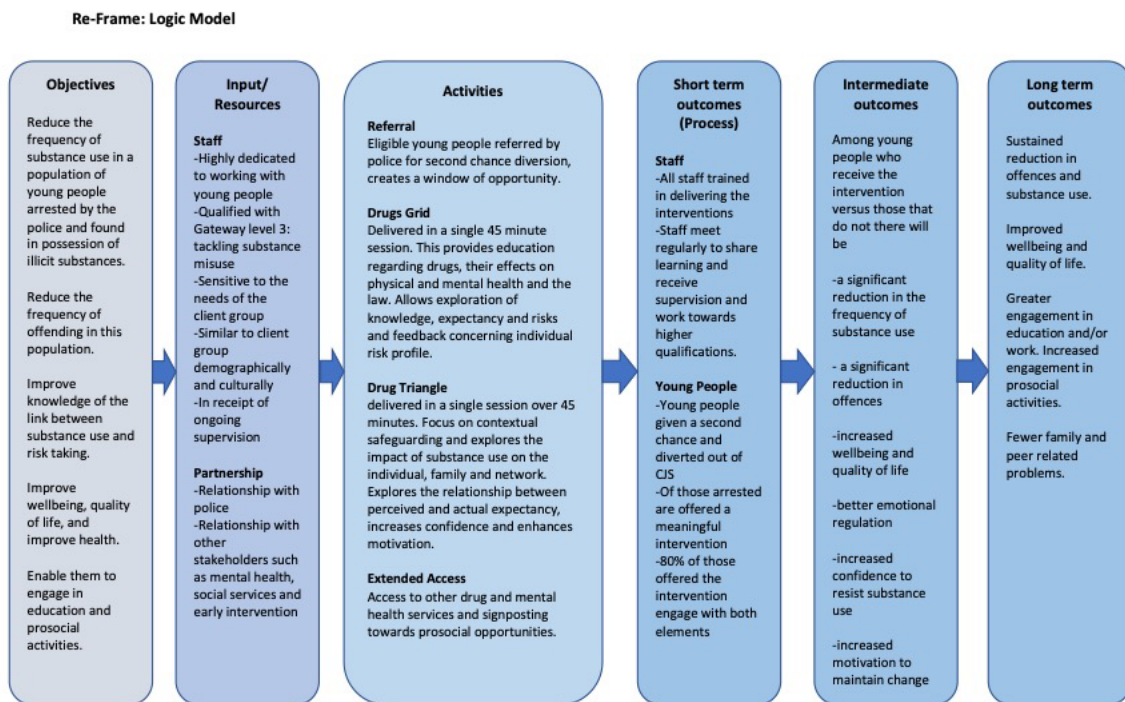
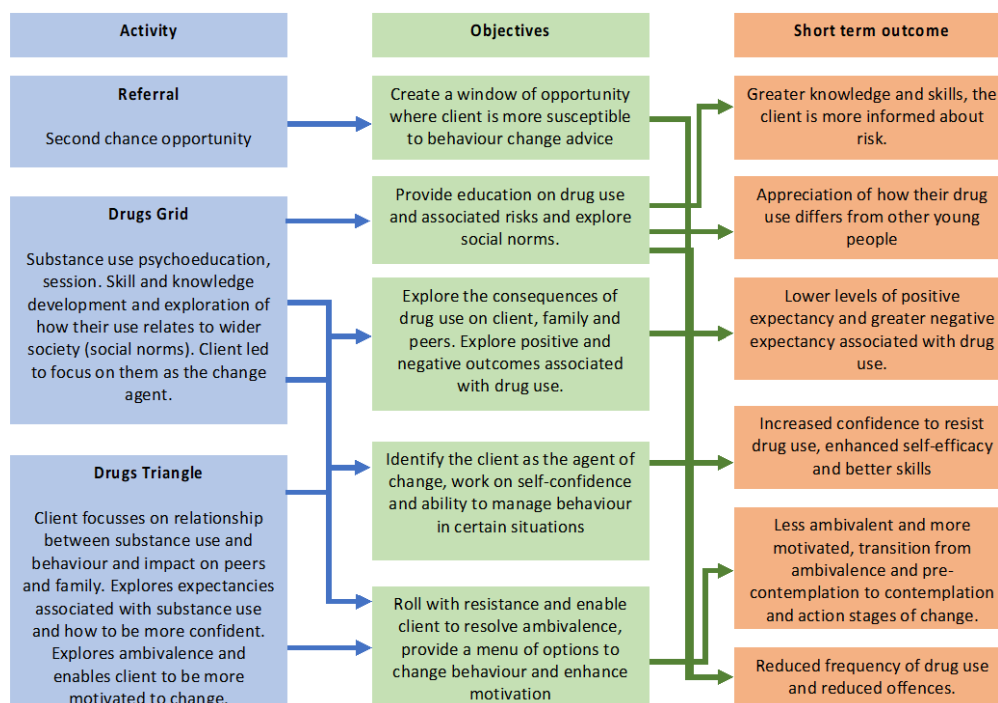


Figure 2 highlights how the overarching theory of change links intervention activities with objectives and outcomes.

Figure 2: Re-Frame intervention theory of change blueprint



Control Group

The young person will receive one session of Advice, Information and Signposting and offered information about the *With You* substance misuse service in their local area and encouraged to access the service for support if required. Advice, Information and Signposting is a tier 1, universal level of support. It is unstructured and is based on a conversation only and is business as usual for initial referrals to the service.

After a young person has received either the intervention or control, they are referred back to the police who enter no further action, the young person receives no formal police charge.

Impact evaluation

Research questions or study objectives

1. To conduct a prospective RCT to evaluate the efficacy of the intervention versus a standardised control on non-violent offences in the 6 months after randomisation and the frequency of substance use and wellbeing.
2. To conduct a micro-costing exercise to provide estimates of the cost of delivering the intervention from the perspective of the intervention delivery organisation.
3. To develop a prognostic model exploring the baseline demographics, psychological and family factors that may impact observed outcomes and using the results to elaborate mechanisms of change and where appropriate revise the intervention logic model.
4. To assess the fidelity of intervention delivery and explore the role adherence, fidelity, therapeutic alliance, interventionist factors, baseline demographic and psychological factors play in the outcomes observed for the intervention group.
5. To conduct a latent class analysis to explore potential interactions between population subgroups, intervention received, and outcomes observed.
6. To explore generalisability and inclusivity using a comprehensive cohort approach.
7. To explore the participant, police, and intervention provider perspectives on the acceptability of the referral process and intervention delivery and to explore key facilitators and hindrances to successful scaling-up of the intervention.
8. If the intervention is found to be effective, to develop a protocol for the scaling up and wider scale delivery of the intervention.

Design

Table 1: Trial design

Trial design, including number of arms		Two-arm individually randomised efficacy trial
Unit of randomisation		Young person
Stratification variables (if applicable)		Age group (10-14 years; 15-17 years) Police Force (Kent, Wigan, Sefton, Cornwall)
Primary outcome	variable	All offences 6 months post-randomisation
	measure (instrument, scale, source)	Local Police Database
Secondary outcome(s)	variable(s)	Self-reported offences, emotional regulation, substance use frequency, psychological health and well-being, situational confidence, readiness to change, expectancies.
	measure(s) (instrument, scale, source)	Self-Report Delinquency Scale (SRDS), Strengths and Difficulties Questionnaire (SDQ), Timeline Follow-Back (TLFB28), Warwick-Edinburgh Mental Well-being Scale (WEMWBS), Short Situational Confidence Questionnaire (SCQ-8), Readiness to Change Ruler (RR), Substance Use Effect Expectancy Scale (SUE)
Baseline for primary outcome	variable	All offences 6 months pre-randomisation
	measure (instrument, scale, source)	Local Police Database (LPD)
Baseline for secondary outcome	variable	Self-reported offences, emotional regulation, substance use frequency, psychological health and well-being, situational confidence, readiness to change, expectancies.

	measure (instrument, scale, source)	Baseline assessments of Self-Report Delinquency Scale (SRDS), Strengths and Difficulties Questionnaire (SDQ), Timeline Follow-Back (TLFB28), Warwick-Edinburgh Mental Well-being Scale (WEMWBS), Short Situational Confidence Questionnaire (SCQ-8), Readiness to Change Ruler (RR), Substance Use Expectancy Scale (SUE)
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Randomisation

Randomisation strings are generated in advance for the research team by an independent, remote, secure randomisation service (Sealed Envelope Ltd). Strings are made up of random permuted blocks of size 4 and 6 with a random block distributed throughout the string to reduce predictability. Strings are stratified by age group (10-14 and 15-17 years) and site (Kent, Cornwall, Sefton and Wigan).

After consent has been provided and the baseline assessment complete the researcher accesses the randomisation service online, they provided the participant ID and stratification variables, and the system automatically provides an allocation.

The researcher has no access to the actual strings in advance of an allocation. After allocation the researcher informs *With You* who contact the young person to deliver the allocated treatment.

All allocations are recorded independently and the allocation schedule is available for quality assurance purposes.

Participants

Participants are assessed for initial eligibility by police custody staff. Inclusion criteria included being aged 10-17 years inclusive and being found in possession of class B or C controlled drugs. Young people are excluded if they had been arrested for a sexual or serious violent offence, had a history of four or more previous offences or who had a substance misuse severity that required specialist clinical intervention such as detoxification or medically assisted maintenance. Assessment of need for specialist intervention is made in police custody, initially by custody staff and confirmed by police custody medical staff. All eligible participants are referred to *With You* using a secure criminal justice email system.

Staff at *With You* establish whether potential participants are interested in participating in the trial and if they are they provide a paper or email copy of the information sheet and pass

their contact details to the trial research staff. If the young person is not interested in participating, they are processed as usual by the police. For those willing to participate, trial research staff contact the young person and check they understood the information sheet and answer any queries. If the young person is considered Gillick competent full signed consent is taken. If a young person is not considered Gillick competent signed assent is taken from the young person and formal consent taken from a primary carer.

Immediately after consent the young person completes the baseline outcome measures and is immediately randomised using a remote, independent secure randomisation service to business as usual or intervention. *With You* are informed of the allocation and deliver the allocated intervention.

Participants can decide how they prefer the intervention is delivered, this can be in person at *With You* offices , at a school or youth centre or it can be delivered remotely using video technology. Six months after randomisation the researcher contacts the young person and conducts the 6 month outcome assessment.

Sample size calculations

Sample size calculations were derived using STATA16. In calculating the sample size, we have used an effect size difference of 0.3, similar to other studies address substance use in adolescents (Coulton et al., 2017) and equates to a number needed to treat (NNT) of 8, where delivering the intervention to eight young people will result in important reduction in offences in at least one. This equates to a small to medium effect size and any smaller is unlikely to be a meaningful effect on the primary outcome. To detect this effect size, or greater, with 80% power, alpha of 0.05 and a two-sided test requires 350 participants followed-up at 6-months. As the pre- and post-test correlations in offence data are not established for this group we have erred on the side of caution and not included them in the sample size calculation, the sample size therefore constitutes a conservative estimate of the number required. As the primary outcome is sourced independent of the participant, we expect the follow-up rate to be close to 100%, but we have erred on the side of caution and allowed a 20% loss to follow-up. This inflates the required sample to 438, 219 in each group. This number is also sufficient to detect a small to medium effect size difference in the frequency of substance use. In our pilot study the consent rate was quite high, about 80% and the eligibility rate was 88%. In our pilot study we successfully recruited 76 young people, leaving 362 to recruit in the efficacy study. We expect to approach 502 participants over the 12-month recruitment period, just over two per police force per week.

The qualitative component of the study will be purposive and include interviews with participants, intervention staff and police. Participants will be chosen purposively to provide diversity in terms of site, and age and ensure appropriate participation by gender, social class, and ethnicity. The sample size considerations of the qualitative component are driven by the

need to achieve data saturation, and this needs to be judged in practice rather than stated a priori.

Sample size calculations overview

Table 2. Sample size calculations

		Protocol
Minimum Detectable Effect Size (MDES)		0.3
Alpha ²		0.05
Power		0.8
One-sided or two-sided?		Two-sided
Number of participants	intervention	219
	control	219
	total	438

Outcome measures

Baseline measures

Primary outcome

Our primary outcome is offences; including arrests, cautions and charges, 6-months post randomisation obtained directly from the local police database.

Secondary outcomes

In addition to the primary outcome this will allow us to extract data for the period 6 months prior to randomisation as a covariate and other outcomes including all offences and specific substance use offences as secondary outcomes. Frequency of substance use will be assessed at 6-months using the Time Line Follow Back Method (TLFB; (Sobell and Sobell, 1995, Levy et al., 2004)), a valid and reliable tool for assessing the frequency and quantity of multiple substances (Martin-Willett R et al., 2020) over time periods ranging from 1 to 365 days and validated specifically for adolescents (Levy et al., 2004) and used in studies of adolescents in criminal justice settings (Coulton S et al., 2023, Dakof et al., 2015). To minimise burden, we will use the 28-day version which takes about 10 minutes to complete and demonstrates an excellent level of agreement with longer versions. This tool allows us to derive the percent days abstinent from substance use and allows derivation of several other outcomes over the period (e.g., quantity and type of substances consumed). As there is evidence of assessment reactivity associated with TLFB in brief intervention studies we will only measure TLFB at 6-months and employ a single frequency of substance use question at baseline for inclusion in the analytical model as a covariate.

Mental health and wellbeing will be assessed using the Warwick-Edinburgh Mental Well-being scale (WEMWBS; (Clarke et al., 2011)). WEMWBS is a 14-item, self-completed scale addressing different aspects of eudemonic and hedonic mental health wellbeing. Health-related quality of life will be derived from a short five level, five domain instrument used extensively in this population (CHU-9D;(Furber and Segal, 2015)).

Emotional regulation and behaviour will be assessed using the self-completed Strength and Difficulties questionnaire (SDQ; (Goodman, 1997)). This assesses behaviour across several domains, conduct, hyperactivity, emotional regulation, peer relationships and prosocial. Self-reported offending will be assessed using the Self-Report Delinquency Scale (SRDS; (Smith and McVie, 2003)) over the previous six months. All these instruments will be assessed at baseline and 6-months.

To explore the process of change within the logic model we aim to assess three domains that are key targets of brief interventions. Motivation to change will be assessed using the readiness to change ruler, a single question that assesses motivational stage in adolescents (RR; (Maisto et al., 2011)). Self-efficacy will be assessed using the short Situational Confidence Questionnaire (SCQ-8;(Breslin et al., 1998)). Positive and Negative Expectancy will be assessed using a four-item expectancy measure that assesses drug effect expectancy (SUE; (Montes et al., 2019)). These instruments will be assessed at baseline and at the 6-month follow-up point and have established psychometric properties in the adolescent population.

In addition to key demographics, age, gender, ethnicity, age of first substance use, family structure that will be assessed at baseline we will use several short, validated instruments to assess potential predictors of change and identify potential subgroups within the study. These include a short assessment of family environment assessing relationships, conflict and

cohesion the Brief Family relationship Scale (BFRS; (Fok et al., 2014)), anxiety using the General Anxiety Disorder Questionnaire (GAD-7; (Mossman et al., 2017)) and depression using the Personal Health Questionnaire for adolescents (PHQ-A; (Mansour et al., 2020)) and adverse child experiences using the Adverse Child Experience Questionnaire (ACEQ; (Dong et al., 2004)). All these instruments are validated for use in an adolescent population.

Table 3. Proposed outcomes at each stage of the evaluation

Compliance

We will assess adherence by recording attendance at each element of the intervention and the control. For those in the intervention group we will assess fidelity by randomly recording 20% of brief intervention sessions stratified by age group, interventionist and site and independently score these using the Behavioural Change Counselling Index (BECCI; (Lane, 2002)). We will ask participants in the intervention arm to complete the short revised therapeutic alliance scale for children after the second intervention session (TASC-r; (Shirk and Saiz, 1992)). There is emerging evidence that the perceptions of interventionists play a key role in the quality of intervention delivered, particularly in terms of their perceived role legitimacy and self-efficacy, both targets of training and ongoing supervision. In order to assess these perceptions, we will ask interventionists to complete the Drug and Drug Using Populations Perceptions Questionnaire (DDPPQ; (Connors et al., 2019)) just prior to training and again 6-months after being trained.

Analysis

In the overall analysis, data from the internal pilot and efficacy study will be combined and analysed blind to group allocation. The efficacy analysis will be conducted and presented in accordance with the CONSORT guidelines. The validity of randomisation will be explored by presenting measures of central tendency and estimates of precision for continuous variables, and proportions for categorical variables broken down by allocation arm and stratification factors.

The primary outcome is the frequency of non-violent offences at 6-months post-randomisation, and this will be conducted as an analysis by treatment allocated (ATA; formerly known as ITT) and will include all available data maintaining participants as members of their allocated group. We expect the primary outcome will take the form of a Poisson distribution, probably with an element of zero inflation or over dispersion. Prior to analysis we will conduct a series of diagnostic tests and assess the underlying assumptions prior to choosing an appropriate and statistically rigorous regression model.

Regression models will be adjusted by baseline values and stratification factors as covariates, estimates of differences will be generated as marginal effects, derived from bootstrapped mean differences between the groups and the 95% confidence interval. To adjust the analysis for any potential bias that may emerge because participants were recruited to the pilot or efficacy stage of the study, we will employ an individual patient data meta-analysis approach whereby a dichotomous variable indicating pilot or efficacy study is entered into the model as a fixed effect.

Sensitivity analyses will be performed using a pattern mixture approach and multiple imputation to compare the sensitivity of conclusions to varying assumptions about the missing data, particularly whether data is missing at random (MAR) or missing not at random (MNAR) this allows for an assessment of both random and systemic bias.

The usual approach to assessing adherence is to conduct a per protocol analysis, dropping those participants who did not comply with their allocated intervention. However, this approach potentially leads to an underestimate of any true effect. We will conduct a Complier Average Causal Effects (CACE) analysis using an instrumental variable framework. CACE weights the analysis by the ATA treatment effect by the proportion of adherence, this allows the estimation of unbiased treatment effects and maintains the allocation in the analysis.

Secondary outcomes will be analysed in a similar manner, adjusting for baseline values and stratification factors as covariates.

The mechanism of change will be explored using a mediation model approach and incorporating motivation, self-efficacy, and expectancy at 6-months, adjusted for baseline covariates. Allocated group will be included as an interaction term.

Stepwise regression analysis will be performed to model the relationship between pre-randomisation factors and observed outcomes at 6 months, separately for the primary outcome and PDA substance use. Interaction terms with allocation arm will be included in the analysis, and a significance level of 0.1 will be used to determine which factors are to be included in the regression model. Pre-randomisation factors will include gender, age, ethnicity, IMD decile, adverse childhood experiences, anxiety and depression and family cohesion. This analysis will be augmented by an additional analysis including participants in the intervention arm only using the same pre-randomisation factors but also including process measures of adherence, intervention fidelity, therapeutic alliance, interventionist, and interventionist perceptions.

The aim of the qualitative analysis will be to link samples by grouping, comparing, and contrasting responses from all data sources to address the research questions. This linking of data allows for a concentrated and more meaningful analysis of the influence of the

programme through its contexts and mechanisms, and of its perceived impact through a thematic blending of data elements.

The coding will proceed through the following steps:

- Creation of a list of provisional, orienting codes based on the theoretical framework of the programme, and the questions and programme elements listed above.
- In the process of coding, new ‘grounded’ codes will be added to the provisional codes based on relevant items found in the data.
- In iterative dialogue between the data and the codes, researchers will organise the codes into thematic categories.
- These themes will be the basis of the written report of the qualitative data.

The analytical approach will allow a detailed description of key themes. Of particular interest will be the extent to which emergent themes can be linked to quantitative outcomes such as changes in self efficacy, peer relationships, pro-social behaviours, expectancy, and motivation to change behaviour.

The qualitative analysis will also provide an opportunity to explore the perceptions of the intervention from the point of view of a variety of stakeholders. The analysis will allow us to explore what elements of the interventions are useful and what elements are unnecessary as well as issues around how the interventions are planned and implemented and the perceived barriers or facilitators of implementation in usual practice.

Implementation and process evaluation

Research questions

Exploring fidelity/ adherence, differentiation, and quality

A stated objective of our efficacy study involves “To assess the fidelity of intervention delivery and explore the role fidelity, therapeutic alliance and baseline demographic and psychological factors play in the outcomes observed.” To achieve this, we plan on recording a random sample of interventions, stratified by interventionist and site, and having these independently scored using an established tool for assessing fidelity in behavioural change interventions, the Behavioural Change Counselling Index (Lane, 2002). This instrument provides an overall score and a domain score, for 16 key domains associated with behaviour change, ranging from 1 to 5 where 1 indicates low fidelity and 5 indicates high fidelity. We propose to conduct an analysis to explore the role fidelity, adolescents’ perception of therapeutic alliance and interventionist role legitimacy impact on the outcomes observed. We will employ a stepwise regression model, with the primary outcome as the dependent variable and adjusting for key

covariates identified using a variable reduction approach. The results of this analysis will allow a quantification of what fidelity dimensions are most associated with changes in outcomes. This will enable an exploration of whether certain domains are more important than others and should be emphasised in the intervention delivery and, by extension, the training. Allied to this the adolescent perception of therapeutic alliance, assessed using the Therapeutic Alliance Scale for Children (TASC-r) and interventionist perceptions of their confidence and legitimacy in delivering substance use interventions for adolescents, will provide an insight into whether therapist style influences outcomes, and if so what aspects of therapist style are associated with better outcomes.

In addition to this we will explore differentiation between intervention and control groups. Our experience with similar large multi-centre RCT's of brief interventions (Newbury-Birch et al., 2014, Deluca et al., 2020, Coulton et al., 2008) would suggest this control would need to consist of a minimally acceptable intervention including the provision of information and sources of support delivered by someone not involved in delivering the intervention. To explore the question of differentiation we will extend our recording to a 20% random sample of control interactions, stratified by interventionist and site. We will use the same BECCI tool to score these interactions, with the expectation they would score low on behaviour change content. Differentiation between intervention and control will be explored using the levels of agreement approach developed by Bland and Altman (Bland and Altman, 1986) to graphically present the extent to which intervention and control differ on each of the key behavioural change domains and to quantify the magnitude of differentiation after adjusting for known covariates.

Exploring Dosage

We plan on conducting a secondary analysis using a Complier Average Causal Effects (CACE) model using an instrumental variable framework. The usual approach to explore the role adherence is to conduct a per protocol analysis, where only those who received the intervention and control as prescribed are included. This can result in dropping large numbers of participants from the analysis and introduce bias. CACE analysis allows us to avoid this bias by weighting the ITT (ATA) treatment effect by the dose of intervention or control treatment received, this provides an unbiased estimate of the role of dosage in the outcomes observed.

In addition to this we would want to explore whether certain factors are associated with non-compliance to identify potential clusters of participants who do not comply. We will conduct a latent class analysis (LCA) to identify potential clusters associated with non-compliance, this will enable an exploration of whether there are sub-groups of participants who are harder to reach than others and by augmenting this quantitative approach with targeted qualitative interviews with young people and interventionists, enable the wider research group to explore what adaptations may be necessary to increase accessibility and compliance.

Exploring Reach

We propose reporting both the pilot and efficacy study using CONSORT guidelines. This will enable us to explore the relationship between those who are potentially eligible, those who consent and those who engage, using key demographic indicators, age, gender, ethnicity, socio-economic status. Significant differences in these key demographic indicators at each point will inform our qualitative research, where we will purposively sample those who do not consent and those who withdraw to explore the reasons why and understand the perceived acceptability of the intervention or control for these participants.

A key area to explore in terms of reach is whether all potential participants are being identified and referred to the scheme. In previous studies of diversionary schemes for substance misuse offences some critics have highlighted the disproportionate inclusion of white, middle class, males that are not necessarily representative of the target demographic. To explore this, we plan on working with public health colleagues with access to PNC data to use a comprehensive cohort approach to understand outcomes for those who are referred or not referred to the scheme. This approach will allow anonymised aggregate analysis of differences between the cohort referred or not referred but also anonymised aggregate analysis of outcomes for those not referred. This information will allow us to quantify any inherent biases associated with referral in terms of key demographics and to further explore these with our stakeholder interviews. This approach will enable us to understand how generalisable the study results are and whether changes need to be made to referral pathways or intervention delivery to make the population more inclusive.

Exploring Responsiveness

An aspect of our qualitative work with key stakeholders involves examining participants' positive and negative experiences of the referral process and intervention, exploring how these perspectives concur with those who deliver the intervention, explore at what points negative and positive experiences are at their greatest and what steps could be taken to ameliorate these experiences to improve the delivery and acceptability of the intervention.

Exploring Adaptation

The mechanism of change will be explored using a mediation model approach and incorporating motivation, self-efficacy, and expectancy at month 6, adjusted for baseline covariates. Allocated group will be included as an interaction term. Exploring factors that impact on the mechanism of change will be assessed using stepwise regression analysis to model the relationship between pre-randomisation factors and observed outcomes at 6 months, separately for the primary outcome and for percent days abstinent from substance use. Interaction terms with allocation arm will be included in the analysis, and a significance

level of 0.1 will be used to determine which factors are included in the regression model. Pre-randomisation factors include gender, age, ethnicity, IMD decile, adverse childhood experiences, anxiety and depression and family cohesion.

In addition to quantitatively understanding the mechanism of action, the qualitative analysis will provide an opportunity to explore the perceptions of the intervention from the point of view of a variety of stakeholders. The analysis will allow us to explore what elements of the interventions are useful and what elements are unnecessary, issues around how the interventions are planned and implemented and the perceived barriers or facilitators of implementation in usual practice.

Through a detailed exploration of the key dimensions, we plan on stating our logic model at the start of the project, revising this during the pilot phase and revise this again at the end of the efficacy stage. The logic model will incorporate the qualitative research exploring stakeholder perceptions of acceptability and usefulness, hindrances and facilitators associated with the process and intervention but will also combine quantitative analysis exploring adherence, dosage, fidelity, and mediators associated with behaviour change. This mixed methods synthesis will enable us to understand what works, how it works, when it works and for whom it works and provide a detailed elaboration of the mechanisms and processes through which it works.

Exploring factors affecting implementation

Within the CJS system there is no central recording mechanism for recording informal out of court disposals and diversions. It is estimated that 40% of first-time youth entrants to CJS receive an informal diversion. As part of the efficacy trial, we plan a survey of police forces in England to explore the nature and extent of diversion for first time substance use offences among young people, working in collaboration with colleagues with the police and senior staff involved in criminal justice at Public Health England. This survey would address the varieties of diversionary schemes employed, eligibility, referral mechanisms, numbers referred annually and source of funding. This will provide an overview of the current state of play, where interventions take place, the process of implementation and the associated costs and source of funding.

Key questions addressed by the qualitative component will both be informed by, and inform, elements of the quantitative analysis, they include:

- Do participants, providers and police perceive any external or logistical issues as impacting referral, intervention delivery, attrition, or study assessments?
- What are participants' positive and negative intervention experiences and how do these fit with providers' perceptions? At what points in the intervention are these most likely?

- What reasons do participants offer for their misuse and for their intervention responses?
- Can practices associated with the intervention be amended to increase its acceptability and impact?
- Do police perceive the intervention as impacting participants' offending?

To address these research questions in depth, the qualitative aspect of the work will involve the collection of narrative accounts from a range of individuals using semi-structured interviews. These will be collected from young people participating, and staff involved in the programme delivery and professionally associated with the young people. Professionals will be sampled purposefully from the different staff groups, and young people will also be purposefully sampled.

To explore beyond the realms of the research project itself, we will also conduct several qualitative focus groups with key stakeholders not involved in the study itself. These groups will comprise 6 to 8 individuals and will be repeated until data saturation is reached. This purposive sample will be guided by the findings of the survey of practice across the country and include areas of low/ high activity, capacity, and deprivation. These focus groups will explore views on organisational capacity, intervention delivery, eligibility, referral mechanisms, the optimum number of standardised measures required to monitor intervention delivery, minimum standards of experience for interventionists, delivery of training and ongoing supervision. These focus groups will allow us to develop a set of minimum standards, standard operating procedures for training and intervention delivery and a training and an intervention delivery manual.

In addition to these focus groups, we will individually interview purposefully selected children and young people from across the country who meet the same criteria as the intervention participants but who have not received any intervention. Again, the purposive sample will be guided by diversity criteria (i.e., areas of low/high deprivation, age, gender, social class, and ethnicity). Participants will be asked to provide views on how their substance misuse has been handled and what might aid them/have aided them in reducing it as well as any involvement in non-violent offences. As with all the qualitative research in this project, sample size will be determined according to data saturation rather than a priori.

Synthesis of these data sources will allow a detailed overview of the implementation and processes associated with successful delivery of the intervention and a firm basis to conduct a pragmatic trial of effectiveness if warranted from the results of the efficacy evaluation.

Table 4: IPE methods overview

IPE Question	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Fidelity/ adherence/ differentiation/ quality	Participant survey, therapeutic alliance, BECCI checklist, session data	438 participant surveys and TASC-r, BECCI fidelity assessment	Regression analysis	Quantification of the role fidelity and quality plays in the outcomes observed	Better quality interventions that involve better alliance and communication between young people and practitioners are associated with better outcomes.
Dosage	Session planned and attended, outcome data	438 participant surveys, process database	Complier Average Causal Effect analysis	Estimation of the role dosage plays on observed outcomes at variable thresholds	Greater frequency of intervention is associated with better outcomes
	Factors associated with non-compliance	438 participant surveys, process database	Latent Class Analysis	Explore factors associated with non-compliance	Create targeted opportunities to reduce non-compliance and maximise acceptability.
Reach	Comprehensive Cohort Approach	Data on all young people referred to the service compared with data for those who consented	Logistic regression model with consent as the dependent outcome	Explore whether the intervention was accessible to all those referred to the services	Identify any potential issues with accessibility.
	Qualitative interviews with service	10 semi-structured interviews	Transcribing and inductive analysis to allow themes to	Identify any populations that experienced	Identify issues with accessibility

	leads and key stakeholders		emerge naturally	limited accessibility and the potential reasons for this.	and how these may be addressed
Responsiveness	Qualitative interviews with participants	15 semi-structured interviews with participants and 10 semi-structured interviews with key stakeholders, purposive sampling to get variety by site, age, and ethnicity	Inductive analysis	To explore acceptability of the referral and intervention process. To explore positive and negative experiences and when these occur.	To understand how the referral and delivery processes can be maximised.
Adaption	Quantitative analysis	438 participant surveys	Mediation analysis including allocated arm as an interaction erm	To explore factors at baseline that mediate the outcomes observed	To understand the mechanisms of change and provide information for refinement of the Theory of Change Model.
	Qualitative analysis	15 semi-structured interviews with participants and 10 semi-structured interviews with key stakeholders, purposive sampling to get variety by site, age, and ethnicity	Inductive analysis	To explore participant and practitioner perspectives on how the intervention works and perceived barriers or facilitators to the intervention	To understand who the how the intervention works and who it works for to refine the theory of change.

Implementation	Qualitative analysis	15 semi-structured interviews with participants and 10 semi-structured interviews with key stakeholders, purposive sampling to get variety by site, age, and ethnicity	Inductive synthesis	Synthesis of qualitative findings to explore positive and negative experiences and how changes can be made to maximise the impact of the intervention.	Identify potential modifications that can be made to maximise the impact of the intervention.
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Cost data reporting and collecting

Costs associated with delivering the intervention will be derived using a micro-costing approach accounting for the actual local costs and resources used in delivering the intervention and associated training. This will include salaries, resources, facilities, overheads, and management costs. The cost perspective will be that of the intervention provider. We will include any costs associated with supervision and additional training and use the time horizon of the trial to estimate staff turnover. We aim to estimate the cost of delivering the intervention in real practice rather than the cost of delivering the intervention in the trial. The cost data will be provided as mean cost per participant with 95% confidence intervals.

Ethics and registration

Ethical approval was sought and provided by an independent ethics committee at the University of Kent (SRC0498). The pilot study registration (ISRCTN133967729) is being updated and extended to cover the efficacy trial.

Data protection

All systems and personnel are approved for the management of clinical and sensitive data and are ISO certified to ISO27001 standard. This includes all physical systems, systems to detect intrusion, encryption of data from point of collection to storage, quality assurance and audit trails associated with any data collected. All identifiable data collected will be done with explicit consent and limited to data to allow participants to be contacted for follow-up. Data linkage will employ a unique identifier where the link to identifiable information will be stored on an encrypted secure database. Researchers will be trained to GCP standard and will comply

with all relevant data protection legislation. Once final follow-up is completed, personally identifiable information will be deleted from the dataset held by the university and where consent has been granted encrypted data will be transferred to the Youth Endowment Fund data archive. Data collection and management will be governed by a trial specific Standard Operating Procedure agreed and approved by ethics.

The basis of processing data was the public task basis to use their personal information. We only use special category information (such as information about health, religion, race or ethnic origin, or any criminal offence information) if it is necessary for research purposes or statistical purposes which are in the public interest. Potential participants and their carers, if applicable, were provided with a trial specific privacy notice (appendix ii) prior to providing consent. This privacy notice outlined what data was being collected, for what purposes and for how long. In addition to the trial specific privacy notice the evaluation team at the University of Kent, the intervention delivery team at With You and each participating police force signed an information sharing agreement highlighting what information would be shared, the reasons for sharing information and the means of sharing information.

Stakeholders and interests

Evaluation team:

Professor Simon Coulton; University of Kent, Principal Investigator, and quantitative methodologist.

Theresa Gannon; University of Kent, Co- Investigator, joint qualitative lead.

Nadine Hendrie; University of Kent, Trial Manager.

Ms Rosa Vass; University of Kent, Trial Researcher.

Delivery team:

Jennifer-Rushworth-Claeys; Head of Young People's Service, With You.

Agnes Wooton; Manager Youth Diversion Service, With You.

Jennifer Nash; Intervention delivery Kent.

Phillipa Nash; Intervention delivery Cornwall.

Sophia Bridges; Intervention delivery Sefton.

Shaquille Williams; Intervention delivery Lancashire.

Risks

Our experience of similar studies has enabled us to develop and pilot several risk mitigation strategies. We have identified the following key risks.

1. Lack of engagement by stakeholders. We plan on actively engaging with all stakeholders to

ensure the importance of the project is recognised. We aim to visit all sites early on and plan on engaging with staff at all levels in the partner organisations (LOW).

2. Potential contamination. As a randomised controlled trial, the potential for contamination is low. The design of the standardised control group, delivered by staff not involved in delivering the intervention, will address any potential for contamination. All follow-ups will be conducted blind to baseline allocation (LOW).

3. Poor recruitment. We have extensive experience of working with marginalised populations. In addition to clear referral and recruitment strategies we will ensure recruitment is constantly monitored to identify emerging issues, reduce barriers to participation by using few inclusion criteria and minimising exclusion criteria, providing clear information, and ensuring participants are clear on what the trial entails. Our previous experience with a similar population recruited 80% of those participants considered potentially eligible, in our pilot study we recruited 80% of those eligible. (LOW).

4. Poor adherence to follow-up. As our primary outcome measure is not participant assessed this issue relates in the main to the collection of secondary and process measures. In our previous studies with similar populations we have met, and exceeded, our target follow-up rate of 70% at 6-months and in our pilot study we followed up 88% across both groups. We have developed several follow-up strategies including multiple contact details, details of contactable others and ensuring participants are recompensed for the time spent engaging in follow-up assessments (LOW).

5. Failure to access PNC data. The PNC data constitutes the primary outcome. We will ensure data sharing agreements with local police forces are in place at the start of the pilot phase of the study. We will ensure consent is provided to access this data and this has been reviewed by the police data controller and ethics. If necessary, we will implement alternative sources for this data using self-report (LOW).

6. Iatrogenic and adverse events. We do not anticipate any iatrogenic effects and brief interventions are not usually associated with adverse events. We will monitor any iatrogenic or adverse events and create a reporting system. Any event that is potentially a consequence of the trial will be reviewed by the trial management group and where appropriate an independent committee, who will decide regarding continued conduct of the trial (LOW).

7. Ongoing COVID restrictions. The trial recruitment and intervention will be conducted in accordance with government and provider guidelines on working with COVID. Follow-ups will be conducted remotely using video technology to reduce both the burden on participants and contact between research staff and multiple participants (LOW).

Timeline

Dates	Activity	Staff responsible/ leading
28/02/23	YEF receive and approve amended information sheets, privacy notices & ethical approvals	Kent (NH)
01/03/23 to 28/02/24	Recruitment and baseline assessments	Kent (SC)
31/03/23	Provide YEF with Statistical analysis plan for peer review	Kent (SC/TG/NH)
31/08/23	Submit final Statistical analysis plan with peer review responses	Kent (SC)
01/09/23 to 31/08/24	Schedule and conduct participant qualitative interviews and focus groups	Kent (TG/ NH)
01/09/23 to 31/08/24	Conduct month 6 assessments	Kent (NH)
01/03/23 to 28/02/24	Schedule and conduct stakeholder qualitative interviews and focus groups	Kent (TG/ NH)
01/03/23 to 28/02/24	Assess and calculate cost data	Kent (SC)
01/11/23 to 30/09/24	Extract LPD data	Kent (NH)
01/09/24 to 30/10/24	Statistical and qualitative analysis	Kent (SC/ TG/ NH)
01/09/24 to 30/10/24	Synthesis of findings	Kent (SC/ TG/ NH)
30/10/24	Submit draft of final report	Kent (SC/TG/ NH)

31/02/25	Respond to peer review and submit final report	Kent (SC/ TG/ NH)
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Appendix 1: Changes since the previous YEF evaluation

Appendix Table 1: Changes since the previous evaluation

Feature		Pilot to efficacy stage
Intervention	Intervention content	<i>No change</i>
	Delivery model	<i>No change</i>
	Intervention duration	<i>No change</i>
Evaluation	Eligibility criteria	<i>No change</i>
	Level of randomisation	<i>No change</i>
	Outcomes and baseline	<i>Measures of anxiety (GAD-7) and depression (PHQ-9) removed from month 6 outcome set</i>
	Control condition	<i>No change</i>

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