

PILOT TRIAL PROTOCOL

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

University of Kent

Principal investigator: Professor Simon Coulton

Pilot trial protocol template (includes a control group)

Evaluating institution: University of Kent

Principal investigator(s): Professor Simon Coulton

Project title¹	Re-Frame: Randomised Controlled Trial of a Diversion Programme for Adolescents in Police Custody who Possess Illicit Substances
Developer (Institution)	We Are With You
Evaluator (Institution)	University of Kent
Principal investigator(s)	Professor Simon Coulton
Evaluation plan author(s)	Professor Simon Coulton
Evaluation setting	Community
Target group	10-17 year olds, found in possession of class B or C illicit substances by police
Number of participants	4 geographical areas, 96 participants

Protocol version history

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).

Version	Date	Reason for revision
1.0 [original]	10/02/22	

Any changes to the design need to be discussed with the YEF Evaluation Manager (EM) and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design, research questions and approach, and the rationale for these.

Intervention

The relationship between substance use and criminal activity is complex but the prevalence of substance use is higher in adolescent offending populations and the two are related in the context of other forms of disinhibitory behaviour, such as aggression and risk-taking (Wilson, 2013). Adolescents who offend experience a range of complex risks and vulnerabilities including neglect and abuse, substance use related problems, and exclusion from education (Newbury-Birch et al., 2015). As a group, they are more likely to experience health and social inequalities in later life. There is a widespread consensus that adolescents who offend are one of the most vulnerable and 'hard to reach' groups. Diversion from the CJS is a key window of opportunity whereby young people can reflect on their drug use and receive a brief intervention they might otherwise never receive. Brief psychosocial interventions delivered using a motivational interviewing approach within a FRAMES paradigm have been shown to be effective in adolescent (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.

As part of a comprehensive evaluation, the key aspects of the proposed study go beyond whether the intervention approach works to explore who it works for, how it works and how it could be implemented into routine practice.

Intervention Group

Two sessions of Brief Intervention by skilled youth workers. In session one they will use a Drug Grid to reflect on how their actions have affected their lives, their family and wider community. The child 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 felt as a result of it.

The Drug Grid is a drug education exercise that enables the child to demonstrate current understanding of substances (including medication, legal highs, and image and performance enhancing drugs). As they go through the exercise they will learn about these substances (eg depressant or hallucinogen), 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 use and overdose.

Brief intervention session two is the Drug Triangle. With You will aim to complete this session within two weeks of the original referral. Ideally session one will take place in week one and session two in week two, depending on the child's availability and preferences.

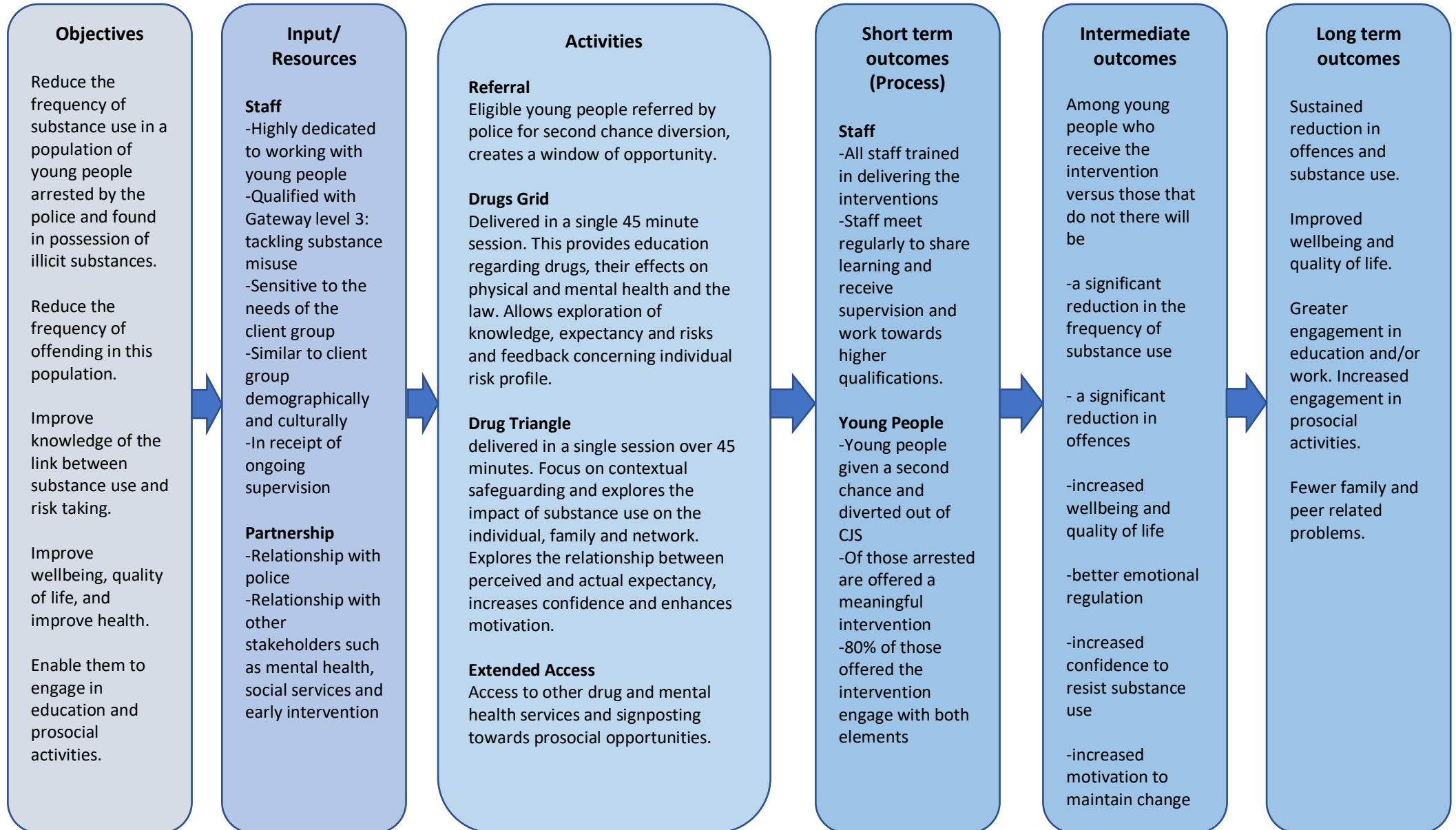
Using the Drug Triangle, the child will focus on the substance, mindset and setting that led them to the session. This holistic harm reduction approach ties in with contextual safeguarding, framing the child's situation within a wider context. They will spend time thinking about how this has affected them, their family, school (if applicable), and community. The child 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 violent offending and the potential of criminal proceedings. The short-term aims are that the child 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.

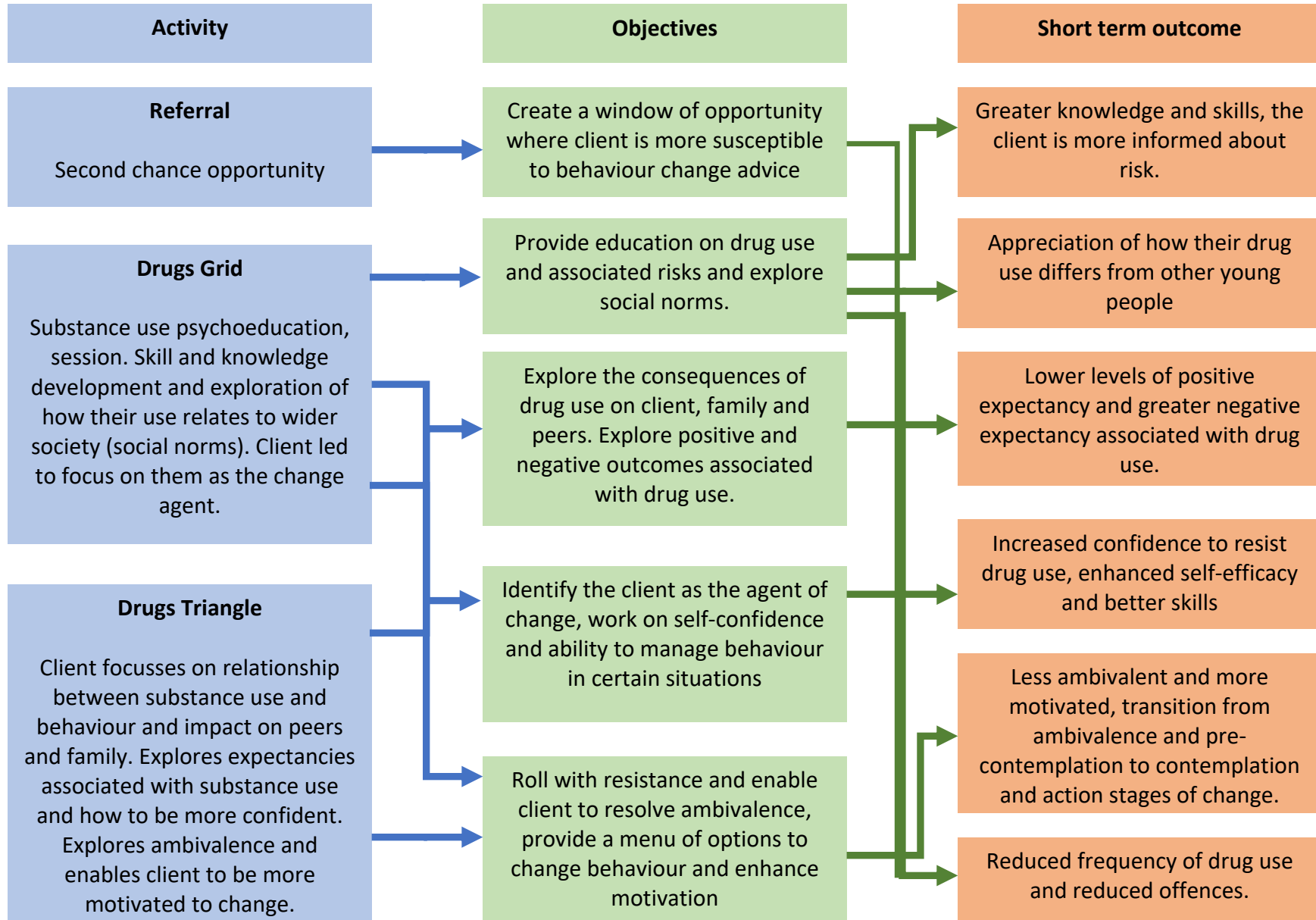
Control Group

The child will receive one session of Advice, Information and Signposting. The child will be offered information about the With You substance 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.

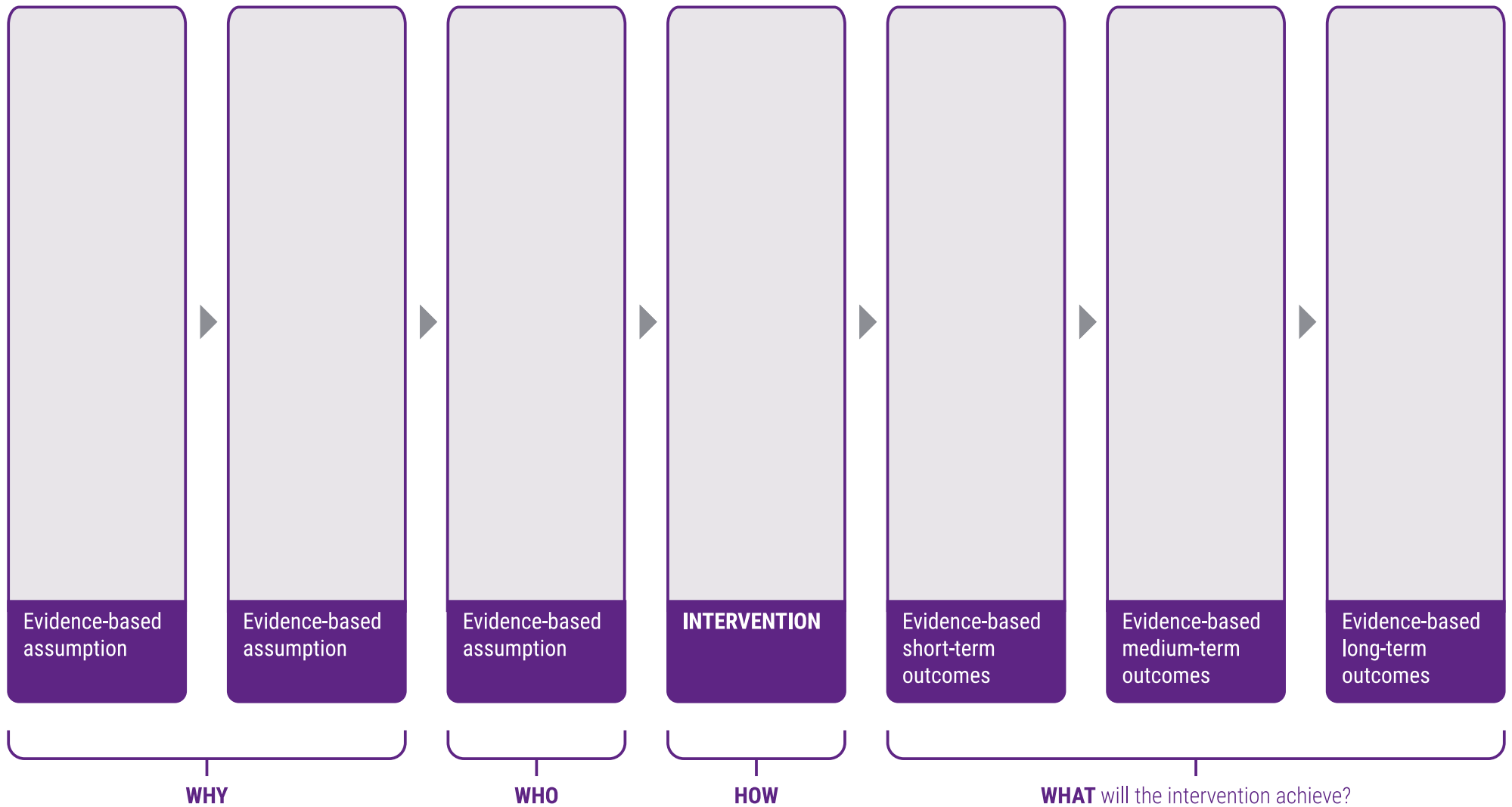
Re-Frame: Logic Model



Re-Frame: Blueprint



Re-Frame: Theory of Change





Primary outcome measures

Our primary outcome is all offences; including arrests, cautions and charges, in the 6-months post randomisation obtained directly from the Police National Computer. 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. Secondary outcomes are listed in detail below..

Research questions and/or objectives

Objectives of the pilot trial

1. To pilot study outcomes and evaluation methods, assess the parameters for conducting an efficacy evaluation and to assess whether operational progression criteria have been met and if so to develop a full protocol for an appropriately powered efficacy study.
2. To assess the acceptability of an ethically appropriate standardised business as usual control.
3. To qualitatively explore the feasibility and acceptability of referral pathways, intervention delivery and study assessments from the perspectives of the police, intervention provider and participants. A key aim is to identify how, when, why and for whom the interventions work.

Success criteria and/or targets

In the pilot phase of the study we will estimate likely proportions of participants who are eligible, who consent, adhere to the intervention and the proportion followed-up at 6 months. Proportions will be compared to predefined progression criteria.

Criteria			
Proportion referred who are eligible	70%	50%	40%
Proportion eligible who consent	70%	50%	40%
Proportion eligible who adhere	80%	60%	40%
Proportion followed-up (secondary)	80%	70%	60%

Where progression criteria are green the efficacy study will continue as planned, if amber or red discussion regarding remedial action will be taken prior to embarking on the efficacy study.

In addition to proportions we will assess data completeness for each outcome instrument. A threshold of 60% complete will be used to assess whether an outcome instrument should be included in the efficacy trial.

Methods

Pilot trial design

Two-armed prospective individually randomised controlled internal pilot trial.

Randomisation

Randomisation will employ random permuted blocks of variable size stratified by site; Kent, Cornwall, Sefton, Lancashire and by age group; 10-14 versus 15-17 years. Random strings will be created for each stratification combination and deployed independent of the research team and each participant will have equal probability of being allocated to the intervention or business as usual.

Randomisation will be conducted after eligibility has been assessed, informed consent provided and baseline assessment conducted. The researcher will enter necessary details into an encrypted database and after necessary data has been checked an allocation code will be provided. This code will indicate the nature of allocated group. The researcher will not be able to access randomisation codes. The participant will not be blind to the intervention.

Participants

Participants will be referred by the police to existing we Are with You Young People's substance misuse services across four geographical areas of England; Kent, Sefton, Cornwall, Lancashire.

Eligibility criteria

Inclusion Criteria:

Aged 10-17 years inclusive

Considered appropriate for diversion by police

In possession of class B or C illicit substances

Exclusion Criteria:

Arrested for a sexual or violent offence

History of four or more offences

Substance use severity that requires specialist clinical intervention such as detoxification or medication assisted maintenance

Inability to understand oral English sufficiently to engage in the intervention or the follow-up to the extent the participant requires an interpreter to engage with the intervention or research. Outcomes are validated for English language populations.

Outcome measures

Our primary outcome is all offences; including arrests, cautions and charges, 6-months post randomisation obtained directly from the Police National Computer. 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; (Levy et al., 2004; Sobell and Sobell, 1995)), a valid and reliable tool for assessing the frequency and quantity of substance use over time periods ranging from 1 to 365 days and validated specifically for adolescents (Levy et al., 2004). 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 assessment of health utility used extensively in this population (CHU-9D; (Stevens, 2012)).

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 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 (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 a number of 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.

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.

All the outcome measures have been used previously in adolescent populations and we estimate the outcome data set takes on average 40 minutes to complete. We will assess burden in the pilot stage with a simple measure of cognitive burden. At the end of the pilot study, we will assess all instruments for data completeness and make informed decisions regarding their inclusion in the efficacy study.



Proposed outcomes at each stage of the evaluation

Outcome	No. of Questions	Baseline	Month 6
Frequency of substance use (Single TLFB item)	1	✓	
Time Line Follow-Back 28-day version ¹	0		✓
Wellbeing (WEBWMS)	14	✓	✓
Quality of Life (EQ5D-5L)	5	✓	✓
Strength & Difficulties (SDQ ²)	25	✓	✓
Self-report Delinquency (SRDS ^{1,2})		✓	✓
Motivation state to change (RR)	1	✓	✓
Substance Use Expectancy (SUE)	4	✓	✓
Self-efficacy (SCQ-8)	8	✓	✓
Generalised Anxiety Scale (GAD-7)	7	✓	
Depression - Personal Health Questionnaire (PHQ-A)	8	✓	
Adverse Childhood Experiences (ACEQ)	10	✓	
Brief Family Relationships Questionnaire (BFRS)	16	✓	

¹ TLFB28 and SRDS are researcher led questionnaires rather than client self-completed

² SRDS and SDQ are YEF Core outcomes



Sample size

In the pilot study we will recruit 96 participants, 48 in each arm, across the 4 sites. This will allow for exploration of key parameters needed to confirm sample size calculation for the efficacy study. It is sufficient to allow estimation of two-sided 95% CI's around the proportions of eligible, consenting, adhering and followed-up at month 6 in each arm of the study with half-widths less than 0.15. It exceeds the 30 per group recommended by Lancaster et al (Lancaster et al., 2004) and the 35 per group recommended by Teare et al (Teare et al., 2014) for estimating the SE of a primary outcome with sufficient precision, including accounting for any variation across site, where 12 participants per arm per site is recommended.

Methods and data collection

Quantitative data collection

Baseline quantitative outcomes, detailed below, will be collected after eligibility has been assessed and consent provided. Assessment will be conducted on-line using a questionnaire designed for on-line completion and tested with peers of a similar age. The researcher will support the participant in the completion of the baseline outcomes and be on hand to answer any questions and ameliorate any difficulties. The participant will be allocated immediately after the baseline assessment has been completed.

Participants allocated to the intervention group will be asked to complete the treatment alliance outcomes after the second session. Participants will be contacted at six months after allocation and will complete the follow-up outcomes. Follow-up outcomes will be collected on-line and the young person will be supported in completion by a researcher.

**Eligible young people are referred to
WAWU at the participating sites**

**WAWU provide information sheet and
check whether the young person is willing
to consent to the trial**

**If no consent young person
receives TAU delivered by
WAWU**

**If informed consent is provided research
staff contact the young person and conduct
the baseline assessment and young person
randomised**

Randomised to the REFRAME intervention

Randomised to TAU

**Receives session 1
Drug Grid**

**Receives TAU
one session of advice, information and
signposting currently delivered to this
population**

**Receives session 2
Drug Triangle**

Completes month 6 follow-up

Completes month 6 follow-up

Qualitative data collection

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 those who withdraw, and staff involved in the programme delivery. Professionals and young people will be sampled purposefully, and young people will be approached for participation within six weeks of completing the intervention.

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.

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 explore beyond the realms of the research project itself, we will also conduct a number of 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

Cost data

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. The cost-perspective will be of the service provider. As staff are already employed in the relevant services no costs associated with training will be included as there is no requirement to backfill posts for the purpose of training. All staff involved in all centres will keep records of the time involved in setting-up, travelling to and conducting both intervention and control sessions. In addition staff will be asked to record any resources employed in delivering the intervention and control. Actual costs will be derived for both intervention and control by allocating actual salary costs to time activity and by allocating actual costs of resources used. As all costs will be incurred in a single year no discounting will be employed nor will any adjustment for inflation be used. We will present cost per participant for both intervention and control groups and the marginal cost difference (the cost of the intervention group minus the control group) with associated 95% confidence intervals. In order to explore the impact of uncertainty we will derive a bootstrapped marginal cost using 1000 bootstrapped replications stratified by centre.

Data analysis

In the pilot phase of the study we will estimate likely proportions of participants who are eligible, who consent and the proportion followed-up at 6 months. Each of these will be assessed against progression criteria agreed a priori.

We will conduct a descriptive analysis of outcomes including measures of central tendency and estimates of precision for continuous outcomes and proportions for categorical outcomes. Inferential analysis at the pilot stage will focus on the primary outcome, offences at 6-months with the aim of providing estimates of the potential effect of the intervention. After conducting diagnostic plots and selecting an appropriate regression approach, adjusting for baseline values and stratification variables as covariates, we will present the marginal effect, mean difference between the intervention and control groups and 80% confidence intervals. This analysis will allow us to confirm or revise our sample size calculation. At this stage we will also explore the pattern of missing data for each outcome and by key demographic indicators such as ethnicity and age, if missing data exceeds 40%, we will make judgements about whether to incorporate the outcome in the efficacy study.

Outputs

The main outputs of the pilot trial will be twofold

1. A full report on the design, conduct, analysis and interpretation of progression to an efficacy trial.
2. If an efficacy trial is warranted a revised protocol for the design of that trial.

Ethics and registration

Ethics has been provided by an independent ethics committee, University of Kent Social Science Research Ethics Committee Ref SRC0498. The trial will be registered in the ISRTN trial registry and www.controlled-trials.com.

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.

Personnel

- Delivery team:
Jennifer-Rushworth-Claeys; Head of Young People's Service We Are With You
Agnes Wooton; Manager Youth Diversion Service, We Are With You
- Evaluation team:
Simon Coulton; University of Kent, Principal Investigator
Jane Wood; University of Kent, Co- Investigator, joint qualitative lead
Theresa Gannon; University of Kent, Co- Investigator, joint qualitative lead
Nadine Hendrie; University of Kent, Trial Manager
Tracy Pellatt-Higgins; University of Kent, Trial Statistician

Risks

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

1. Lack of engagement by stakeholders (**LOW**). 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.
2. Potential contamination (**LOW**). 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.
3. Poor recruitment (**MEDIUM**). 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.

4. Poor adherence to follow-up (**MEDIUM**). 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. 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.

5. Failure to access PNC data (**MEDIUM**). 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.

6. Iatrogenic and adverse events (**LOW**). 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.

7. Ongoing COVID restrictions (**LOW**). 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.

Timeline

Dates	Activity	Staff responsible/ leading
12/01/22	Study start-up meeting with we Are with You Draft pilot protocol submitted to YEF Draft analysis plan submitted to YEF Draft consent form delivered to YEF Draft information sheet delivered to YEF Ethics application submitted Data sharing agreements Data management and randomisation systems developed and piloted	Coulton
31/01/22	Site staff training complete PNC data sharing agreements organised	Hendrie
31/01/22	Final pilot protocol delivered to YEF Final pilot analysis plan delivered to YEF Final consent form delivered to YEF Final information sheet delivered to YEF	Coulton
31/05/22	Complete recruitment of 96 participants	Hendrie
31/10/22	Complete quantitative outcomes at 6 months for 96 participants	Hendrie
31/10/22	Schedule and conduct qualitative interviews	Wood/ Gannon
31/10/22	Progression recommendation made	Coulton
31/12/22	Conduct interim analysis Revise and submit efficacy study protocol Submit draft pilot evaluation report Revises information and privacy notices and seeks YEF approval	Coulton
29/04/23	Submit final evaluation report	Coulton

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