EVALUATION PROTOCOL

Using a creative writing programme (New Chapters) to improve behavioural difficulties for young people in prison: A randomised controlled trial.

University of Manchester

Principal investigator: Charlotte Lennox

YOUTH ENDOWMENT FUND

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Evaluation protocol

Evaluating institution: The University of Manchester
Principal investigator: Dr Charlotte Lennox

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Evaluation settings	Prison (3 x Young Offender Institutions & 1 x Secure School)
Target group	Boys aged 15-18 serving a custodial sentence
Number of participants	375
Primary outcome and data source	Self-reported Strengths and Difficulties Questionnaire (SDQ) difficulties total score

Secondary outcome and data source	1. Self-reported empathy via Basic Empathy Scale (BES) 2. Self-reported pro-social identity via Pro-Social IDentity Scale (PIDS) 3. Self-reported self-esteem via Self-Esteem Measure for Prisoners (SEM-P) 4. Self-reported mental wellbeing via Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) 5. Self-reported creativity via Creative Self-Efficacy Scale for Children and Adolescents (CASES) 6. Behaviour incidents via prison record.

PROTOCOL VERSION HISTORY

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1.1 [*latest*]	10.10.24	To address peer review comments
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Any changes to the design or methods need to be discussed with the YEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design. Please ensure that these changes are also reflected in the SAP (CONSORT 3b, 6b).

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Abbreviations

AE	Adverse Event
ANCOVA	Analysis of Covariance
AR	Adverse Reaction
BAU	Business as Usual
BES	Basic Empathy Scale
CASES	Creative Self-Efficacy Scale for Children and Adolescents
CFIR	Consolidated Framework for Implementation Research
CJS	Criminal Justice System
CONSORT	Consolidated Standards of Reporting Trails
CRF	Case Record Form
CYPSE	Children and Young People Secure Estate
DfE	Department for Education
DMEC	Data Monitoring and Ethics Committee
DPA	Data Protection Act 2018
EHCP	Education, Health and Care Plan
HMIP	HM Inspectorate of Prisons
HMPPS	HM Prison and Probation Service
HMPYOI	His Majesty's Prison Youth Offender Institution
ICC	Inter Cluster Correlation
IPE	Implementation and Process Evaluation
MDES	Minimum Detectable Effect Size
MoJ	Ministry of Justice
MRC	Medical Research Council
NLT	National Literacy Trust
NRC	National Research Committee
ONS	The Office for National Statistics
PI	Principal Investigator
PIDS	Pro-social Identity Scale
PIS	Participant Information Sheet
PM	Project Manager
P-NOMIS	Prison National Offender Management Information System
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SCH	Secure Children's Homes
SDQ	Strengths and Difficulties Questionnaire
SEM-P	Self-Esteem Measure for Prisoners
SEN	Special Education Needs
STC	Secure Training Centres
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWEMWS	Short Warwick-Edinburgh Mental Wellbeing Scale

TMG	Trial Management Group
TMG	Trial Management Group
ToC	Theory of Change
TSC	Trial Steering Committee
UK GDPR	UK General Data Protection Regulation
UoM	University of Manchester
UoM EC	The University of Manchester Ethics Committee
USM	Urgent Safety Measures
USM	Urgent Safety Measures
YCS	Youth Custody Service
YEF	Youth Endowment Fund
YJB	Youth Justice Board
YOI	Youth Offender Institutions

TRIAL SUMMARY

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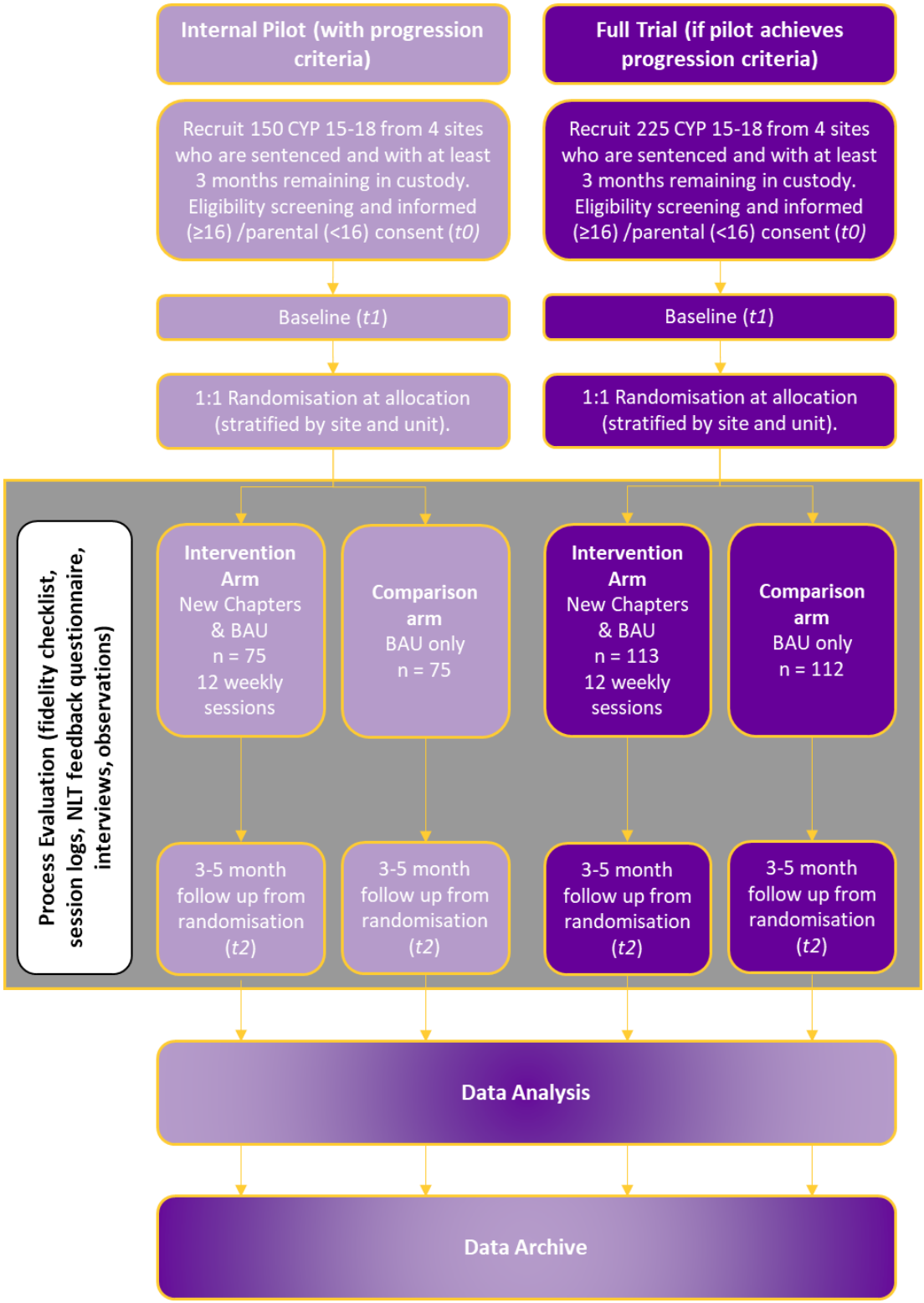
	• Self-reported creativity via Creative Self-Efficacy Scale for Children and Adolescents (CASES) • Behaviour incidents via prison record.
Inclusion Criteria	• Boys aged 15-18 years old • Serving a custodial sentence • Having at least 3 months remaining on sentence
Exclusion Criteria	• On remand • Having less than 3 months left on sentence • Not able to provide informed consent • Parental consent not provided for those under 16 • Requires an interpreter • Those presenting a risk to the research or intervention team • Those identified by the site as being unable to mix with others in a group setting or are in a small 'community group'.
Intervention Duration	12 weeks
Follow-up Duration	Between 91 and 152 days post randomisation
Planned Trial Period	30 months

TRIAL FLOWCHART



1. Study rationale and background

The Children and Young People's Secure Estate (CYPSE) consists of three accommodation types, Young Offender Institutions (YOI), Secure Training Centres (STC) and Secure Children's Homes (SCH). A new type of accommodation is being introduced and opened in 2024 called a Secure School and categorised as a SCH. All types of secure accommodation can hold young people who are serving custodial sentences. Those aged 15 to 18 tend to be held in YOIs, the largest setting type.

As of January 2024, there were about 520 young people aged 15 to 18 in custody in England and Wales (HM Prison and Probation Service [HMPPS] & Youth Custody Service [YCS], 2024). Boys make up 97% of the custody population, but only 51% of the general population (Youth Justice Board [YJB], 2024). Young people from racially marginalised backgrounds are also disproportionally represented within the CYPSE and data suggests that around 50% of young people in custody are from non-white backgrounds, despite only accounting for 37% of the general population. Young people from black ethnic groups make up 26% of the population in CYPSE, but only account for 6% of the general population (YJB, 2024). The proportion of young people in the CYPSE with educational needs and other vulnerabilities, such as mental health difficulties, is also overrepresented when compared to the general population, e.g., 80% of young people have a Special Educational Needs & Disability (SEND) (Department for Education [DfE] & Ministry of Justice [MoJ], 2022); 37-50% of young people have been in contact with social care services at some point in their lives (Day, 2021); 66%-90% of young people have below average language skills and 46-67% falling into the poor and very poor group (Bryan et al., 2010); and 57% of young people have at least one mental health or neurodevelopmental need or diagnosis (Children's Commissioner for England, 2018). While the overall number of young people in the CYPSE has been declining (HM Inspectorate of Prisons [HMIP], 2023), the proportion of those from racially marginalised backgrounds and those with multiple and complex needs is increasing (Case & Browning, 2021). The proportion of boys within the CYPSE has remained consistent at around 95%-97% (HMPPS & YCS, 2024).

Even before entering the CYPSE, boys, those from racially marginalised backgrounds, those with SEND and other intersectionality, have poorer educational experiences and outcomes. There is a well-documented gender gap in education attainment, with girls outperforming boys at all stages (Bolton & Lewis, 2024). Teachers have also tended to consider boys more problematic in the classroom, both in terms of academic ability and behaviour (Downey & Vogt Yuan, 2005). These negative stereotypes often have an impact on boys' subsequent academic performance as they become a self-fulfilling prophecy (Hartley & Sutton, 2013). Schools can also foster gender stereotypical attitudes that disadvantage male academic achievement, being 'macho' is often equated with athletic ability, defiance of authority and a poor academic record (e.g. see Jamison et al., 2015). Masculinity is rarely connected to studying, excelling in school or getting good grades (Moreau & Brownhill, 2017). Gendered behavioural norms can be internalised and encourage boys to be disruptive and noncompliant in class, and to not ask for help from teachers leading them to falling behind academically

(Morris, 2012). In addition, the lack of positive male role models, both in the family, and in professionals in contact with young people has been credited with the challenges that boys experience (Centre for Social Justice, 2013). The normative feminisation of school culture – in part a result of the fact that the teacher workforce is predominately female – is argued not to provide boys with positive examples of masculinity in a school setting (Moreau, 2014). There is a lack of male teachers in British schools: the most recent government statistics for 2023 show that only 14% of primary school teachers, 35% of secondary school teachers and 25% in special schools are male (School Workforce Census, 2024). Same sex teaching role models are needed in order to promote a sense of a positive self-identity related to educational attainment (Francis et al., 2008).

There are educational attainment gaps for racially marginalised, but the picture is complex and heterogeneous. Attainment varies significantly among pupil ethnic groups: Gypsy/Roma pupils are almost three years behind White British pupils at GCSE level. In contrast, Chinese pupils are two whole years ahead of White British pupils in learning at this stage of their education. Gaps have also widened for pupils from black backgrounds, and for pupils with English as an additional language who arrived late to the school system (Hutchinson et al., 2020). A similar argument has been made for recruiting more teachers from racially marginalised backgrounds to provide role models to address underachieving pupils.

Many children with SEND are not identified for some years into their formal education, despite presenting with indicators as early as infancy. Research has shown that children from ethnic minority backgrounds are less likely to have SEND, but this may reflect structural inequalities in identification that may arise due to variation in views relating to child development between cultures or knowledge of and access to services and support within ethnic minority families (Emerson, 2012; Golson et al., 2022; Moody, 2016; Schmaus, 2022). Young people with unidentified communication needs are at risk of a range of negative outcomes later in life, including impacts on literacy, numeracy and educational attainment, mental health, employment and involvement in the criminal justice system.

Problems at school and poor attendance are risk factors for criminality (Shepard & Purcell, 2015; Hirschfield & Gasper, 2011), and there is substantial research showing that school exclusion is a risk factor for later criminal involvement (e.g., Henry et al., 2012; Maynard et al., 2015; Arnez & Condry, 2021). The Edinburgh Study of Youth Transitions and Crime (The Edinburgh Study), for example, found that young people excluded from school at the age of twelve were subsequently four times more likely to be incarcerated (McAra & McVie, 2010). Little (2015) found that 90% of young people in contact with the justice system had dropped out of school prior to incarceration. While school exclusion does not cause criminal behaviour, it is a strong predictor of offending (Assink et al., 2015; Scott & Brown, 2018).

Boys have twice the rate of exclusion than girls: 0.15 compared to 0.07, which works out at 1,406 boys permanently excluded for the academic year 2022/23, compared to 656 girls

(Bolton & Lewis, 2024). Boys from poorer socio-economic backgrounds – measured according to their eligibility for free school meals – fair particularly poorly and are almost five times more likely to be permanently excluded from school than those not eligible for free school meals (Bolton & Lewis, 2024). Young people from racially marginalised backgrounds experience higher rates of school exclusion (Timpson, 2019). Boys from racially marginalised backgrounds are twice as likely to have been excluded from school, with those from Roma Gypsy or Irish Traveller backgrounds having exclusion rates of 0.43 and 0.35 respectively, compared to the exclusion rate of 0.13 for White British children. Children with SEND have higher suspension & exclusion rates of over 600 per 10,000 pupils, compared to 144 for pupils with no SEND (Nasen, 2022). The most common reason for pupils being excluded from mainstream education is disruptive behaviour; research shows that many young people who are excluded or at risk of exclusion have behavioural difficulties which co-occur with communication needs that are often unidentified and unsupported. In a study of pupils at risk of exclusion, two thirds were found to have speech, language and communication needs (Clegg, 2004), whilst another study of excluded boys found 100% had undetected communication needs and behavioural issues (Ripley & Yuill, 2005).

The interplay between gender, ethnicity and SEND is complex and these young people are at risk of experiencing accumulated disadvantages. When young people enter custody, they have often had a disrupted educational background and experiencing accumulated disadvantages. Whilst in custody, young people are entitled to receive education. Currently, the CYPSE aims to provide 30 hours of education a week (YJB, 2016), however lower levels of educational attainment have been found in those who have received a custodial sentence (MoJ & DfE, 2016). Only 1% of young people sentenced to less than 12 months in custody achieved 5 or more GCSEs (or equivalents) graded A* to C (MoJ & DfE, 2016). Literacy levels of those sentenced were particularly low with 56% of young people achieving the expected level in reading and only 28% in writing at Key Stage 2, compared with 87% and 68% of total pupils in the cohort respectively (MoJ & DfE, 2016). Additionally, education quality is poor and reported to be declining. Inspections of prisons judged that only 27% had educational programmes that were “good” or “outstanding” (Ofsted, 2023b). Specifically, Ofsted and HMIP (2022) deemed reading in prisons to be extremely poor, stating that reading ability was improving too slowly and interventions were needed to improve reading ability (Ofsted, 2023a).

Within the CYPSE, there have been rising levels of violence and behavioural difficulties. From 2021 to 2022, the rate of incidents for assault in custody per 100 children has increased by 25%, with the rate of Restrictive Physical Interventions growing by 17% (YJB, 2023). Alongside the prevalence of violent incidents inside custody, the rate of young people in custody due to committing a violent offence has almost doubled in recent years from 33% in 2015-16 to 65% in 2022-2023 (Youth Custody Report, 2023). These statistics reflect a trend of increasing violence and complexity in young people, highlighting an urgent need for effective

interventions to target these issues, especially considering the overrepresentation of behavioural disorders for children in custody (Teplin et al., 2023). While externalising behavioural factors, which are characterised as behaviours towards the physical environment, such as violence and aggression, are of key importance for the CYPSE, there is evidence to suggest that addressing the underlying emotional or psychological state is also important. These are internalising behaviour, which are behaviours that are directed inwards, such as depression or anxiety. These behaviours can cause harm, often co-exist with externalising behaviours and are linked to educational performance (Liu et al., 2011). In addition, there is evidence that the identification of internalising behaviour difficulties is under detected within the CYPSE (Mitchell & Shaw, 2011).

Interactions with the justice system as a youth person has a far more serious derailing effect, compared to interactions as an adult (Aizer & Doyle, 2013; Kirk & Sampson, 2013). This is because it interferes with crucial adolescence developmental processes, such as the development of autonomy and identity (Lambie & Randell, 2013; Sampson & Laub, 2005). Educational experiences during incarceration have been demonstrated to act as a 'turning point', associated with less re-offending and more pro-social outcomes upon release as it reconnects young people with normative developmental contexts that diverts them away from offending and facilitates investment in further education and employment (e.g. see Blomberg et al., 2011; Cavendish, 2014; Hirschfield & Gasper, 2011). Within a custody setting, the mechanisms through which educational experiences leads to positive outcomes is through enabling a maturation process and subsequent internal transformation (e.g. see Todis et al., 2001; James et al., 2013). The reason creative interventions are particularly useful in a custody setting is because they encourage this internal self-transformation, by fostering social development, self-esteem, and autonomy (Clennon, 2013; McNeill et al., 2011; Tett et al., 2012). Research has demonstrated that changing criminal behaviour is not successful if self-esteem is not addressed (e.g. see Smeijsters et al., 2011). Arts based interventions are a stepping stone to empowering and encouraging engagement with formal education, which, in turn, is strongly associated with desistance from crime (Blomberg et al., 2011; Cavendish, 2014).

Creativity has been associated with numerous positive outcomes. A meta-analysis of creativity and well-being analysed 26 quantitative studies, finding evidence of a significantly positive, modest relationship between creativity and well-being (Acar et al., 2020). Involving concrete steps towards goals and having an audience witness the outcome of the creative activity strengthened creativity's effect on well-being. Creativity has also been associated with positive outcomes in an adult prison setting. A qualitative study into artist-led prion interventions, including mostly male prisoners, found that participating in a creativity-based intervention led to feelings of increased self-confidence, increased trust in the outside world and decreased aversion to vulnerability (Diamond & Lanskey, 2023). Arts based interventions have the potential to support a transformative process, studies have also found evidence that

creativity promotes positive change in prisoners, such as improved social skills (e.g. see Caulfield et al., 2016). Creative interventions have also been shown to increase engagement with further education for adult (mainly male) prisoners (Anderson et al., 2011; Halperin et al., 2012).

There is currently limited evidence for the use of art-based interventions with young people at risk of, or already involved in, violence and/or crime. Qualitative studies reviewed from a recent mixed methods systematic review suggested that art-based interventions may lead to positive emotions, development of the sense of self, successful engagement in creative processes and practices, and the development of positive personal relationships (Mansfield et al., 2024). These qualitative studies primarily reviewed music-based interventions, including song writing (Masso-Guijarro & Montes-Rodriguez, 2020), music composition (Baker & Homan, 2007) and learning to play a musical instrument (Tett et al., 2012; Thompson, 2022), while drama programmes (Bowey & Alex, 2006; Cesar & Decker, 2020), video game interventions (Ruggiero e al., 2013) and poetry (Lea et al., 2019) were also studied. Anderson & Overy (2010) found that engagement in a group musical intervention amongst young people in a Scottish institution helped create a social identity and led to increased engagement in other educational programs. Caulfield et al. (2010) found that involvement in a musical intervention, The Good Vibrations Project, led to improved social skills, which they attributed to the participants learning to take part in decision making, which in turn led to them taking on roles of responsibility after the project. However, the review found insufficient evidence from quantitative studies to support the effectiveness of art-based interventions on behavioural, psychosocial, cognitive, and offending outcomes. This is likely due to the relatively small number of studies that focused on quantitative outcomes, of which also tended to be of poor methodological quality and limited detail of analysis. The majority of studies tend to be qualitative, and while these offer some consensus on best practices, they do not provide outcomes evidence. There is a clear need to develop the evidence base with a dearth of robust evaluations examining the ability of arts-based interventions to impact on violence-related child outcomes. Additionally, there is sparse evidence from robust impact evaluations of creative writing programmes, with none to date focusing on young people in custody.

3.1 Rationale for current trial

New Chapters is a creative writing programme delivered to people in both YOIs and adult prisons. The programme began in 2018 and as of 2022 was delivering sessions in nine YOIs/prisons across England. The programme aims to enable individuals to express themselves through their own forms of creative writing; building self-esteem and supporting them to build a more positive, prosocial identity. Preliminary evidence presented in the 2022 New Chapters impact report suggests the intervention has a positive effect. The report found that 85% of the sample of 178 young people engaging with the project reported that the

sessions made them 'feel better in general'. Also, 82% said that the sessions 'inspired them to think about their futures more'. In terms of literacy outcomes, 80% of the sample said the sessions encouraged them to write more, followed by 71% who felt more encouraged to read. Additionally, almost three-quarters (73%) of the sample felt the sessions made them enjoy writing more and 82% felt more confident expressing themselves in writing. The quality of the intervention was also rated highly, with 93% rating the sessions as 'excellent' or 'good'. Furthermore, the report highlighted qualitative support for the positive impact of New Chapters, identifying three key impacts of the intervention: improving confidence with, and enjoyment of, writing; improving well-being and raising aspirations; and encouraging participants to tell their stories and feel their voice is being heard (National Literacy Trust, 2022).

However, there is a lack of robust experimental evidence for arts-based interventions for young people in contact with the criminal justice system. As highlighted above, a review of arts interventions found that there was not enough quantitative data to make any conclusions and for the qualitative data, there were found to be many methodological flaws, with much focusing on the experiences of the young people, but lacking focus on intervention design/implementation and limited analysis of demographics. This also sits within the context of few robust experimental studies of any type of intervention within the CYPSE (Chitsabesan et al., 2022; Lennox et al., 2020; Mitchell et al., 2011).

In addition, there is still a need for research to consider constructions of masculinity and the impact of this on educational literacy (Wells, 2016). Masculinity is a key risk factor for male violence (Whitehead, 2005). Thus, how the boys talk about themselves as 'literate', and construct, manage and negotiate their masculine identities within New Chapters will be examined. The evaluation will also examine how the intervention addresses issues around masculinity (or not), as well as how practitioners construct masculinity and the role they play in challenging or reinforcing certain notions of masculinity (Baumgartner, 2014). Prisons typically do not offer alternative versions of masculinity (Maguire, 2021). Interventions that engage boys in masculinity issues and promote alternative positive constructs of masculinity are needed, and are showing promise (e.g. Blagden and Perrin, 2018).

In the proposed research, we will conduct a randomised controlled trial (RCT) with process evaluation and internal pilot (to assess trial feasibility) where young people in prison will be randomly allocated to receive New Chapters plus Business as Usual (BAU) or BAU alone to evaluate reduction in behavioural difficulties.

2. Intervention

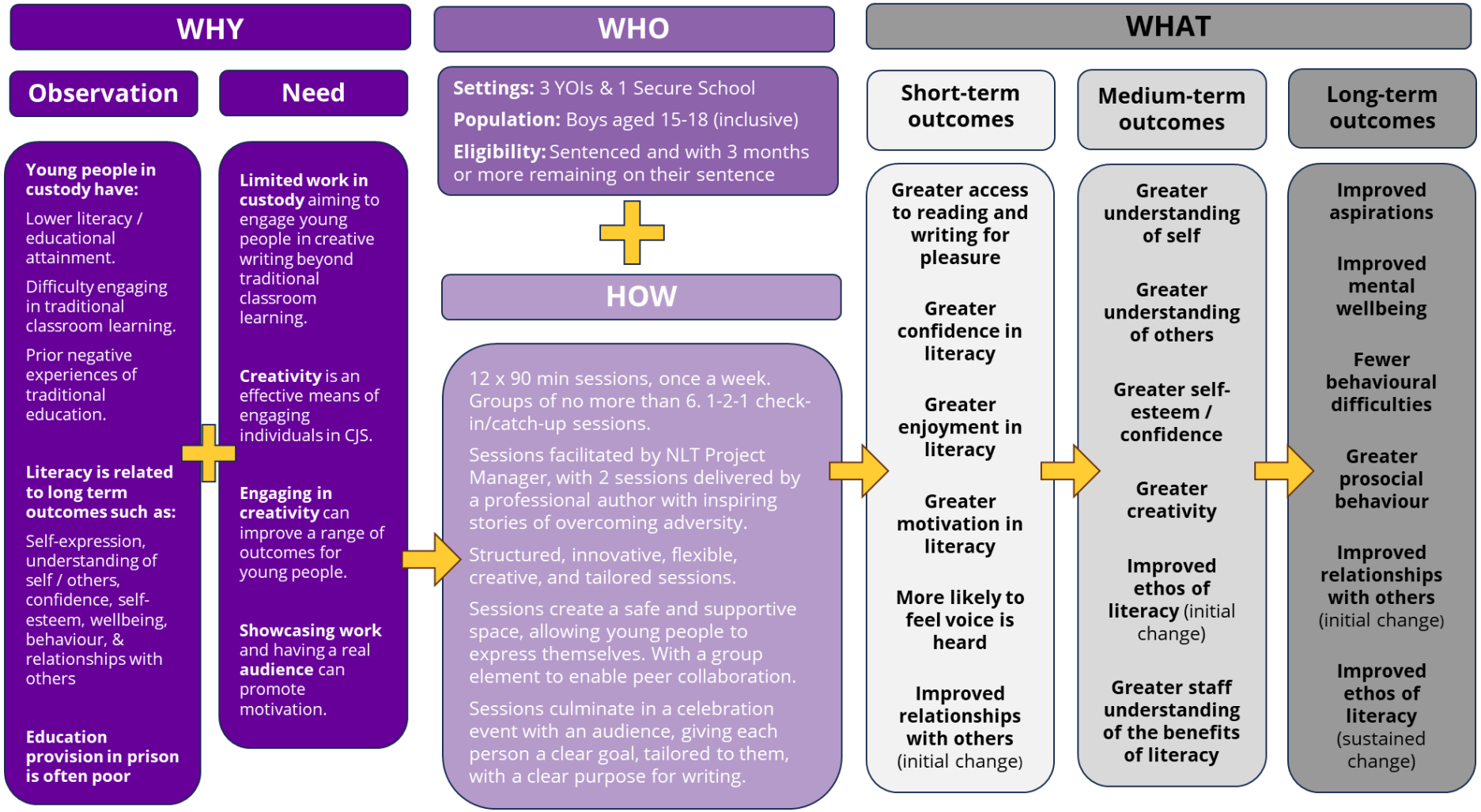
2.1 New Chapters

New Chapters is a 12-session manualised creative writing intervention, delivered face-to-face, once a week, in a group of no more than six. Each session will last for up to 90 minutes. It aims to enable individuals to express themselves through their own forms of creative writing; building self-esteem and supporting them to build a more positive, prosocial identity, which in turn will reduce behavioural difficulties. Each session is delivered by a National Literacy Trust (NLT) Project Manager (PM) who will develop a series of sessions that are structured, yet innovative, flexible, and creative. Each young person has a clear, tailored goal to work towards and they have a clear purpose for writing. Professional authors will deliver two sessions. The authors have the status as "professional authors" and have inspiring stories of overcoming adversity, one of the sessions will also include an author with lived experience of the criminal justice system. At the end of each 12 sessions it will culminate in a celebration event, with an audience, via The National Prison Radio. See appendix 1 for a fuller description of New Chapters.

Figure 1 provides a summary of the Theory of Change (ToC) for New Chapters. Appendix 2 has a more detailed ToC with a narrative description, associated references and mapping against the evaluation outcomes. Appendix 3 is the TIDieR (Template for Intervention Description and Replication) Checklist (Hoffmann et al., 2014).

New Chapters will be delivered between November 2024 and June 2026. Time from allocation to intervention commencing will be monitored throughout the trial and reported on as will all aspects of delivery (see Implementation and Process Evaluation).

Figure 1: New Chapters Theory of Change



2.2 Business as Usual (BAU)

All young people in both trial arms will receive BAU. There is currently no direct comparator to New Chapters offered in the CYPSE. BAU in this trial will be the standard education offer (30 hours education per week). Young people in both trial arms will also continue to access all other services available (e.g., offending behaviour interventions), enrichment activities (e.g., sports) and other arts activities. BAU at each site and for each young person will vary . For example, each site has a different education provider: Feltham (Shaw Trust); Werrington (PeoplePlus)) Wetherby (Novus) and Oasis Restore (Oasis). In the process evaluation, BAU will be mapped for each site and current education receipt will be captured for each young person from records. The randomisation stratified by site will balance out any BAU differences.

3. Trial research questions

3.1 Primary research question

Question 1: Does a group-based creative writing intervention (New Chapters) plus BAU, compared with BAU alone reduce behavioural difficulties for boys aged 15-18 years old currently serving a custodial sentence?

3.2 Secondary research questions

Question 2: Does an internal pilot in the first nine months demonstrate evidence to move to a definitive trial?

Question 3: Does a group-based creative writing intervention (New Chapters) plus BAU, compared with BAU alone increase empathy, pro-social identity, self-esteem, mental wellbeing and creativity?

Question 4: Does a group-based creative writing intervention (New Chapters) plus BAU, compared with BAU alone reduce behaviour incidents?

Question 5: Does the implementation and process evaluation (IPE) demonstrate fidelity and acceptability of New Chapters? (Please see the IPE section for further detailed research questions related to the IPE)

Question 6: Does the IPE demonstrate evidence to support the ToC? (Please see the IPE section for further detailed research questions related to the IPE)

Question 7: Are there adverse events related to New Chapters?

4. Trial Design Summary

This is a two-arm, individually randomised controlled trial (RCT) of New Chapters plus BAU compared to BAU alone, for boys aged 15-18 years old, currently serving a custodial sentence. The trial includes an internal pilot to be reported on at month nine of data collection. There will also be a parallel IPE, which will run along with the internal pilot and main trial.

Table 1: Trial design

Trial design, including number of arms		Two-arm, individually randomised (1:1), superiority RCT
Unit of randomisation		Individual Participant
Stratification variables		Recruitment site
Primary outcome	Variable	Self-reported behavioural difficulties
	measure (instrument, scale, source)	Self-reported Strengths and Difficulties Questionnaire (SDQ) difficulties total score at follow-up
Secondary outcome(s)	variable(s)	1. Self-reported empathy 2. Self-reported pro-social identity 3. Self-reported self-esteem 4. Self-reported mental wellbeing 5. Self-reported creativity 6. Behaviour incidents
	measure(s) (instrument, scale, source)	1. Self-reported empathy using Basic Empathy Scale (BES) at follow-up. 2. Self-reported pro-social identity using Pro-Social IDentity Scale (PIDS) at follow-up. 3. Self-reported self-esteem using Self-Esteem Measure for Prisoners (SEM-P) at follow-up. 4. Self-reported mental wellbeing using Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) at follow-up. 5. Self-reported creativity using Creative Self-Efficacy Scale for Children and Adolescents (CASES) follow-up. 6. Behaviour incident data using prison records at follow-up.
	variable	Self-reported behavioural difficulties

Baseline for primary outcome	measure (instrument, scale, source)	Self-reported Strengths and Difficulties Questionnaire (SDQ) difficulties total score
Baseline for secondary outcome	variable	1. Self-reported empathy 2. Self-reported pro-social identity 3. Self-reported self-esteem 4. Self-reported mental wellbeing 5. Self-reported creativity 6. Behaviour incident data
	measure (instrument, scale, source)	1. Self-reported empathy using Basic Empathy Scale (BES) 2. Self-reported pro-social identity using Pro-Social IDentity Scale (PIDS) 3. Self-reported self-esteem using Self-Esteem Measure for Prisoners (SEM-P) 4. Self-reported mental wellbeing using Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) 5. Self-reported creativity using Creative Self-Efficacy Scale for Children and Adolescents (CASES) 6. Behaviour incident data using prison records

4.1 Settings

This trial will take place in four settings (three YOIs; Wetherby, Werrington, Feltham) and one secure school (Oasis Restore). YOI Parc is not being included as the site requested implementation of New Chapters would have needed to be within enrichment (evening and weekends), whereas in all other sites delivery is in education. This would impact the implementation and ToC, in addition YOI Parc has small numbers of young people and creating the groups would have been a significant challenge. Other sites may be added if there are delays in recruitment.

4.2 Randomisation

Young people will be randomised on a 1:1 basis using concealed random allocation conducted using an online pseudorandom list hosted by Sealedenvelope.com with random permuted blocks of varying sizes. Randomisation will be stratified by site and by unit. Randomisation minimises selection bias and stratification will address site-based differences such as demographics and different education providers. Additionally, stratification by unit is necessary. In some sites, there are restrictions on mixing between units, so randomisation will need to occur within each unit separately. We also recognise that young people in

different units may have varying characteristics. The evaluation team will be responsible for allocation and informing young people and New Chapters PMs of allocation.

The evaluation team understand the issues around resentful demoralisation from those young people allocated to BAU. Prior to randomisation and when allocation is communicated this will be conducted in a way that emphasises the importance of involvement, regardless of randomisation outcome, and that young people are involved in something that is important and valuable, but that this does not oversell the potential benefits of the project. The evaluation team had developed and refined this approach to communication in previous trials (Chitsabesan et al., 2022)

4.3 Blinding

Given the nature of the intervention, it is not possible to blind young people or those involved in delivering New Chapters as this is a novel intervention which individuals would not normally expect to receive or provide. Baseline measures will be collected prior to randomisation and so allocation will not impact these scores.

It is also not possible to maintain researchers being blind to the trial arm allocation. The researchers and the team delivering New Chapters are both working within the confines of a prison environment, causing many occasions when un-blinding will occur: researchers seeing young people receiving the intervention; young people seeing the researcher around the prison and informing the researcher that they received the intervention. It is often possible to have a second researcher unknown to the participant to collect outcome data. In this case, within a prison environment is logistically very challenging and ultimately conflicts with the idea of building a strong researcher-young person relationship to enhance engagement with the study. This is also important in terms of the research team managing resentful demoralisation throughout the study. Therefore, a decision has been taken to accept that researcher blinding would not be possible in the trial and so we will minimise any potential bias by protocolising collection and scoring of the primary outcome measure. Specifically, the researchers will use a highly scripted section for the Strengths and Difficulties Questionnaire (SDQ), reading each question to the participants and only deviating from this to clarify the meaning of the question if they indicate they do not understand the question. The SDQ will not be scored by this researcher but will be scored by a researcher blind to allocation. In this trial the research team are independent of the NLT (intervention providers) and the delivery of New Chapters and therefore risk of bias is further reduced. The integrity of data analysis will be protected by specifying all analyses in a statistical analysis plan (SAP) which will be signed off by the Independent Data Monitoring Committee prior to database lock.

4.4 Contamination

There is unlikely to be contamination between the intervention and BAU, New Chapters will be delivered within discrete groups of young people. Education staff may sit in and observe some of the New Chapters sessions and so theoretically it is possible that they will see some practice that they might then integrate into their own work, but these are anticipated to be minor. We will record and report any protocol deviations.

5. Study Participants

Participants are eligible for the trial if they meet all the following inclusion criteria and none of the exclusion criteria apply.

5.1 Inclusion Criteria

- Aged 15-18 years old
- Serving a custodial sentence
- Has three months or more until release

5.2 Exclusion Criteria

- On remand
- Having less than 3 months left until release
- Not able to provide informed consent
- Parental consent not provided for those aged under 16
- Requires an interpreter
- Those presenting a risk to the research or intervention team
- Those identified by the site as being unable to mix with others in a group setting or are in a small 'community group'.

5.3 Rationale for exclusion criteria

- On remand – For those young people on remand the length of stay is very uncertain, and they may leave at very short notice. This could cause disruption to the running of the New Chapters groups and would increase trial attrition and data loss.
- Having less than 3 months left until release – Here there needed to be a balance between having a large enough pool of eligible participants, given the small numbers of young people within the CYPSE, with the risk of attrition. The average length of stay for young people in custody is three months (Beard, 2022).
- Not able to provide informed consent – The trial requires participants to provide informed consent. This is covered in more detail in the consent section.

- Parental consent not provided for those aged under 16 – For young people aged 15 we require the consent of parents/carers. This is covered in more detail in the consent section.
- Requires an interpreter - Due to the delivery of the intervention in groups and in a prison setting, provision of interpreters is not possible.
- Those presenting a risk to the research or intervention team – It is not possible to include young people who pose a safety risk to the research or intervention team, where this risk cannot be mitigated, and the prison service do not permit contact. The staff at each site will inform the research team of those young people who present a risk. Further details are provided in the strategies for identification section.
- As New Chapters is a group-based intervention, young people need to be able to mix with others in a group setting. The study is not able to produce New Chapters groups with young people who are unable to mix as this could lead to serious security issues or harm to young people and staff. The staff at each site will inform the research team of those young people who are not able to freely mix with other young people. Further details are provided in the strategies for identification section.

6. Strategies for identification and recruitment

6.1 Prison records (t0)

Potential young people will be identified at each site using the site records system e.g. Prison National Offender Management Information System (P-NOMIS) or equivalent. This will identify young people who are sentenced and their anticipated release date. The level of risk presented by the potential young people can also be assessed using the prison records system as young people's records will be 'flagged' if they are considered to present a risk.. This does not mean that all young people will always be excluded if they have a 'flag', as risk is dynamic and contextual. For example, if a young person was only ineligible for the trial due to current risk, that does not mean they will always be ineligible. The young person may work on conflict resolution skills or other offending behaviour interventions and at a later point in the project the prison staff may feel that they are now able to take part. The research team will work closely with staff at each site to understand potential participants risk and develop suitable mitigation strategies to maximise participation e.g. no lone working.

During COVID-19 YOIs adopted a system of 'bubbles', keeping young people in small groups to manage COVID-19 transmission and lower staffing levels. All YOIs have been unable to return to a regime where young people are able to freely mix across units and for some young

people there is limited mixing within the unit. Currently, the YOIs have fluctuating numbers and sizes of 'community groups' and community groups may change over time. To produce a New Chapters group and a corresponding number of young people in BAU, the minimum randomised is 4 and the maximum is 12. However, to get to these numbers we need to also account for young people not being eligible for other reasons e.g. remand (approximately 50% of the population) or not consenting to take part. These rates will be different in each community group. Therefore, flexibility is required around this eligibility criteria and each community group will be considered individually. If we were to specify a size of community group, we potentially run the risk of excluding young people who could be included. We will work closely with the staff at the point of identification to understand the groupings in each unit. As a result, it is not possible to provide specific criteria on community groups prior to the start of the trial, but this will be reported on during the running of the trial. The priority at first will be on recruiting young people in large community groups, but where there is a possibility to run additional New Chapters groups, young people in smaller community groups will be considered. After the first cycles of New Chapters delivery in the YOIs we will have a better estimate of other eligibility rates to inform these choices, for example, if consent rate is high then smaller community groups can be approached compared to if consent rates are low. Oasis Restore is not planning to operate restrictions on mixing.

6.2 Initial Approach (t0)

Potential young people will be approached initially by a member of the education staff, who will briefly verbally explain that there is a research project taking place and ask if the young person would like the opportunity to hear more about it. The research team will work with the education staff to ensure that what is verbally explained is consistent. For those young people that express an interest in hearing more about the study, a meeting will be arranged with the researcher to explain the study in more detail.

7. Study schedule

This section describes the conduct of the study in chronological order, detailing procedures for data collection at each of the time points. A tabulated summary of the study schedule is given in Table 2 below.

7.1 Consent process (t0)

The researcher will be trained to assess capacity to consent in young people. This will include assessing if the young person has the ability to understand the information relevant to the decision, retain the information, use or weigh the information as part of the process for decision making and communicate the decision to the researcher.

For those young people aged under 16 if after the initial verbal approach, they express an interest in hearing more about the study, the researcher will make arrangements to contact the parent/guardian (person with parental/legal responsibility) to explain the study by post. For those young people where the state is the responsible adult, a Social Worker, Residential or Foster Carer, may provide consent. Where necessary, parent/guardian information sheets and consent forms can be translated. If they are happy for the young person to be involved, then arrangements will be made to obtain written consent. Should the parent/guardian consent but the young person does not give assent the wishes of the young person will preside.

For those young people aged over 16 who expressed an interest in hearing more about the study and for those under 16 where parent/carer consent has been obtained, the researcher will meet with the young person to obtain informed consent/assent. The researcher will provide the young person with a copy of the participant information sheet (PIS). The PIS will be designed to be image/picture based and any text will be appropriate for their literacy level. The researcher will read and explain the information in the PIS, showing sensitivity to the high levels of literacy difficulties in this population.

The researcher will explain what participation in the study involves and how much time will be involved. The researcher will ensure that the potential young person fully understands what randomisation means and that they have an equal chance of being allocation. They will also explain that participation is voluntary and their decision to participate, or not, will have no adverse effect on the care that they receive or their other legal rights. The researcher will also discuss the arrangements in place to ensure confidentiality (and limits of this) and data protection. Throughout this process, the young person will be given the opportunity to ask questions. Young people will be made aware of circumstances in which confidentiality would be broken (if they or someone else identified may be at potential risk of harm; for example, self-harm, breaches of security and violence, including acts of terrorism/radicalisation). Having had the opportunity to discuss their involvement in the study and ask questions about it, potential young people will be given time (minimum 24 hours) to consider taking part. Potential young people who wish to have longer to consider their involvement will be seen within a week.

The consent form will be explained to the young person before they sign it, and the researcher will sign the form after it has been completed by the young person. A copy of the signed consent form will be given to the young person (if appropriate for them to keep a copy in the prison), a copy will be kept in their prison records and a copy will be retained by the researcher. We will record the number of young people who do not consent/assent to take part and where a written parental consent is not received. Once written informed consent has been obtained, the participant will begin the baseline data collection immediately. The reason for commencing so shortly after the taking of consent is because of the chaotic nature

of the prison environment and the difficulties in working around the prisons' security needs (which always takes priority and can rapidly change).

Table 2: Tabulated summary of study schedule

		Initial Approach	Baseline	Allocation	Follow-Up
TIMEPOINT		*t0*	*t1*		*t2*
ENROLMENT:					
Eligibility check		X			
Informed consent		X			
Parental consent (< 16)		X			
Allocation				X	
INTERVENTIONS:					
Intervention Group:	*New Chapters BAU*	◆———	———◆		
Comparison Group:	*BAU*	◆———	———	———	———◆
ASSESSMENTS :					
Demographics			X		
SDQ			X		X
BES			X		X
PIDS			X		X
SEM-P			X		X
SWEMWBS			X		X
CASES			X		X
Prison Records			X		X
Contact Sheet			X		
Withdrawal Form					X
SAFETY MONITORING:					
Adverse event reporting		◆———	———	———	———◆

7.2 Withdrawal

Young people (and parents/guardians for those under 16) have the right to withdraw consent for participation in any aspect of the trial at any time. The participants care or legal rights will not be affected. If a participant initially consents and is randomised, but subsequently withdraws from the trial, clear distinctions will be made as to what aspects of the trial the participant is withdrawing from. These aspects will be:

- Withdrawal from the intervention (New Chapters only)

- Partial withdrawal from future data collection (e.g. some questionnaires, interviews, data linkage/archive)
- Withdrawal of consent from using previously collected data, prior to anonymisation

Participants cannot withdraw from the trial and still receive New Chapters. If they withdraw from the trial then they will receive BAU only. Participants who consent and subsequently withdraw will be asked to complete a study withdrawal form. This form will set out what they are withdrawing from and reason for withdrawal but the individual's rights to not state a reason will be respected. This will be reported on.

Once data has entered the data archive it cannot be deleted as it is in anonymised form.

7.3 Participant retention

In the project attrition rates will be based on the t2 follow-up.

There are several ways in which the project can try to ensure participant retention.

- To maximise the numbers of young people eligible in the study, a decision has been made to include young people who are at least three months before release.
    - However, there is a risk that those close to three months could leave before the end of the intervention delivery and follow-up. Attrition rates, if young people are still in prison, will be lower than if they are being released and are in the community. The research team have developed ways to maximise community follow-ups and this is detailed in the follow-up section below.
- For young people will longer sentences, we will consider the use of transfer holds, these limit young people from being transferred from one site to another during the project. However, use of this is subject to prison approval.
- The team will monitor the time it takes between allocation and the intervention starting and this will be reported on. In previous studies (Chitsabesan et al., 2022) where there were delays between allocation and intervention starting appears to have an impact on participant engagement.
- Participants in both arms will receive a certificate saying they have taken part and drinks and snacks will be available for all young people (subject to prison approval).
- NLT donate books to the education department and these are accessible to all young people regardless of arm allocation.
- Young people in prison can find it frustrating and demoralising to have to share their story to multiple professionals. Having to see different researchers at different time points for data collection can impact engagement. In the study, the same researcher who took consent from the young person, will be the same researcher to see them at all data collection points. They will also do regular check-ins with the young person

between data collection points to maintain engagement. In the infrequent event that a young person will need to be seen by another researcher e.g. annual leave, the original researcher will introduce the new researcher to the young person in advance.

7.4 Baseline data collection (t1)

The researcher will either continue with the baseline data collection following consent or arrange another appointment. If required, more sessions will be arranged to meet the needs of individual young people.

The researcher will deliver the baseline data collection using a narrative conversational format. Demographics, standardised questionnaires and other open-ended questions are incorporated into a specially constructed flexible interview which avoids duplication in order to reduce disengagement or irritability and enhance engagement. Data will be recorded in the Young Person Baseline Case Report Form (CRF), using a paper document. The researcher will record in the CRF completion quality (Gold = Full CRF completed, Silver = Young person (section 1) completed but missing parts in other sections, Bronze = parts missing in young person and other sections; Not completed = whole CRF not completed) and this will be reported on.

In addition to the baseline data collected directly from the young person, data will also be collected from prison records e.g. literacy screen level on admission, index offence (category).

The researcher will complete a contact sheet for each young person. This will include contact numbers and addresses for the participant, as well as a list of services they may likely to be in contact with post-release. This sheet will be completed from file records and in collaboration with the participant and the participant will sign the form to confirm they give the research team permission to contact them via the relevant services to arrange the follow-up, if it is not possible to complete them in prison.

7.5 Randomisation and allocation process

Using the online hosted randomisation process, the researcher can log in to obtain allocation as soon as a young person has completed the baseline without needing to rely on the study statistician.

The researcher will visit the young person to deliver an allocation letter. This will inform the young person of whether they have been randomised to New Chapters or BAU. The researcher will go through the letter with the young person, ensuring that they understand which group they are in.

Experience has shown that continuity of researcher has a positive effect on participants' continued engagement and out-weights concerns around maintaining blinding. Also, we

know that young people may be naturally disappointed about being allocated to BAU, the researcher will reiterate that it is nothing that they have said or done that has influenced the decision and that we do not know if New Chapters has any benefit and so their role in the BAU group is really important.

Confirmation that randomisation has been performed will be communicated via email in an un-blinded fashion to the PI, key members of the research team and New Chapters PMs.

7.6 Follow-up (t2)

If young people are still in prison at the point of follow-up, then follow-up will take place in prison. If the young person has been transferred to another prison establishment, all attempts will be made to follow them up. This will be easier if this is within a current recruitment site. Where they are transferred to a non-recruitment site, the research team will arrange a legal visit at the prison to see the young person. If the young person has been released into the community during the study, the researcher will use the contact details provided and make contact with them and arrange the follow-up in the community.

The follow-up (t2) can take place between 91 and 152 days post randomisation. The reason for having a follow-up window rather than a fixed follow-up time is to work within the complexity of prison regimes. For a variety of reasons, it may not be possible to see young people on specific days and it may take several attempts to see young people. Therefore, there is a risk that young people fall out of the follow-up time point and increase attrition rates of no fault of their own. Additionally, this flexibility accounts for young people's release dates not always being fixed.

This is the study's primary follow-up point and we aim to see as many young people as possible at this point while still in prison. However, if the young person has been released, the researcher will arrange to meet the young person at a convenient location. Where possible, interviews will be conducted in the premises of services that the young person is engaging with to minimise risk to the researcher. Where this is not possible, the researcher will arrange to conduct the interviews in a suitable location in the community and adhere to the Local Lone Working Policy. If the researcher is in contact with a participant but experiences problems in setting up a follow-up interview or the participant fails to attend a follow-up appointment, the research will attempt to complete the interview via a phone call with the participant.

Data will be recorded in the Young Person Follow-up CRF. This CRF will be constructed to standardise (minimise bias) and prioritise (minimise attrition) the collection of the SDQ. If there is limited time to see the young person or if the young person does not want to complete all aspects of the data collection, the researcher will record in the CRF completion quality (Gold, Silver, Bronze, Not completed) and this will be reported on.

The researcher will remind the young person of the PIS and consent, drawing attention to data confidentiality and instances of disclosure where the researcher would need to breach confidentiality.

7.7 End of trial

The trial will end after the last young person randomised has completed the follow up. The declaration of end of trial will be submitted to the ethics committee within 90 days of its completion. Following this, all sites will be advised on the process for closing the trial at sites.

8. Outcome measures

8.1 Baseline measures

A range of demographic and descriptive variables will be collected to enable us to describe the sample and to ensure randomisation has been effective e.g., age (in months), ethnicity, school attainment and attendance and literacy screen results. We will also use this information to monitor that the project is recruiting a sample that is broadly representative of young people within the CYPSE.

8.2 Primary outcome measure

The primary outcome measure is the Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997) a measure of internalised and externalised behaviour difficulties. It contains 25 items divided between five scales: emotional symptoms; conduct problems; hyperactivity/inattention; peer relationship problems and prosocial behaviour. The total score for the measure will be used as the primary outcome.

There is the possibility that other measures could been selected as a primary outcome, for example, using prison records of behavioural incidents. This was discussed with the evaluation team, NLT teams and the YEF race equity advisor. It was agreed that there were too many concerns with the prison records to use this as a primary outcome, many of which are overcome with the use of the SDQ as a standardised self-report measure. These include:

- Inherent racial and other biases in the ways in which behavioural incidents are perceived by staff, investigated and then officially reported.
- Does not reflect the actual feelings/views of the young people, official reporting is always an underreporting of the actual.
- Inconsistencies in perception, investigation and reporting by site.
- Time lag of events being reported on the system.

8.3 Secondary outcome measures

Empathy (Basic Empathy Scale [BES]; Sánchez-Pérez et al., 2014).

The BES consists of 20 items, divided into two factors: cognitive empathy (9 items) and affective empathy (11 items). Each item has a 5-point scale, ranging from 1 (no agreement) to 5 (full agreement). A recent systematic review highlighted that the BES was one of only a few scales that had been validated with children and those in contact with justice systems (Pechorro et al., 2017; Nunes et al., 2018; Euler et al., 2017 and clinical samples (Cristofani et al., 2020; Gambin et al., 2016; Gambin & Sharp, 2018; McLaren et al., 2019).

The Pro-Social IDentity Scale (PIDS); Hazel & Birkbeck, 2024)

PIDS is a short (six-item) validated instrument designed to measure 'pro-social identity', on an axis of pro-social to antisocial, with an additional (seventh) item to measure 'identity resilience'. The scale fills the need for quantitative assessment of a concept that qualitative research has found is critical to positive behavioural outcomes and desistance from offending. It has been developed to be suitable for research, evaluation, and practitioner assessments of service users. All items are positive / pro-social, which limits potential stigmatising effects, and appropriate for young people.

Self-esteem (Self-Esteem Measure for Prisoners [SEM-P]; Debowska et al., 2017).

The SEM-P is an 8-item self-report measure assessing self-esteem among incarcerated populations. The measure consists of two subscales: prison-specific self-esteem (four items), looking at self-esteem in a specific context, and personal self-esteem (four items), inquiring into self-esteem in a context-free manner. Responses are indexed on a 4-point Likert scale (1 = never, 4 = always). People strive to attain a positive social identity in order to protect their self-esteem. Seeing self-esteem as context-free is misguided and it is strongly associated with an individual's social setting. Therefore, general context-free self-esteem questionnaires may not be appropriate for this study (Boduszek et al., 2013; Boduszek et al., 2012).

Mental Health Wellbeing (Short Warwick-Edinburgh Mental Wellbeing Scale [SWEMWBS]; Vaingankar et al., 2017).

SWEMWBS is a seven-item scale about thoughts and feelings, which relate more to functioning than feelings and so offer a slightly different perspective on mental wellbeing. The seven statements are positively worded with five response categories from 'none of the time' to 'all of the time'. This has been validated in clinical samples and with young people (Vaingankar, et al., 2017; Hauch et al., 2023)

Creative Self-Efficacy Scale for Children and Adolescents (CASES; Valquaresma et al., 2022)

CASES is a nine-item scale about creativity. Items are scored on a 5-point scale from not confident to totally confident. Creative self-efficacy can be defined as the belief one has in their ability to do something creative in a specific time and context. It is active during and after a person's engagement with a task. However, there very few questionnaires to assess it in young people. The CASES is a very recently developed tool, with promising psychometrics (Valquaresma et al., 2022) and with a small number of items.

Behavioural Difficulties (Incident data from Prison National Offender Management Information System [P-NOMIS]).

This is for recording of incidents including self-harm, assaults, finds and disorder. Data recorded includes information at incident and person level. The team have previous experience of collecting data from P-NOMIS.

9. Internal pilot

The trial design includes an internal pilot, with clear progression criteria to determine whether continuing on to a definitive trial is warranted. The proposed progression criteria will be reviewed by the Trial Steering Committee (TSC) to provide an initial independent opinion and then by the funder, who will make the final decision. This will be submitted nine months after the commencement of trial recruitment. The criteria are set out in the Table 3.

Table 3: Internal pilot criteria

Criteria	Target Set	RAG Rating
Recruitment	150 young people consented within the first nine months of data collection, representing 40% of the overall target.	Green ≥ 80% Amber = 79% to 70% Red ≤ 69%
Randomisation	The percentage of young people randomised. Number randomised / Number consented.	Green ≥ 90% Amber = 89% to 70% Red ≤ 69%
Retention (i)	The percentage of young people not explicitly withdrawn. Number not explicitly withdrawn / Number randomised	Green ≥ 80% Amber = 79% to 70% Red ≤ 69%
Retention (ii)	The percentage of young people not lost to follow-up. Number attended follow-up session / Number outside the end of the follow window.	Green ≥ 70% Amber = 69% to 60% Red ≤ 59%
Fidelity (i.e., extent to which the intervention is delivered as planned)	Using the fidelity checklist, the percentage of intervention groups assessed as meeting the criteria (see IPE for criteria) Number of groups meeting criteria / Number of groups completed	Green ≥ 80% Amber = 79% to 50% Red ≤ 49%
Outcomes	The percentage of CRFs rated as silver and above. Number of CRFs rated silver or gold / Number of CRFs completed.	Green ≥ 80% Amber = 79% to 70% Red ≤ 69%

10. Sample size and analysis

Table 4: Sample size calculations

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.31
Pre-test/ post-test correlations	level 1 (participant)	0.5
	level 2 (cluster)	--
Intracluster correlations (ICCs)	level 1 (participant)	--
	level 2 (cluster)	0.01 in the treatment arm, 0 in the control arm
Alpha		0.05
Power		0.81
One-sided or two-sided?		Two-sided
Average cluster size (if clustered)		6
Number of clusters	Intervention	25
	Control	150
	Total	175
Sample for primary outcome analysis	Intervention	131
	Control	131
	Total	262
Attrition		30%
Number of participants	**Total**	375

The data obtained from this study design are that of a 'partially nested' data structure. This is due to there being clustering in the intervention arm, but not in the BAU arm i.e. that the intervention arm is group-based while those allocated to the BAU arm does not involve being formed into BAU groups (although routine education, offending behaviour intervention and enrichment may involve groups, it is not the same within the same trial allocation e.g. these groups can involve young people not involved in the trial). The sample size calculation is based on a mean comparison of the SDQ total score between the two groups, specifically accounting for this complex data structure. The calculation was carried out using the 'clsampsi' command in Stata, specifically:

clsampsi 0.31, sd(0.866) k1(25) m1(6) varm1(6) k2(150) m2(1) varm2(0) rho1(0.01) rho2(0)

The following assumptions were made:

- Minimally Detectable Effect Size (MDES) – the trial is powered based on clinical superiority compared to BAU. We have powered to detect a standardised mean difference of 0.31, which equates to a mean difference of 1.6 on the SDQ using a standard deviation of 5.2 derived from normative data (https://www.sdqinfo.org/norms/UKNorms.html) in line with the SD estimate from the team's previous feasibility study in HMPYOI Wetherby using the SDQ as the primary outcome (Chitsabesan et al., 2022; Lennox et al., 2020).

- Cluster size – the intervention is delivered in groups of six. We have therefore assumed a mean cluster size of six but allow for a variance in cluster mean in line with a Poisson distribution.

- Clustering - We account for differential clustering of 25 practitioners over trial duration in intervention plus BAU arm, with an average number of 6 young people in each group and ICC=0.01. No prior estimate of the ICC is available, but we consider this a conservative estimate to what is typically found in psychotherapy trials (Baldwin et al., 2011). We will include pre-specified prognostic variables for the outcome in our analysis models to further reduce the ICC. This approach is robust to observed increases in ICC as the number of practitioners (clusters) increases. For the calculation, we consider the control arm as clusters of size 1 with ICC=0.

- We assume a baseline-endpoint correlation of 0.5 (0.75 in previous pilot work in YOIs, 95% CI 0.53 to 0.87; (Chitsabesan et al., 2022). This is modelled in the adjusted standard deviation of 0.866 and derived from the relative efficiency gained from an ANCOVA analysis, as seen using the Stata command: sampsi 0 .31, sd(1) power(0.8) alpha(0.1) pre(1) r01(0.5).

- Attrition – It is widely accepted that in prison and offending population trial attrition rates are approximately 50% (Butler et al., 2021; Byng, et al., 2023; Kraanen et al.,

2013). Byng et al., (2023) achieved one of the lowest attrition rates of 44% at 6 months and many of the techniques used in that trial will be utilised here e.g. maintaining researcher consistency, regular check-ins with participants, taking and updating contact details. However, that study involved mostly community follow-ups. In this study, it is anticipated, with eligibility being limited to sentenced young people with more than 3 months left to serve [the reason for not extending this to more than 6 months left to serve, is that this significantly reduces the pool of potential participants as many young people do receive short sentences], that more follow-ups can be conducted while in prison. In our previous trial within a YOI (Chitsabesan et al 2022), we also anticipated that more young people would be followed up while still in prison. Here we had an attrition rate of 22% at 3 months follow-up. However, this feasibility trial took place prior to COVID-19 and as highlighted above there are restrictions on mixing between young people. In this trial we anticipate attrition to be 30% but will utilise techniques used within our previous trials to bring attrition under 30%. Given these assumptions, we will randomise 375 participants to obtain an analysis set of 262 131 per arm) which will have 81% power to detect an effect size of 0.31. Power will be increased by inclusion of baseline covariates where possible.

10.1 Analysis

Analysis of primary and secondary outcomes will follow intention-to-treat principals – participants will be analysed in the groups to which they were randomised. We will follow the CONSORT extension for nonpharmacological interventions. Estimates of intervention effects will be presented alongside 95% confidence intervals. Statistical significance will be set at 5%.

The primary analysis of the SDQ will use a linear mixed model, given the partially nested structure of the data where there is clustering in the intervention arm only. This will model the clustering in the intervention arm and treat individuals as cluster size 1 in the BAU arm. The random effects specification will explicitly model the between-treatment heteroskedasticity, as advised by Roberts and Roberts, 2005.

Secondary outcomes will be analysed similarly. All inferential analyses will adjust for stratification factors used in randomisation. Additionally, baseline outcome and prognostic variables will be adjusted for to improve power. Where outcome variables are skewed, bootstrapped confidence intervals will be presented.

There are no interim analyses planned.

A statistical analysis plan will be developed detailing all analyses planned which will be reviewed by the TSC before final approval from the funder prior to the database lock and release of allocation codes.

11. Implementation and process evaluation

The design of the IPE follows the Medical Research Council (MRC) guidance on process evaluations of complex interventions. We will draw on a recognised implementation framework, the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2022) This mixed method IPE will draw on multiple sources of data to create a rich picture of implementation in practice, enabling us to understand both barriers and facilitators to delivery of the intervention, and to determine if and how implementation success or failure contributes to the RCT outcomes.

Data to inform the different elements of the process evaluation will be collected via semi-structured interviews, observations, documents and quantitatively regarding the level of implementation of New Chapters. The strategy has been developed to enable the IPE research questions to be addressed, but sufficiently flexible to enable the IPE to adapt to the needs of the project. A key consideration for the data collection strategy was to ensure a balance was struck between capturing a representative breadth of data and views as well as the depth of information to understand participant journeys, but not to overburden.

11.1 Research questions

The IPE will aim to answer the following questions:

Question 1: To what degree are the core components of New Chapters as detailed in the ToC and manual delivered?

Question 2: To what degree are the key mechanisms of New Chapters as detailed in the ToC activated?

Question 3: How acceptable is New Chapters from the perspective of participants, staff and key stakeholders?

Question 4: What does BAU look like?

Question 5: Are there any unintended consequences to delivering New Chapters?

Question 6: Are there aspects of New Chapters implementation and delivery that could be improved or need refinement to deliver the intervention in real-world settings (not under trial conditions)?

11.2 Research methods

While the MRC Framework provides an established framework for guiding what process questions need to be addressed and the kinds of data relevant to providing answers, the CFIR constructs will be used to add analytical depth to the findings through suggesting how and

why these factors were important to delivery, and how they work together to enable or constrain successful implementation. The constructs have been mapped onto the MRC Framework in the following ways (Table 6).

Table 6: Mapping of CFIR and MRC framework against IPE data collection

CFIR	MRC	Knowledge produced	Data Collection
Innovation	Intervention description	Collectively agreed model of how the intervention works, including understanding of benefit, clarity on how it will be delivered, agreement on observable results, local/user knowledge and evidence underpinning use	ToC and Logic Model
Implementation Process	Implementation process	Understanding of the resources, training, supervision and support provided to deliver the intervention in practice, including adaptations or tailoring	Interviews with New Chapters staff and NLT supervisors, professional authors, prison staff Documentary analysis of intervention materials
Individuals	Mechanisms of impact - participant responses	Understanding of how both staff and young people work within the intervention, such as their goals are achieved. Examination of differences in uptake or engagement across different profiles of young people.	Interviews with New Chapters staff, professional authors, young people, prison staff Observations of sessions Quantitative process measures
Inner Setting	Context	Understanding of how the setting in which the intervention is carried out impacts on its delivery, for example relationships, priorities, culture	Interviews with New Chapters staff, prison staff and young people Observation of sessions
Outer Setting	Context	Understanding of how the system in which the intervention is carried out impacts on its delivery, for example relationships, priorities, culture	Interviews with New Chapters staff, prison staff and young people Observation of sessions

The IPE will include a range of research methods. Table 7 provides a summary.

Table 7: IPE methods overview

Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Intervention fidelity checklist and session logs	185 fidelity checklists completed by New Chapters PMs 185 session logs completed by New Chapters PMs	Descriptive statistics	Question 1 & 2	Adherence to the delivery model leads to better outcomes
NLT Feedback questionnaire	185 feedback questionnaires (after session 1 and last session)	Descriptive statistics	Question 1, 2, 3 & 6	Adherence to the delivery model leads to better outcomes Understanding acceptability
Semi-structured interviews	40 young people 10-20 staff 12 intervention delivers (New Chapters PMs, NLT staff, professional authors)	Thematic analysis	Question 1, 2, 3, 5 & 6	Understanding acceptability, unintended consequences, barriers and facilitators can identify modifications to be made
Observations	1 session in each 12-week block	Thematic analysis	Question 1, 2 & 6	Adherence to the delivery model leads to better outcomes. Understanding barriers and facilitators can identify modifications to be made
BAU	375 CRF records	Descriptive	Question 4	Important to understand how New Chapters can be distinguished from BAU

Intervention fidelity checklist and session logs

New Chapters attendance/engagement will be recorded in compliance logs kept by New Chapters PMs and will include start date and end date of intervention, number of sessions offered, number of sessions attended, number of sessions completed, which sessions (if any missed) and if missed, if a 1-2-1 session took place. To measure fidelity, each PM will be asked to complete a fidelity checklist at the end of each 12-week session block to log the core components of the intervention as described in the ToC and manual, this will also capture adaptations needed to fit with the context of the young people or the setting. Those being assessed as meeting the criteria are where, code of conduct has been created, two author sessions delivered (one of which is an author with lived experience) and did the groups end with a celebration event.

NLT feedback questionnaire

We will use an adapted version of the NLT feedback questionnaire to obtain feedback from the young people. This will be given to the young people to complete at the end of their first session and final New Chapters session.

Semi-structured interviews

Individual semi-structured interviews will be conducted with young people receiving New Chapters, the New Chapters PMs, those supervising the PMs, the authors, and staff employed in key roles within each site.

Young People

For young people participants, across the four sites, we plan to recruit up to forty young people who are receiving New Chapters. Of these 40, up to 20 will be interviewed once (breadth) and up to 20 will be a longitudinal case study (depth). The rationale for interviewing some young people twice is to take a longitudinal multiple case study approach, this will better enable us to unpick 'how' the intervention is working overtime, and if it is working in the way we think it is based on the ToC, for example, are the key mechanisms being activated? In addition, it allows us to more deeply assess how the intervention works for different young people, and if the intervention would require modification. This depth of analysis and understanding of the intervention cannot be obtained if young people are only interviewed at one time point as this only provides a snapshot. There will be some prioritisation to interview participants during the internal pilot stage to identify any early implementation issues.

Young people will be a purposively sampled by the research team to obtain a subsample of participants, which represents our approach to assess intersectionality and process issues. We will use a sampling framework to ensure that we capture a range experiences. Sampling

by individual characteristics will include age, those who identify from racially marginalised groups, those with a range of literacy/education levels, those with a SEND/EHCP. We will also capture young people at different points of delivery (pilot, main trial), at different sites, in groups of different sizes and with different NLT Project Managers and with a range of engagement in New Chapters. However, we will also be flexible to sample by other criteria should that emerge from the data.

In the consent form for the trial, young people will provide consent to be approached to take part in the process evaluation interviews. Potential young people for the process evaluation interviews will be approached by a member of the research team and invited to take part. All potential participants will be offered a minimum of 24 hours after provision of the study information to consider whether they would like to take part.

Each young person will be invited to participate in two semi-structured interviews to provide information about their experience. Topic guides for these semi-structured interviews have been developed and it is anticipated that interviews will last for approximately 30 minutes. The interviews will take place in a private room within the prison, and for those in the community the interviews will take place in a suitable location, such as in the premises of a service that the participant is engaging with.

For those participants that we intend to interview twice, the first interview will focus upon participant expectations and concerns prior to or just starting New Chapters. The second interview will be conducted towards the end or just after the participant has completed New Chapters. These two time point interviews will allow us to scrutinise how intervention component delivery led to outcomes by examining underlying mechanisms that promoted or hindered progress. This is important for understanding if the mechanisms are promoted or hindered differently for different young people

Staff

Staff participants (n = 10 - 20) will be identified from prison-based staff involved in key roles related to New Chapters delivery. Individuals working in these roles will be contacted, on behalf of the research team, by an appropriate person in the prison (Education Governor). Potential staff participants will be provided with a copy of the relevant PIS and invited to contact the researcher if they are interested in taking part. Written informed consent will be taken by a trained researcher prior to participation in the interviews.

New Chapters PMs directly involved in delivering New Chapters (n = 5), the professional authors (n = 4) and NLT staff providing management and supervision to the New Chapters PMs (n = 2) will also be invited to take part in semi-structured interviews.

To capture early implementation challenges faced by the New Chapters PMs for the internal pilot, as well as obtaining a good understanding of how such challenges are resolved or persist

throughout the life of the trial, we plan to interview each New Chapters PM approximately every six months, up to a maximum of four interviews over the two years of the trial.

The professional authors and NLT staff providing management and supervision to the New Chapters PMs will be interviewed at one time point during the study. They will be approached by email by a member of the research team, inviting them to take part in the interview study. They will be sent a copy of the relevant PIS and invited to contact the researcher if they are interested in taking part. Written informed consent will be taken by a trained researcher prior to participation in the interviews.

Interviews will take place in a suitable location that is convenient for the staff member (inside or outside of the prison), telephone or MS Teams. It is anticipated that interviews will last for approximately one hour and that each participant will be interviewed once (except for the New Chapters PMs, although some may be interviewed again to clarify or expand on particular aspects of the interview). Similarly, if an interview is terminated early (e.g. due to operational reasons) an additional interview session will be arranged to compensate for this.

Observations

Across the four sites, we will observe at least one session in each 12-week block. In the internal pilot this will be focused on those sessions core to the ToC, such as the initial session, author session and the final session. Data will be collected in the form of researcher field notes using a template containing the core components of the ToC, the researcher will be observing and reflecting on whether the ToC can be observed in action. These field notes will be anonymous and contain no identifiable information.

BAU

Using the CRF to record this data, we will access prison records to describe for each young person BAU between baseline and follow-up. This will include attendance in education, education level and receipt of offending behaviour interventions or other enrichment interventions.

11.3 Analysis

We will produce descriptive statistics for the quantitative outcomes. For the qualitative data, we will combine interview transcripts and field notes recorded from the observation case studies in Nvivo. We will use thematic analysis, guided by the CFIR framework, to create higher order themes. The initial qualitative analysis will be completed blind to the trial outcome to enable open exploration of the themes.

We will use a convergence coding matrix to synthesise the different data sources (Tonkin-Crine et al., 2016), with the sampling framework. The synthesis will be interpretative rather

than aggregative (as the qualitative and quantitative data cannot be formally combined). We will tabulate the data from each part of the evaluation according to the MRC framework (see Table 6). This will be in the form of summary statistics for the quantitative data, higher order themes and selectively coded exemplar text from the qualitative data. We will organise data corresponding to each site and intersectionality, to enable us to check for differences and similarities across settings.

We will iteratively review within and across the organised data to identify patterns, guided by the CFIR framework and reflecting back on the ToC. At the end of this analytical process, the ToC may require revision. If the main trial does not demonstrate efficacy of the intervention, additional analysis of the qualitative data may be conducted using the same analytical approach as above, with additional deductive and inductive coding to explore possible explanations for this and to glean any additional learning that may have application to other studies.

As noted in the introduction, we will take a gender conscious approach to the evaluation. We will explore notions of masculinity in our interviews (with staff and young people) and observations, as well as in our examination of documentary evidence. We will also be guided by this within our analysis of the IPE data. This will enable us to examine how the intervention addresses the concept of masculinity, which has not only been linked to educational literacy, but is also a key factor for male violence, with interventions that support young men to navigate and construct alternative masculine identities showing promise.

12.Cost data reporting and collecting

Costs associated with delivering New Chapters will be calculated based on YEF costing guidance https://youthendowmentfund.org.uk/wp-content/uploads/2022/01/21.-YEF-Cost-reporting-guidance.pdf using a micro-costing approach accounting for the actual local costs and resources used in delivering New Chapters and associated training and supervision. This will include salaries, resources, facilities, overheads, and management costs. The cost perspective will be that of the service. We will include costs associated with supervision and any additional training and account for staff turnover. We will 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 reported as average cost estimates for a single group receiving the 12-week intervention. Data will be collected using the intervention fidelity checklist and session logs, highlighting all activity associated with a single young person and per group. The main uncertainty is assumptions regarding time and costs associated with non-attendance or non-delivery due to prison regime issues and then the amount of 1-2-1 sessions to be delivered. Results will be presented as a table including a full list and description of the items included in the cost; and a detailed breakdown of cost estimates by item.

13. Safety reporting

Table 8: Safety reporting terms and definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom the intervention and/or assessment has been administered.
Adverse Reaction (AR)	An untoward and unintended response in a participant to the intervention/assessment. The phrase "response to the intervention /assessment" means that a causal relationship between a trial intervention/assessment and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out. All cases judged by the PI (acting on behalf of the Sponsor) as having a reasonable suspected causal relationship to the intervention /assessment qualify as adverse reactions.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the intervention / assessment, based on the information provided.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A serious adverse reaction, the nature and severity of which is not consistent with the effects or consequences of the intervention.
Charity Commission Serious Incident	A serious incident is an adverse event, whether actual or alleged, which results in or risks significant: • harm to an organisation's beneficiaries, staff, volunteers to others who come into contact with the organisation through its work • loss of an organisation's money or assets • damage to an organisation's property • harm to an organisation's work or reputation

13.1 Operational definitions for (S)AEs

AEs

Young people may disclose suicidal ideation, self-harm, harm to others and property during the trial. These could include, ideation alone with no behaviour (suicidal ideation or self-harm ideation), self-harm or suicidal behaviour, violence towards an inanimate object (e.g. a wall or door), events involving others (threats to harm others / violence, actual harm to others / violence). It should be noted that these may be SAEs depending on the severity of injuries and outcomes of the behaviour. These events do not require further follow up unless there is evidence that these are research related but each event should be recorded from consent until 30 days after the final follow-up assessment is completed.

AEs that do not require reporting:

any untoward medical occurrence that is not included in the definition above.

SAEs

All SAEs occurring from the time of consent until 30 days after the final follow-up assessment completion must be recorded on the SAE report form and emailed to the PI (as sponsor's representative) immediately and within 24 hours of the research staff becoming aware of the event. Refer to the SAE form for the information that will be collected for all SAEs.

Any change of condition or other follow-up information should be emailed to the PI as soon as it is available or at least within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached.

Email completed SAE Report Forms FAO: charlotte.lennox@manchester.ac.uk

SAEs must be followed-up until resolution and sites must provide follow-up SAE reports if the SAE had not resolved at the time the initial report was submitted.

On receipt of the SAE Report Form, the PI will send an acknowledgement of the SAE to the participating site. This acknowledgement will include an SAE reference number which should be included on all future correspondence regarding the SAE.

Sites should respond as soon as possible to requests from the PI for further information that may be required for assessment of the SAE.

The PI will review for assessment of causality. If the SAE is related to the intervention/assessment, the PI will review the expectedness in relation to the nature or severity of which is not consistent with the effects or consequences of a psychological intervention. In the case that the SAE is related and unexpected, the PI will submit a report to the University of Manchester Ethics Committee (UoM EC) within the expedited timeframes.

Monitoring of adverse events

Due to the nature of the participant sample, it is anticipated that a number of self-harm/violence-related adverse events may occur in both trial arms. Should the TSC (has Data Monitoring and Ethics Committee (DMEC) function) and the UoM EC become aware of an inflated rate in the intervention, relative to the BAU, arm of the trial that is attributable to participation in the trial, then the TSC may be alerted to consider recommending to the funder a premature discontinuation of the trial.

All adverse events that are research related will be reported by the PI to the relevant host prison, TSC and funder on a regular basis and in an expedited fashion. Fatal or life-threatening events will be reported to the TSC and the UoM EC within seven days of knowledge of such cases.

All adverse events meeting the Charity Commission definition will be reported to the funder within 48 hours via serious.incident@youthendownmentfund.or.uk

Any safeguarding concerns will be reported to the funder on a quarterly basis.

Reporting urgent safety measures

The Sponsor or PI may take appropriate Urgent Safety Measures (USMs) in order to protect the participant of a trial against any immediate hazard to their health or safety without prior authorisation from the UoM EC.

Where the PI takes urgent action that is not consistent with the protocol to prevent harm to a young person in the trial, the PI must immediately inform the wider evaluation team by email and give full details of the measures taken and the decision making process surrounding the action(s) taken.

The PI will inform the UoM EC of these measures immediately, but no later than 3 days from the date the actions were taken.

14. Data handling

14.1 Data collection

All information will be kept strictly confidential and held in accordance with the principles of the Data Protection Act. Any information about the participant obtained following their consent will be recorded against a trial identification number (pseudonymised format). Data will be recorded on paper data collection forms (CRFs). Interviews will be recorded using an encrypted Dictaphone.

14.2 Data storage

Consent forms, CRFs and session logs will be stored securely at each site until the research team can transport them directly to The University of Manchester. Audio recordings will be stored securely (indexed by study number only) on an encrypted and password-protected UoM computer. Only the research team will have access to this data.

Paper copies of the relevant trial documentation will be stored at UoM for a minimum of 15-20 years after publication of the trial results. For audit purposes, electronic copies will be retained for 5 years.

14.3 Data confidentiality

All trial data will be held in pseudonymised format. The PI will hold the data key which will hold name and trial identification number, and this will be stored separately from all other data.

The contact details (address and phone numbers) of participant's will be collected as a means of contacting them if they are released from prison. This will include any services they are likely to be involved with on release e.g. Youth Offending Team, Social Worker, drug and alcohol team etc. Hard copies of these will be stored in a locked cabinet, in the locked office of the PI, separate to all other study data, with access limited to members of the research team.

Consent forms containing participant names will be held separate to all other study data, with access limited to members of the research team.

The research team will ensure that the participants' anonymity is maintained on all other documents. Names and locations will not be used during interviews. The audio recordings will be uploaded for transcription using a UoM approved transcription service. Once transcription is complete and checked, all audio files will be deleted.

In prison research, the right to confidentiality must be balanced with the nature of the environment and the duty of care of the Prison Service. Before providing informed consent, participants will be informed that their information will remain confidential, with the exception of the participant providing information regarding immediate risk to their own safety, the safety of another individual, or the security of the establishment. Participants will be duly informed on any occasion when the research team will break confidentiality for these reasons. In the event that the research team believes the participant to be in immediate danger of an adverse event, e.g. suicide attempt, self-harm, violence, the researchers will inform the relevant prison staff.

14.4 University of Manchester archiving

Essential documents will be retained for at least 15-20 years from conclusion of the trial (submission of the end of study report) for possible audit or inspection purposes. Documents will be securely stored and access restricted to authorised personnel. Archiving and destruction of essential trial documentation will be authorised by the Sponsor.

14.5 Access to data

Direct access will be granted to authorised representatives from UoM and the regulatory authorities to permit trial-related monitoring, audits and inspections.

14.6 Youth Endowment Fund data archive

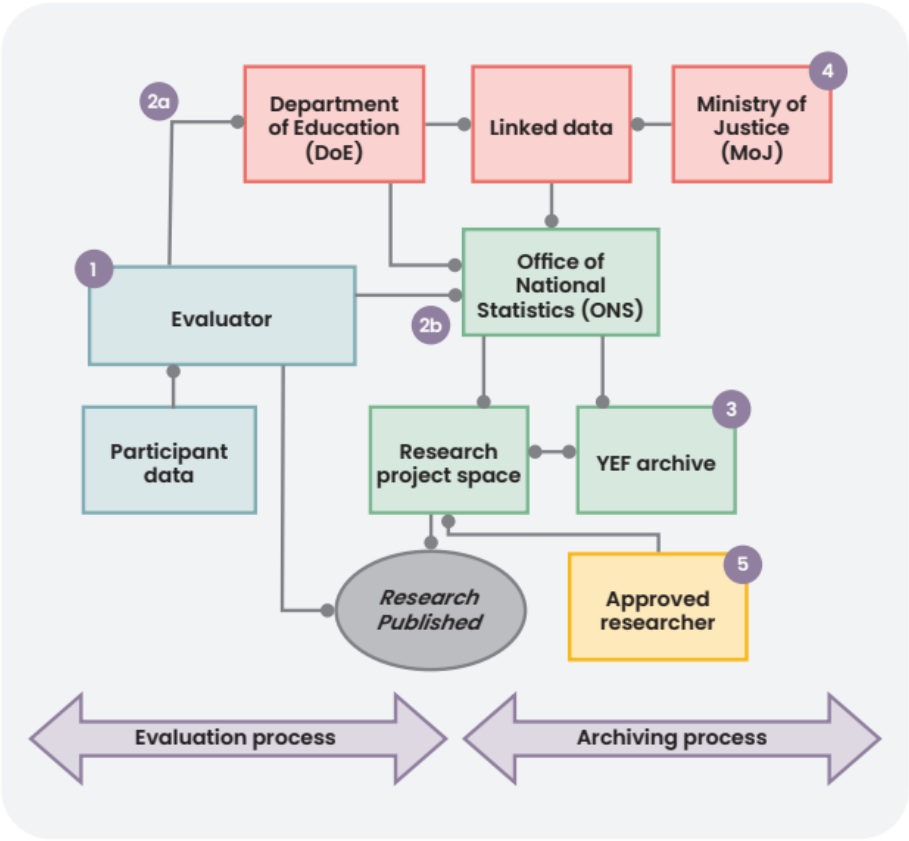
UoM is the Evaluator (1) and will collect personal data from participants. At the end of the trial The University of Manchester will create two data sets, one submitted to the Department for Education (DfE) and one to The Office for National Statistics (ONS). Following this technical guidance https://youthendowmentfund.org.uk/wp-content/uploads/2022/12/YEF-Data-Guidance-Submitting-data-Dec-2022.pdf

- DfE: This will contain young people's identifying data and a unique data archive participant ID (different to their trial ID) allowing the data to be linked to DfE data. This will be submitted to the DfE, and they will pseudonymise the data. In this case replacing the identifying data with the DfE pupil matching reference numbers (PMRs). The PMRs and the unique participant ID will then be submitted to the ONS.
- ONS: This will contain a list of variables from the evaluation dataset (see Annex 1 & 2 https://youthendowmentfund.org.uk/wp-content/uploads/2022/12/YEF-Data-Guidance-Submitting-data-Dec-2022.pdf) and the unique participant ID and this will be submitted directly to the ONS.

The use of the unique participant ID in both datasets allows datasets to be linked once they are in the ONS secure environment.

Both datasets are held in the YEF archive by ONS (3). The DfE and MoJ routinely link data and on request this can be made available in the ONS secure research environment (4). Approved researchers can apply to access YEF data via the ONS secure research service (5).

Figure 2: Overview of the Youth Endowment Fund data archiving process



14.7 Data protection

UoM (We) conducts research to the highest standards of research integrity to ensure it is both beneficial and enriches higher learning. As stated in our University Charter our research outcomes are in the public interest. As part of our commitment to research integrity, we follow the UK General Data Protection Regulation (UK GDPR) and the UK Data Protection Act 2018 (DPA), (hereafter referred as UK data protection law). Research conducted by our staff is defined as making an original contribution to knowledge which is published in order to share that knowledge. We are the Data Controller for research studies. This means that we will decide how personal information is created, collected, used, shared, archived and deleted (processed). When we do this, we will ensure that we collect only what is necessary for the project and that participants have agreed to this. UK GDPR requires us to be explicit with you about the legal basis upon which we rely in order to process information about you. For research the legal reason is "Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller" (Article 6 of the UK GDPR). For sensitive information the legal reason is: "the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes… which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard

the fundamental rights and the interests of the data subject" (Article 9 of the UK GDPR). When research involves criminal convictions, the legal reason is listed in Schedule 1 of the DPA which requires that special safeguards are in place. Where we need to rely on a different legal reason, such as consent, this will be listed in the PIS. We may also use personal information for additional research purposes, such as other analysis or future projects on the same research topics. This is known as a secondary use or purpose. If we want to do this, it will be explained in the PIS and we will ensure that information will not be used in ways which might have a direct impact on you (such as damage or distress) or will lead to decisions being made.

14.8 Data processing roles

UoM and NLT will be joint Data Controllers during the evaluation up to the point where data is deleted by the UoM and NLT.

YEF will become the Data Controller once the data has been submitted to the DfE and ONS.

15. Diversity, equity and inclusion

In the development of this study, UoM and NLT have worked in collaboration with YEF Race Equality Associate, to actively consider issues of diversity, equity, and inclusion. An ongoing, collaborative dialogue will allow us to engage with these crucial elements throughout the project, to ensure an equitable approach. Our approach incorporates and adapts the principles of an embedded racial and ethnic equity perspective in research, set out by Child Trends (2019).

The evaluation will take an intersectional approach by recognising that individuals may experience multiple forms of marginalisation simultaneously based on factors such as ethnicity and race, gender, education and disability. Intersectionality has been considered in the design and implementation of the evaluation, acknowledging that individuals' experiences and needs are shaped by the complex interplay of various social identities. Within the IPE longitudinal case studies, aim to capture different intersections of experience by considering various aspects of intersectionality such as age, ethnicity, literacy and education levels. It is likely that no exclusions will be made based on literacy levels, other than in exceptional circumstances where a participant requires an interpreter.

This approach will inform the analysis and interpretation of the data, ensuring a nuanced understanding of the impact of the intervention across different intersecting identities. Our co-design ensures that the evaluation is accessible to all participants.

Inclusive communication: The evaluation and intervention will strive to be welcoming and inclusive, fostering an environment where all participants feel comfortable and empowered to engage fully, using plain language and being mindful of potential barriers (such as formal

or technical language) that may hinder participants' understanding or engagement. We will provide information and materials in formats that cater to different learning styles and abilities, such as visual alternatives to written materials. All information for young people and the questionnaire for the data collection will be read out to them. All interview wording will be reviewed for inclusive language and adapted where necessary. Our information sheets for young people are picture and image based and this includes images of diverse races and ethnicities. For the intervention, the workshops are about creative expression. Young people will be supported and encouraged to write in languages other than English if that is how they feel most comfortable expressing themselves, as well as in all manner of forms (prose, poetry, lyrics).

Culturally Responsive Data Collection: We will employ culturally responsive data collection methods to capture a comprehensive understanding of the participants' experiences. This includes using narrative interviews as part of the IPE that allow participants to express their perspectives in meaningful ways.

Young people's data pertaining to their ethnicity will be collected at baseline and incorporated into analyses. The Ethnicity categories used here are those proposed in YEF documentation and taken from the 2021 Census of England and Wales. The overall categories are: Asian or Asian British ethnicity; Black, Caribbean, or African ethnicity; Mixed or multiple ethnic groups; White; Other ethnic group. In addition to identifying their ethnicity within those set out in the Census, participants will be invited to self-identify within their own definitions of ethnicity and race. This will capture wider definitions of identity potentially incorporating race, ethnicity, religion, and other cultural indicators. Cultural indicators refer to various aspects or factors that reflect the cultural characteristics, values, beliefs, or practices that influence young people, such as language, customs, traditions, social norms, religious practices, artistic expressions, and historical context. These indicators can help assess and understand the influence of culture on young people's life stories and, more specifically, their responses to the intervention.

By considering cultural indicators, we aim to acknowledge and account for the cultural diversity and specificities of the young people involved. In addition, adapting and responding to cultural indicators in the IPE means that our research will be sensitive to the cultural context in which it takes place i.e. in an enclosed (and often painful) setting with a vulnerable population. It will involve understanding and empathy on the part of the researchers. This will be addressed in their training ahead of fieldwork.

The evaluation team are experienced in culturally responsive data collection and will approach the interviews with cultural sensitivity, adapting key features to accommodate diverse communication styles and cultural norms. We will hold in-house training to ensure the research team understand our approach to equity, in particular: understanding

categorisation and self-identification of ethnicity and race; the legacy and history of the secure estate including racial injustice; the various histories of offending and sentencing involving discrimination and deprivation that young people may have experienced; an awareness of unequal power relations; and how to manage disclosures of racism or other forms of discrimination.

Data Analysis: We will employ an intersectional lens when analysing the data gathered for the IPE to identify themes across different demographic groups based on the sampling framework. The findings will be reported in a way that respects the diversity of the participants. The trial will not be powered to undertake detailed subgroup analysis: for instance the small sample size will not allow for an analysis of difference in effect in terms of ethnicity. However, in the IPE we will interview young people at two time points, this longitudinal approach will allow us to consider the intersectional experiences of young people taking part in the evaluation. This will enable us to unpick 'how' the intervention is working for different subgroups and if the intervention would require modification.

Continuous Learning and Improvement: The evaluation and intervention will incorporate a continuous learning and improvement approach. This involves ongoing reflection and adaptation of the evaluation and intervention processes (during the IPE) based on feedback from participants, stakeholders, and the evaluation team to ensure that any issues can be addressed using a purposive selection of participants. Regular check-ins and debriefing sessions will be conducted to identify and address any challenges or barriers to inclusivity that arise during the evaluation – we will monitor demographics in our quarterly reviews and have analysis reflection sessions where we feedback emerging analysis to NLT. This iterative process will ensure that the evaluation remains responsive and adaptive to the evolving needs and contexts of the participants.

Dissemination and Knowledge Exchange: The evaluation will prioritise the dissemination of findings and knowledge exchange to promote learning and inform future inclusive evaluation designs. The evaluation report will be accessible and disseminated through various channels to reach diverse audiences, including policymakers, practitioners, and stakeholders. We will actively seek opportunities to present the methods and findings of the research at conferences, publish research articles, and collaborate with relevant stakeholders to ensure that the knowledge generated from the evaluation has a meaningful impact on research methods, policy and practice.

The evaluation will actively promote sensitivity and inclusion by addressing the needs of groups that are disproportionately affected and underserved by existing services or delivery. This will involve tailoring the interviews to account for the unique circumstances and challenges faced by these groups and identify any anomalies, inconsistencies, or gaps in the delivery of New Chapters or in other features of daily life in custody.

All activities, materials, and surveys used in the evaluation and intervention will be designed to be accessible, inclusive, and culturally sensitive. This includes using clear and plain language, avoiding jargon, and considering the literacy levels and language preferences of the participants. Culturally sensitive approaches will be employed, including incorporating culturally relevant examples, images, and scenarios in the research tools, recognizing the importance of diverse cultural backgrounds and experiences (see Inclusive Communication above).

The use of appropriate language and terminology will be carefully considered to avoid cultural insensitivity or misunderstandings. The evaluation team will engage in ongoing dialogue with NLT and the YEF Race Equity Associate to ensure that the materials are respectful, accurate, and relevant to the cultural contexts of the participants. The IPE will have the flexibility to adapt and respond to cultural indicators.

The evaluation and intervention uses a participatory approach to actively seek input (through co-design sessions, interviews and focus groups, detailed earlier) from young people. Their involvement in the design and implementation of the intervention will ensure that the evaluation is informed by the voices of those directly impacted by the intervention and the wider issues being addressed. Their insights and perspectives will inform the development of the intervention, ensuring that the study is relevant, responsive, and respectful of their experiences. Engaging participants as active partners in the research process will enhance researchers' understanding of the issues young people face and strengthen the validity and impact of the data.

Our design recognises and explores the racialised impact of a young person's life experience on their response to the intervention by purposefully and creatively incorporating a racial equity perspective at all stages. This ensures that the research produces findings that reflect the diverse lived experiences of racially minoritised young people and other intersectionality. The intervention and evaluation will prioritise key racial, diversity, and inclusion considerations. This includes recognising and addressing systemic biases, discrimination, and disparities that may exist within the CJS and the specific context of the CYPSE. Efforts will be made to ensure that the evaluation process does not perpetuate any inequities and actively works towards promoting fairness and justice. The evaluation team will be attentive to issues of racial justice and equity, aiming to identify and mitigate any potential biases in the evaluation process.

The research sits on a foundation of knowledge about race and racism within a youth custody context. Our research draws on the current evidence base that underpins effective interventions with young people of diverse backgrounds, specifically in the area of violence reduction. Our team has expertise in this area, ensuring a deep understanding of the historical and political context in which youth justice operates. The intervention sits within a justice system that has seen a dramatic fall (80%) in young people receiving sentences over

the last 20 years but a year-on-year rise in the proportion of those young people that come from racially minoritised communities. In addition, within the youth justice system, racially minoritised young people experience unequal treatment at every stage. More broadly disproportionality in sentencing and experiences of justice reflect disparities in social, educational and health opportunities prior to justice system experiences. Due to racial disparities, racially minoritised young people are more likely to be justice experienced and face more disadvantage and vulnerabilities. In custody, they are more likely to be restrained and less likely to feel safe. Histories and contexts of inequalities in treatment and experience are embedded in our understanding of the intervention and our research design. Our methods explore participants perceptions of their experiences with this context in mind. One of the rationales for using the SDQ over behaviour data recorded by the prisons as the primary outcome measure was due to the above; it is highly likely that, the behaviour of racially minoritised young people, is perceived and reported differently.

Demographic data on age and ethnicity will be recorded in relation to numbers: referred to the programme; recruited to the evaluation; dropped out. We will also consider Refugee status; English native/first language; SEND/EHCP; Index offence type; and Literacy level on reception.

The evaluation of New Chapters aims to ensure a diverse sample of young people that is broadly representative of young people within the CYPSE through a multi-step process:

1. Potential young people for the study are identified using the prison records system, to include those aged 15-18, currently serving a custodial sentence with at least 3 months until release. Some exclusions are required, in order to reduce attrition, or for ethical reasons. Due to the geographical coverage of each site, we are expecting differing profiles of young people across the sites and randomisation will be satisfied by site.
2. Initial approach: Education staff members approach potential young people initially and briefly explain that a research project is taking place. If the young person expresses an interest in hearing more about the study, a meeting will be arranged with the researcher for a more detailed explanation. Researchers have undergone mandatory diversity and unconscious bias training (detailed below) and sessions will be held with Education staff (during the mobilisation phase) ahead of recruitment. This will ensure that everyone taking part in the delivery of the research works to the inclusion and exclusion criteria set out in 5.1 and 5.2. Any risks will be mitigated as far as possible though the use of training sessions. This will be monitored as part of a protocol violations process.
3. The researchers will be trained to assess capacity to consent. This involves evaluating their ability to understand the relevant information, retain it, use it in the decision-making process, and communicate their decision. The PIS is image-based and

appropriate for diverse literacy levels. The researcher will read and explain the information, taking into account the high levels of literacy difficulties in this population. This step ensures that the young people's autonomy and ability to provide informed consent are respected.

4. In the case of interviews, as part of the IPE, a purposive sampling approach is employed. This means that participants are selected intentionally to represent diverse backgrounds, literacy/education levels, and engagement in New Chapters. This approach ensures that a variety of perspectives and experiences are included in the evaluation.

By following these steps, the evaluation of New Chapters aims to include a diverse sample of young people. This will be mapped against demographics in a 'fidelity checklist'.

As well as responding to the usual ethical guidelines and regulations (gaining informed consent, building trust, protecting participant confidentiality where possible, and addressing potential power imbalances), the evaluation design will account for specific requirements and support needs of the participants. For instance, the information sheets and consent forms are designed to respond to the needs of the population (as mentioned in Inclusive Communication, above).

We will work closely with participants to identify and address any potential barriers that may impede their engagement or affect the accuracy and reliability of the data collected.

UoM team have received mandatory training ('Diversity in the workplace' and 'Unconscious Bias') to gain an understanding of the broader issues of equality and diversity, enhancing understanding of the unique needs and experiences of diverse populations, creating a supportive and inclusive research environment that values diversity, encouraging continuous learning, and promoting culturally sensitive research practices.

A reflexive research process including research team analysis and debrief sessions will help to position the researchers and participants within the research. The PI and CIo-Is will support researchers throughout the evaluation to engage in self-reflection, critically examining their own biases, assumptions, positions of privilege and sensitivity to the cultural contexts and power dynamics inherent in studying ethnicity. Regular mentoring and debriefs will be in place to support the research team to engage sensitively with participants, foster a respectful and inclusive environment and navigate the potential cultural or social challenges that may arise during the evaluation process. This will also help the team to examine their own biases and backgrounds and ensure that they approach the study with an inclusive mindset.

Our combined expertise makes us ideally placed to ensure a fully inclusive evaluation from initial design to dissemination. The interdisciplinary nature of the research team encourages a wide dialogue among researchers from various academic disciplines (psychology,

criminology, sociology, public health) and with extensive practice experience. The diversity within the team will broaden perspectives, foster innovative approaches, and promote a more comprehensive understanding of inclusivity.

The research team have expertise in undertaking research with diverse, hardly reached, excluded, vulnerable, and marginalised communities, children and young people. CL, PC & KT were all involved in the development and implementation of the Comprehensive Health Assessment Tool within the CYPSE. PC lead on the development of the CHAT, which involved qualitative and quantitative data collection with young people in YOIs, CL, PC, and LAC have undertaken RCTs within the CYPSE and in YOI Wetherby. JD has undertaken research to understand the impact of interventions on young people (PROMISE, Mi-Men, Exclusion and Education) with a focus on aspects of diversity, stigma and discriminatory treatment.

The research team have a track record in co-design, participatory methods and using creative methodologies (such as art, photography, drama) to engage diverse and excluded young people.

This expertise will ensure that the team is well-equipped to engage effectively with diverse populations, understand their unique circumstances, and mitigate potential barriers to participation. Our prior experience will contribute to the successful implementation of the evaluation in an inclusive and equitable manner.

The approach set out here emphasises our commitment to an inclusive, fair, and equitable evaluation design and process that acknowledges the unique needs and experiences of young people. By incorporating these measures, the evaluation seeks to ensure that every participant's voice is heard, their experiences are respected, and the outcomes of the trial are representative and meaningful for all those involved.

16. Ethics and registration

This research has been ethically reviewed and approved by The University of Manchester Ethics Committee (UREC 5) (Reference: 2024-20067-36975) and HM Prison and Probation Service (National Research Committee) (Reference: 2024-1053)

16.1 Randomisation and Resentful Disengagement

Young people will be randomised on a 1:1 basis using concealed random allocation conducted using an online pseudorandom list with random permuted blocks of varying sizes to test the efficacy of the intervention. Randomisation will be stratified by site. Randomisation minimises selection bias and stratification will address site-based differences such as demographics and

different education providers. No care is withheld to young people, New Chapters is an addition, but a trial design is needed as the efficacy of New Chapters is untested.

The evaluation team will be responsible for allocation and informing young people and New Chapters staff of allocation. The evaluation team understand the issues around resentful demoralisation from those young people allocated to BAU. Prior to randomisation and when allocation is communicated this will be conducted in a way that emphasises the importance of involvement, regardless of randomisation outcome, and that young people are involved in something that is important and valuable, but that this does not oversell the potential benefits of the project.

16.2 Blinding

Given the nature of the intervention, it is not possible to blind young people or those involved in delivering New Chapters as this is a novel intervention which individuals would not normally expect to receive or provide. Young people and research team will be blind to allocation at the time of collection of the baseline measures.

It is also not possible to maintain researchers being blind to the trial arm allocation. The researchers and the team delivering New Chapters are both working within the confines of a prison environment, causing many occasions when un-blinding will occur: researchers seeing young people receiving the intervention; young people seeing the researcher around the prison and informing the researcher that they received the intervention. The research team have conducted several trials in prison settings testing the feasibility of blinding. In most cases allocation is always revealed prior to the end of data collection and blinding impacts the relationships the researchers have with participants and intervention delivers, which are both important to the successful running of a trial. Therefore, we will minimise any potential bias by protocolising collection and scoring of the primary outcome measure. Specifically, the researchers will use a highly scripted section for the SDQ, reading each question to the participants and only deviating from this to clarify the meaning of the question if they indicate they do not understand the question. The SDQ will not be scored by this researcher but will be scored by a researcher who is blind to allocation. In this trial the research team are independent of the NLT (intervention providers) and the delivery of New Chapters and therefore risk of bias is further reduced. The trial statistician and researcher analysing the data will be blind to allocation arm, ensuring a secure process.

16.3 Coercion

Eligibility to take part and initial approach of the young people will be undertaken by education staff. Education staff are not employed directly by the prison service and therefore this reduces the potential for young people to feel that taking part may have an impact on criminal justice outcomes. Education staff have routine access to the prison records system

as part of their role. Education staff conducting the initial approach ensures that the young people do not feel under any pressure from the research team to take part. In the PIS all participants are informed that participation is voluntary and that agreeing/declining to take part will have no impact on the care and/or education they are receiving.

NLT staff may feel under pressure to take part in the research as it is their intervention being evaluated. It will be made clear to staff that participation is voluntary and that agreeing/declining to take part will have no impact on job prospects. The evaluation team will not share details of which staff have or haven't taken part and we will ensure that any analysis/write up is anonymous (given small sample e.g. we will not say which sites the NLT Project Managers are from)

16.4 Consent/Assent

A robust consent procedure has been put in place which includes extra care to ensure that young person participants are able to give full informed consent/assent to all parts of the study. Age appropriate PIS and consent forms have been developed to support this, with the involvement of young people within YOI Feltham. Where a parent consents but a young person does not provide assent the wishes of the young person will preside.

All participants will be given a minimum of 24 hours after receipt of the PIS to consent.

The PIS for parents will be translated, where this is required.

In the observations refusal by any person present will mean the researcher does not attend. If on the observation day, any attendee expresses that they do not wish for the researcher to be present, the researcher will cease observation and leave.

16.5 Confidentiality

In prison research, the right to confidentiality must be balanced with the nature of the environment and the duty of care of the Prison Service. Before providing informed consent, participants will be informed that their information will remain confidential, with the exception of the participant providing information regarding immediate risk to their own safety, the safety of another individual, or the security of the establishment. Participants will be duly informed on any occasion when the research team will break confidentiality for these reasons. In the event that the research team believes the participant to be in immediate danger of an adverse event, e.g. suicide attempt, self-harm, violence, the researchers will inform the relevant prison staff.

- It is made clear to participants in the PIS the situations where there may need to be a breach of confidentiality and participants are required to indicate that they understand this in the consent process. It will be the responsibility of the research team to escalate these concerns.

- A staff member may disclose professional malpractice that requires breach of confidentiality. This has been detailed in the PIS and participants are required to indicate that they understand this policy in the consent process. It will be the responsibility of the CI (Charlotte Lennox) to escalate these concerns.

16.6 Data Protection

This project is being conducted in line with UoM data protection procedures, the Data Protection Act and the General Data Protection Regulation

Written consent forms - Any physical copies of consent forms will be brought back to the UoM as soon as possible following completion in the prisons and stored in a locked filing cabinet at the UoM. This will only be accessible by the core UoM research team. These will be digitalised as soon as possible and then stored on a server at the UoM and will be will only be accessible by the core UoM research team. Hard copies will be permanently destroyed. Digital files will be labelled with a unique participant ID pseudonym (different to that used within the data collection).

Verbal consent recordings - Verbal consent audio recordings will be stored separately to transcription and all other data on the UoM server and labelled with a unique participant ID pseudonym (different to that used within the data collection). These will be encrypted and only be accessible by the core UoM research team.

Case Record Forms - Physical copies of the CRFs will be brought back to the UoM as soon as possible following completion in the prisons/community and stored in a locked filing cabinet at the UoM. This will only be accessible by the core UoM research team. These will be digitalised as soon as possible and then stored on a server at the UoM and will be will only be accessible by the core UoM research team. Hard copies will be permanently destroyed. Digital files will be labelled with a unique participant ID pseudonym (different to that used within the data collection).

Contact information - Physical copies of the contact information will be brought back to the UoM as soon as possible following completion in the prisons/community and stored in a locked filing cabinet at the UoM. This will only be accessible by the core UoM research team. Once a young person comes to the end of their follow-up window, the hard copies will be permanently destroyed.

Interview audio recordings - The research team will use an encrypted device approved by the UoM for all interviews. The audio file will be transferred off the device onto the UoM server as soon as is possible after the interview and will only be accessible by the core UoM research team. Audio recordings will be transcribed by a third party, UoM approved transcription service. Once transcripts are received and checked for accuracy, the stored audio file will be deleted. The interview transcript will then be de-anonymised upon receipt by a member of

the research team and stripped of any identifiable information (including names, locations). Transcripts will be labelled with a unique participant ID pseudonym.

Observation field notes - Observation field notes will be brought back to the UoM as soon as possible following completion in the prisons/community and stored in a locked filing cabinet at the UoM. These will be digitalised as soon as possible and then stored on a server at the UoM and will be will only be accessible by the core UoM research team.

ID Key - There will be an excel file held separately which links the unique participant ID pseudonym for their data and their unique participant ID pseudonym for their personal information (consent). This will be password protected and stored on a server at the University of Manchester and will be accessible to Dr Charlotte Lennox only. Direct access will be granted to authorised representatives from UoM and the regulatory authorities to permit trial-related monitoring, audits and inspections

16.7 Data Archiving and Data Linking

A condition of YEF funding and contract is that data be made available for the YEF data archive. At the end of the trial UoM will create two data sets, one submitted to the Department for Education (DfE) and one to The Office for National Statistics (ONS). The use of the unique participant ID in both datasets allows datasets to be linked once they are in the ONS secure environment (This ID will be different to that used in the UoM ID Key). Both datasets are held in the YEF archive by ONS. The DfE and Ministry of Justice (MoJ) can link data on request and this can be made available in the ONS secure research environment. Only approved researchers (approved by the ONS) can apply to access YEF data via the ONS secure research service. This archiving process is clearly explained to trial participants in the PIS.

16.8 Distress and Safeguarding

All participants are informed in the PIS and consent that there is the possibility that topics discussed may be distressing.

The researchers will follow the study distress protocol.

- Each member of the research team will receive up to date training on working in prisons and safeguarding concerns, issues and what to do, for example, the right course of action if a young person discloses intentions to harm themselves or others e.g. opening an ACCT document (prison processes).

- The researchers will receive regular supervision with the CI (Charlotte Lennox) where they are able to reflect on any distress/risk information/malpractice that may have occurred during the research. The CI (Charlotte Lennox) will be contactable if researchers experience personal distress as a result of triggering information discussed in research. In the event that

the CI (Charlotte Lennox) is not available, the researchers may contact an assigned senior colleague.

- Any safeguarding concerns are required to be reported to the funder (YEF) on a quarterly basis. The CI (Charlotte Lennox) may take appropriate Urgent Safety Measures (USMs) in order to protect a participant in the study against any immediate hazard to their health or safety without prior authorisation from UREC. Where the CI takes urgent action that is not consistent with the protocol to prevent harm to a young person in the trial, the CI must immediately inform the wider evaluation team by email and give full details of the measures taken and the decision making process surrounding the action(s) taken. The CI will inform the UREC of these measures immediately, but no later than 3 days from the date the actions were taken.

16.9 Researcher Safety and Lone Working

Data collection will take place primarily within the prisons. The research team will be lone-working within the prisons, which can hold risks for that researcher. Each member of the research team will receive training on lone-working procedures and prison training, will follow the lone-working procedure guidance at all times, and will be instructed to check-in and check-out of each visit with another member of the research team. The research team will be responsible for maintaining contact and ensuring check-ins and check-outs are conducted accordingly.

For researcher safety, the research team will always use appropriate rooms for data collection with windows and will have easy access to alarms in the case of an emergency or danger. The research team will ensure that officers within the prison will be aware of the research team members' locations at all times. Researchers will endeavour to build working relationships with multiple staff within the prison sites to ensure efficiency of data collection and safety of all participants and staff involved in the research.

If a young person was to be disruptive during a session then the lone working protocol would be followed, and prison staff would be made aware of the session taking place. The session would be stopped if an incident occurred.

Data collection may also take place in the community. The research team will arrange to see a young person in the community within a service that the young person is in contact with e.g. Youth Offending Team etc. Each member of the research team will follow the lone-working procedure guidance at all times, and will be instructed to check-in and check-out of each visit with each participant with another member of the research team. The research team will be responsible for maintaining contact and ensuring check-ins and check-outs are conducted accordingly.

16.10 Adverse Events

Due to the nature of the participant sample, it is anticipated that a number of self-harm/violence-related adverse events may occur in both trial arms. All adverse events that are research related will be reported by the CI to the relevant host prison, Trial Steering Committee (TSC) and funder on a regular basis and in an expedited fashion. Fatal or life-threatening events will be reported to the TSC and UREC within seven days of knowledge of such cases. All adverse events meeting the Charity Commission definition will be reported to the funder within 48 hours via serious.incident@youthendownmentfund.or.uk - this is due to the funder being a registered charity.

The research team will ensure that the study is conducted in line with all relevant guidelines. Upon commencement, the trial will be registered on the ISRCTN registry (ISRCTNXXXXX).

16.11 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol. Prospective, planned deviations or waivers to the protocol are not allowed under the Clinical Trials Regulations and must not be used e.g. it is not acceptable to enrol a participant if they do not meet the eligibility criteria or restrictions specified in the trial protocol. Accidental protocol deviations can happen at any time. They must be adequately documented on the protocol compliance form and reported to the PI immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

The PI will notify UoM EC in writing of any serious breach of the protocol.

17. Stakeholders and interests

17.1 New Chapters delivery team

Rebecca Perry; National Literacy Trust: Overall responsibility for the delivery of New Chapters.

Melisa Muhanguzi; National Literacy Trust: Support new Project Managers, familiarising them with the project and supporting them with session set up.

Anne Teravainen-Goff; National Literacy Trust: Responsible for internal evaluation.

17.2 Trial Team

Dr Charlotte Lennox; University of Manchester: PI with overall responsibility for the delivery of the trial.

Dr Lesley-Anne Carter; University of Manchester: Trial statistician, provide methodological advice, develop the Statistical Analysis Plan (SAP), ensure that data collected during the trial is analysed using appropriate methods and is interpreted correctly.

Dr Jo Deakin; University of Manchester: Criminological perspective and race equity lead, ensuring issues of diversity are central at all stages of the project.

Dr Claire Fox; Manchester Metropolitan University: Educational psychology perspective and ToC lead, ensuring IPE data collection tests ToC.

Dr Kim Turner; Manchester Metropolitan University: Speech, Language and Communication and neurodevelopmental perspective, ensuring these issues are recognised and considered throughout the project. Training researchers to deliver CRFs.

Professor Prathiba Chitsabesan; Pennine Care NHS Foundation Trust: psychiatry and clinical input into primary outcome delivery and interpretation.

All the project team will be involved in report writing and dissemination activities.

17.3 Trial Steering Committee (TSC)

A TSC will be established and will comprise an independent chair, an experienced clinician, an independent statistician, and at least one person with lived experience of the CJS. The PI will also attend the TSC accompanied by other senior study collaborators, where necessary. The TSC will oversee all aspects of the research including the trial and will make independent recommendation on its continuation including the go/stop criteria for the internal pilot. All final decisions sit with the funder. The TSC will also function as the DMEC and will review serious adverse events considered to be research related and look at outcome data regularly during data collection. The TSC will meet at least twice per year.

17.4 Trial Management Group (TMG)

The TMG will consist of the PI, co-investigators and Trial Statistician and will consider day-to-day management issues and the overall progress of the trial. They will meet on at least monthly basis.

No members of the trial team or UoM have any financial or other competing interests that might influence the trial design, conduct or reporting. All oversight committee members will be asked to disclose any potential conflicts of interest as part of the membership agreement. If any financial or other competing interests are identified during the course of the trial, this information will be declared.

18. Timeline

Dates	Activity	Staff responsible/ leading
June-Aug 24	Finalise study documentation and apply for ethical approval	PI
Aug 24	Finalise protocol	PI
Oct 24	Commence trial	PI
Oct 24-Jun 25	Internal Pilot	PI/Statistician
Jun-Jul 25	Decision to proceed to full trial	TSC/Funder
Oct 24-Sept 25	Trial	PI
Nov 24-Jun 26	Process evaluation	PI
Jun 24-Oct 26	Analysis	PI/Statistician
Feb 27	Final Report	PI

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20. Appendix 1: New Chapters Project Manager Manual

About this manual

This manual has been designed to support New Chapters Project Managers to deliver successful, engaging creative writing interventions to young people aged 15-18 in custodial settings.

New Chapters is an intervention delivered by the National Literacy Trust which aims to support and engage young people in custody through the power of creative writing.

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About the National Literacy Trust

The National Literacy Trust is an independent charity that empowers children, young people, and adults with the literacy skills they need to succeed.

Literacy changes everything. It gives you the tools to get the most out of life, and the power to shape your future. It opens the door to the life you want. But low literacy is inextricably linked to poverty. Over the last 30 years, we have continued to work with people who need us the most, supporting schools, families and communities on a local and national level.

Our work in prisons and Young Offender Institutions

The National Literacy Trust currently runs a range of projects in prisons and Young Offender Institutions – Books Unlocked, New Chapters, Inside Stories with Audible and Readconnect – which span reading for pleasure, creative writing, audio creation, and parent and child storytelling. We also deliver work as part of the Ministry of Justice's Literacy Innovation Fund. These projects are delivered in approximately 100 prisons and Young Offender Institutions across the UK. We work in these settings because we know adult literacy levels among the prison population are lower than among the general population, and that access to cultural and enrichment activities in these settings are few and far between but can make a huge difference.

Our projects not only help to support and improve the literacy skills of participants and create a culture of reading for pleasure within their settings, they also support family connections, raise hopes and inspirations for the future, enable people to share their stories and have a positive impact on wellbeing.

What is literacy?

Literacy is the ability to read, write, speak and listen effectively and make sense of the world.

Why is literacy important?

Literacy is essential. Without literacy it's hard to live the life you want. From your earliest years, literacy skills help you develop and communicate. But when you have a tough start in life, it's easy to fall behind.

At school, reading, writing, speaking and listening are vital for success. If you find these things hard, then you struggle to learn. It affects your confidence and self-esteem.

As an adult, you can't get the jobs you want, and navigating everyday life can be difficult – from using the internet, to filling out forms or making sense of instructions on medicines or road signs. If you have children, it's hard to support their learning, and so the cycle continues.

Literacy in custodial settings

Research continues to indicate that a disproportionate number of people in custody struggle with literacy compared with the general population (Prison Reform Trust, 2021). Nearly two-thirds (62%) of people entering prisons were assessed as having literacy skills expected of an 11-year-old (Department for Education, 2017) and 47% of people in custody have no qualifications at all (Prison Reform Trust, 2021).

Young people in custody are less likely to have attained the expected literacy levels at the end of primary and secondary education than the overall pupil population (DfE & MoJ, 2016) and 89% have been excluded from school. This means that many New Chapters participants will have had a negative experience of school.

About New Chapters

New Chapters has been running since 2018, when NLT received funding to develop a project specifically for delivery in YOIs. We initially devised a reading for pleasure project, which centred the books and stories of people with lived experience of the criminal justice system, and was delivered in HMYOI Aylesbury. After three years, in consultation with the young people involved in the project, New Chapters was redesigned to focus on creative writing. Since then, it has supported young people and adults in prisons, YOIs and other secure settings, encouraging them to find their voice and tell their stories through the power of creative writing. Our creative writing workshops continue to be led by authors with lived experience of the issues the young people face.

As part of the project, we collate anthologies and organise writing competitions to showcase the work of participants, with the support of National Prison Radio. Together with partners like Buckinghamshire Culture, we seek to build connections between people in custody and the local community through creative writing.

Why creative writing?

As well as being able to improve confidence, motivation and enjoyment of literacy, creative writing has the power to improve understanding of the self and others, and enable young people to feel that their voice is heard and their story matters. Improving literacy can be related to improvements in long-term outcomes such as self-expression, understanding of self and others, confidence and self-esteem, wellbeing and mental wellbeing, pro-social behaviour/behavioural difficulties, and relationships with staff.

There is a wealth of evidence that recognises the importance of creativity in engaging people in contact with the criminal justice system. Despite this, there is limited work in youth custody that aims to engage young people in creative writing that moves beyond traditional classroom learning.

New Chapters recognises this need and aims to create a safe space in which participants can express themselves and explore their creativity.

Delivery model

Each setting has a designated Project Manager who runs all New Chapters activity in that setting. This enables them to build up a relationship with the young people in their sessions that is based on trust, familiarity and respect.

New Chapters is delivered to each group of young people as a stand-alone 12-session course. Ideally, sessions will be timetabled by setting staff to take place on a weekly basis, but NLT staff will need to be flexible in response to last-minute regime changes. Sessions will last no more than 1.5 hours. It is also likely that young people will miss sessions due to unavoidable clashes with i.e. court visits and legal visits. When this happens, young people can be brought up to speed in the one-to-one follow up sessions and their absence will be noted for evaluation. It is not anticipated that missing a small number of sessions will have an impact on the benefits a young person will take from the project.

In the weekly sessions, the National Literacy Trust Project Manager who will guide young people through a variety of texts and writing exercises. On-wing one-to-one check-in sessions will follow the group session in order to ensure that young people are encouraged and given feedback between sessions. This is also an opportunity for any queries to be addressed, and for any young people who were unable to attend the sessions due to illness or scheduling conflicts to be briefed on the session that took place and what is coming next. This also allows for young people who may lack confidence, or not be comfortable asking questions in front of their peers, to get some dedicated time with the Project Manager. These one-to-one sessions will be less formal, and can vary in length and location of delivery (i.e. communal area or bookable room on the wing) but will be a key component of New Chapters delivery.

Module breakdown

The content of the 12-session course is flexible and responsive to the interests and needs of each group of young people, as well as to each young person in the group. However, to ensure consistency for each group, every 12-session course will follow the basic format outlined below.

- Session 1 – poetry, spoken word and lyric writing

- Session 2 – poetry, spoken word and lyric writing
- Session 3 - poetry, spoken word and lyric writing
- Session 4 - poetry, spoken word and lyric writing – features external facilitator visit
- Session 5 – writing about social and cultural issues
- Session 6 – writing about social and cultural issues
- Session 7 – writing about social and cultural issues
- Session 8 – writing about social and cultural issues - features external facilitator visit
- Session 9 – life writing
- Session 10 – life writing
- Session 11 – life writing
- Session 12 – celebration event – features National Prison Radio recording

These overarching areas of focus are designed to give the course structure at the same time as allowing for a wide range of themes and genres to be explored, with input from the participants. For example, social and cultural issues could explore anything from sports journalism to film reviews, and life writing could focus on memoir or biography/autobiography.

A typical session will feature an ice-breaker, a warm-up writing exercise, writing exercises and discussion, and time for sharing at the end. Sessions will also be a chance to introduce the author/themes ahead of an external facilitator coming in, or follow on from that session with follow-up activities which expand on the work created in that session. External facilitator sessions serve as powerful points during project delivery when the young people will feel validated and have the chance to share what they have been working on with someone outside of the weekly sessions.

Project Managers will regularly check in with young people, both in group sessions and during one-to-one sessions, to see how they are finding the course and whether they have any feedback to share.

Creating a code of conduct

In the first session with a new group of young people, a Project Manager should co-create a code of conduct with the young people so that everyone is clear what the sessions are for and on what spirit they are attending. The code would

usually include things like being respectful when people are sharing their work, encouraging each other, agreeing that whatever happens in the sessions is not to be shared outside of the group etc. If the sessions consistently take place in the same room, the code of conduct would be placed somewhere visible.

This process is also a good time to outline what the young people can expect from NLT and the New Chapters project. An overview of the course can be shared in printed format and the Project Manager should explain that they will be present throughout the course and will always be respectful of the young people and their ideas, and will always be open to suggestions and feedback.

External facilitators

The National Literacy Trust's Equality Diversity and Inclusion statement and framework outlines that 'We promote equality, diversity and inclusion in the design and delivery of all our work. Our programmes are focused on the needs of children, families, adults and groups who are most likely to experience injustice and exclusion. We work with participants to co-create solutions in which they can fully participate – ensuring that there are no barriers to their participation.'

For New Chapters, Project Managers will ensure that facilitators and resources reflect a diverse range of identities and experiences, and that the make-up of the youth custody estate is also reflected as much as possible. Young people will also be able to feed into this work in a meaningful way.

Each group will receive two visits from external facilitators during their 12-week course. All authors have the status as professional authors and all with inspiring stories of overcoming adversity. Authors can include anything from lyrists and poets, to journalists and novelists. There is growing recognition and evidence that people with lived experience of the justice system can provide enormous benefit to organisations working in the CJS and, more importantly, participants. As such, we have made a commitment that each group will receive at least one

visit from someone with lived experience of prison (that could be through serving a custodial sentence, being held on remand, being on the YOT caseload in the community in their youth etc.). Other authors we work with may have lived experience of school exclusion, racial discrimination, poverty (i.e. experiences we know it is highly likely the young people will share) but they will all be united by the fact that they have an inspiring story to tell.

Author support

We work with a huge variety of authors, some of whom are very experienced in workshop facilitation and others may never have delivered a creative writing workshop before. We always meet with facilitators ahead of time to explain the project, what a session might look like, to brainstorm ideas for activities with them, and share examples of previous workshops. We would also offer to co-facilitate if an author needed extra support.

Clinical supervision – in addition to being a mandatory part of a working within NLT's criminal justice team – will also be offered to authors who have experienced of being in custody and for whom the experience of being in the prison environment may be triggering or upsetting.

External facilitators usually spend a full day in the prison working with two groups (AM and PM) and are paid a £600 fee plus travel.

Celebration events and showcasing work

There is a lot of evidence highlighting the value of showcasing work and having real audience and purpose as a motivating factor for reading and writing, particularly for young people.

In order to provide a meaningful audience for their work, in addition to sharing their writing with each other, young people will have the opportunity to be recorded by Prison Radio Association for broadcast on National Prison Radio. They will be supported and encouraged throughout the session to work on one or two pieces that they are particularly proud of and would like to share on air.

These celebration events will be a wonderful opportunity to celebrate the achievements of the young people. They can be attended by prison staff (and family, if possible) and should feature certificates, snacks and drinks.

Staff training

Project Managers will have a range of different experiences, and may or may not have experience of working in the criminal justice system. IN order to ensure that all staff are adequately supported they will receive:

- Prison training in safety
- Prison key training
- Accompaniment to initial sessions by an existing NLT staff member
- Working in Prisons training (provided by Clinks)
- Trauma-informed relationships training delivered by the Mental Health Foundation
- Safeguarding children and young people training
- Clinical supervision/reflective practice
- Facilitation training
- Project Management training

Theory of change and project evaluation

Detailed information about the Theory of Change for this iteration of new chapters, as well as information about project evaluation and eligibility and randomisation can be found in the trail protocol.

21. Appendix 2: Detailed ToC with associated references and mapping to evaluation outcome data collection

Why (evidence-based observation)	Why (evidence-based need)	Who (target population)	How	Short-term outcomes (achieved during/by the end of intervention)	Medium-term outcomes (achieved at the end of the intervention)	Long-term outcomes (achieved beyond the end of the intervention)
- Young people in custody have lower literacy[1]/educational attainment [1]. - Young people in custody can find it hard to engage[2] in traditional classroom learning [1]. - Young people in custody often have prior negative experiences of traditional education [1]. - Young people in custody have a right to receive education [2] - The education provision is custody for young people is often poor, especially in terms of literacy [2, 3].	- There is often limited work in custody that aims to engage young people in creative writing that moves beyond traditional classroom learning [13]. - Creativity is an effective means of engaging individuals in the criminal justice system [14, 15]. - Engaging in creativity can improve a range of outcomes for young people [16, 17, 18, 19]. - Showcasing work and having a real audience can promote motivation [20, 21].	- **Settings**: 3 YOIs [Wetherby, Werrington, Feltham] & 1 Secure School - **Population:** Boys aged 15-18 (inclusive) years. - **Eligibility:** Sentenced and with 3 months or more remaining on their sentence.	-12 sessions delivered on a weekly basis. -Each session up to 90 minutes. -All sessions facilitated by National Literacy Trust Programme Manager, with the exception of 2 sessions which will be delivered by a professional author (1 of these professional authors will have lived experience of the criminal justice system in some form). - All authors have the status as professional authors and are chosen because they are felt to have inspiring stories of overcoming adversity (based on previous participant feedback). -Sessions will be run in groups of no more than 6. -Two groups can run concurrently, but no more than this. - Brief 1-2-1 sessions by National Literacy Trust Programme Manager will be	- Greater opportunities and access for reading and writing for pleasure.* - Greater confidence in literacy.* - Greater enjoyment in literacy.* -Greater motivation in literacy.* - More likely to feel voice is heard.* - Improved relationships with others (other young people and staff) – initial changes.*	- Greater understanding of self.* - Greater understanding of others (e.g. empathy) [21].** - Greater self-esteem/confidence [22].** -Greater creativity [23].** - Improved ethos in staff and setting towards literacy (initial changes).* - Staff greater understanding of the benefits of literacy.*	- Improved aspirations.* -Improved mental wellbeing [24].** -Fewer behavioural difficulties [25].** - Greater engagement in further learning opportunities.* -Greater prosocial behaviour [25, 26].** - Improved relationships with others (other young people and staff) – sustained change.* - Improved ethos in staff and setting towards literacy (longer term changes).*

[1] Literacy is defined as the ability to read, write, speak and listen in a way that lets us communicate effectively and make sense of the world.

[2] Engagement is a complex construct with varied conceptualisations. Here we define it as the most common behavioural dimensions, attendance, overall level of investment in the program, and intention to engage in the future.

- Improving literacy can be related to improvements in long-term outcomes (self-expression [4, 5], understand of self and others e.g. empathy [6, 7], confidence and self-esteem [8, 9], wellbeing and mental wellbeing [10], pro-social behaviour/behavioural difficulties [11], relationships with staff (due in part, to changing staff perceptions of the young people) [12].			provided as check-in sessions. These ensure that young people are encouraged and given feedback between sessions, especially to those who may have missed a session. - Sessions are structured, yet innovative, flexible, and creative. Tailored to their specific interests. - Each person has a clear goal to work towards, tailored to them. They have a clear purpose for writing. - The last session culminates in a celebration event, with an audience via The National Prison Radio. - Sessions creates a safe and supportive space. - Opportunity to express themselves how they want to. - Exposed to different forms of writing and relevant topics. - Group element to enable peer collaboration. - Use of literature that promotes reflection.			- Staff improved relationships with young people.

Note: * = captured by the implementation and process evaluation; ** = captured by quantitative measures in case record form

New Chapters aims to move beyond a model of traditional classroom learning[3]. Being guided through a structured programme and working towards key milestones that they might not have thought possible (i.e., finishing their own piece of creative writing, or performing their own poem on National Prison Radio) encourages the young people to think about their future personal goals and improve aspirations. Furthermore, the radio performances, and celebration events provide recognition and validation of what they have achieved, helping them to shift how they see themselves, partly through others recognising this change.

Through having the opportunity to express themselves how they want to via their own forms of creative writing, New Chapters aims to build self-esteem, confidence, and general wellbeing, enabling young people's voices to be heard.

Being exposed to different forms of writing, relevant topics and encouraging reflection can lead to improvements in young people's understanding of the self and others and is therefore critical to the intervention. The group element of the intervention enables peer collaboration to enable the young people to share experiences and understand others' perspectives[4].

By seeing young people engage in creative writing in this way may encourage staff to challenge their own perceptions of the young people. This also aims to lead to a change in the culture of reading for pleasure through greater staff understanding of the benefits.

A key aim is to support the young people to build a more prosocial identity, displaying fewer behavioural difficulties with improved relationships in the long-term, through these key elements, and via short- and medium-term outcomes.

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[3] Delivery is different to traditional classroom leaning and the young people are there because they want to be.

[4] Also, the flexible nature of the intervention, such as 1-1s when group sessions do not happen (for whatever reason) also adds value.

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22. Appendix 3: TiDeR Checklist

Item number	Item	Where located ** Page Number
	BRIEF NAME	
1.	Provide the name or a phrase that describes the intervention.	16
	WHY	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	13-15, 68-69, 75-77
	WHAT	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed.	70-72
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	70-74
	WHO PROVIDED	
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	74
	HOW	
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	13-15; 70-74
	WHERE	
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	20, 76
	WHEN and HOW MUCH	

8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	16, 17, 70-71
	TAILORING	
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	70, 77
	MODIFICATIONS	
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A
	HOW WELL	
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	N/A
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A

** use N/A if an item is not applicable for the intervention being described.

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item. The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

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