MBT for ASPD

Mentalization for Offending Adult Males

Mentalization for Offending Adult Males: A Randomised Controlled Trial

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Please note: This trial protocol must not be applied to patients treated outside the MOAM trial. UCL can only ensure that approved trial investigators are provided with amendments to the protocol.

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TABLE OF CONTENTS

1. PROTOCOL SUMMARY 5

1.1. SUMMARY OF TRIAL DESIGN 5
1.2 TRIAL SCHEMA 7

2 INTRODUCTION 8

2.1 BACKGROUND 8

3 TRIAL DESIGN 10

3.1 TRIAL OBJECTIVES 10
3.2 TRIAL ENDPOINTS 11
3.3 TRIAL ACTIVATION 11

4 SELECTION OF SITES/SITE INVESTIGATORS 12

4.1 SITE SELECTION 12
4.1.1 Selection of Principal Investigator and other investigators at sites 12
4.1.2 Training requirements for site staff 12
4.2 SITE INITIATION AND ACTIVATION 12
4.2.1 Site initiation 12
4.2.2 Required documentation 12
4.2.3 Site activation letter 13

5 INFORMED CONSENT 14

6 SELECTION OF PATIENTS 15

6.1 PRE-RANDOMISATION EVALUATION 15
6.2 SCREENING LOG 15
6.3 PATIENT ELIGIBILITY 15
6.3.1 Inclusion criteria 16
6.3.2 Exclusion criteria 16

7 RANDOMISATION PROCEDURES 17

7.1 RANDOMISATION 17

8 TRIAL TREATMENT- INTERVENTIONS 18

8.1 WHO WILL DELIVER THE INTERVENTIONS? 19

9 ASSESSMENTS 21

9.1 SCREENING ASSESSMENTS 21
9.2 PRE-TREATMENT ASSESSMENTS 21

10 DATA MANAGEMENT AND DATA HANDLING GUIDELINES 25

10.1 MISSING DATA 25

11 SAFETY REPORTING 26

11.1 DEFINITIONS OF ADVERSE EVENTS 26
11.2 REPORTING PROCEDURES 26
11.2.1 All Adverse Events (AEs) 26
11.2.2 Serious Adverse Events (SAEs) 28
11.2.3 Reporting Procedures for Serious Adverse Events 28
11.3 SAFETY MONITORING 30

12 TRIAL MONITORING AND OVERSIGHT 31

12.1 CENTRAL MONITORING 31

12.2 OVERSIGHT COMMITTEES 31
12.2.1 Trial Management Group (TMG) *31*
12.2.2 Trial Steering Committee (TSC) *31*
12.2.3 Independent Data Monitoring Committee (IDMC) *31*
12.2.4 Role of UCL *32*

13 WITHDRAWAL OF PATIENTS **33**

13.1 DISCONTINUATION OF TRIAL TREATMENT 33
13.2 FUTURE DATA COLLECTION 33
13.3 LOSSES TO FOLLOW-UP 33

14 TRIAL CLOSURE **34**

14.1 END OF TRIAL 34
14.2 ARCHIVING OF TRIAL DOCUMENTATION 34
14.3 EARLY DISCONTINUATION OF TRIAL 34
14.4 WITHDRAWAL FROM TRIAL PARTICIPATION BY A SITE 34

15 STATISTICS **35**

15.1 SAMPLE SIZE CALCULATION 35

16 ETHICAL APPROVALS **37**

16.1 ETHICAL APPROVAL 37
16.2 SITE APPROVALS 37
16.3 PROTOCOL AMENDMENTS 37
16.4 PATIENT CONFIDENTIALITY & DATA PROTECTION 37

17 SPONSORSHIP AND INDEMNITY **39**

17.1 SPONSOR DETAILS 39
17.2 INDEMNITY 39

18 FUNDING **40**

19 REFERENCES **41**

APPENDIX 1: ABBREVIATIONS **47**

Structured Clinical Interview for DSM Disorders *47*

APPENDIX X: PROTOCOL VERSION HISTORY **48**

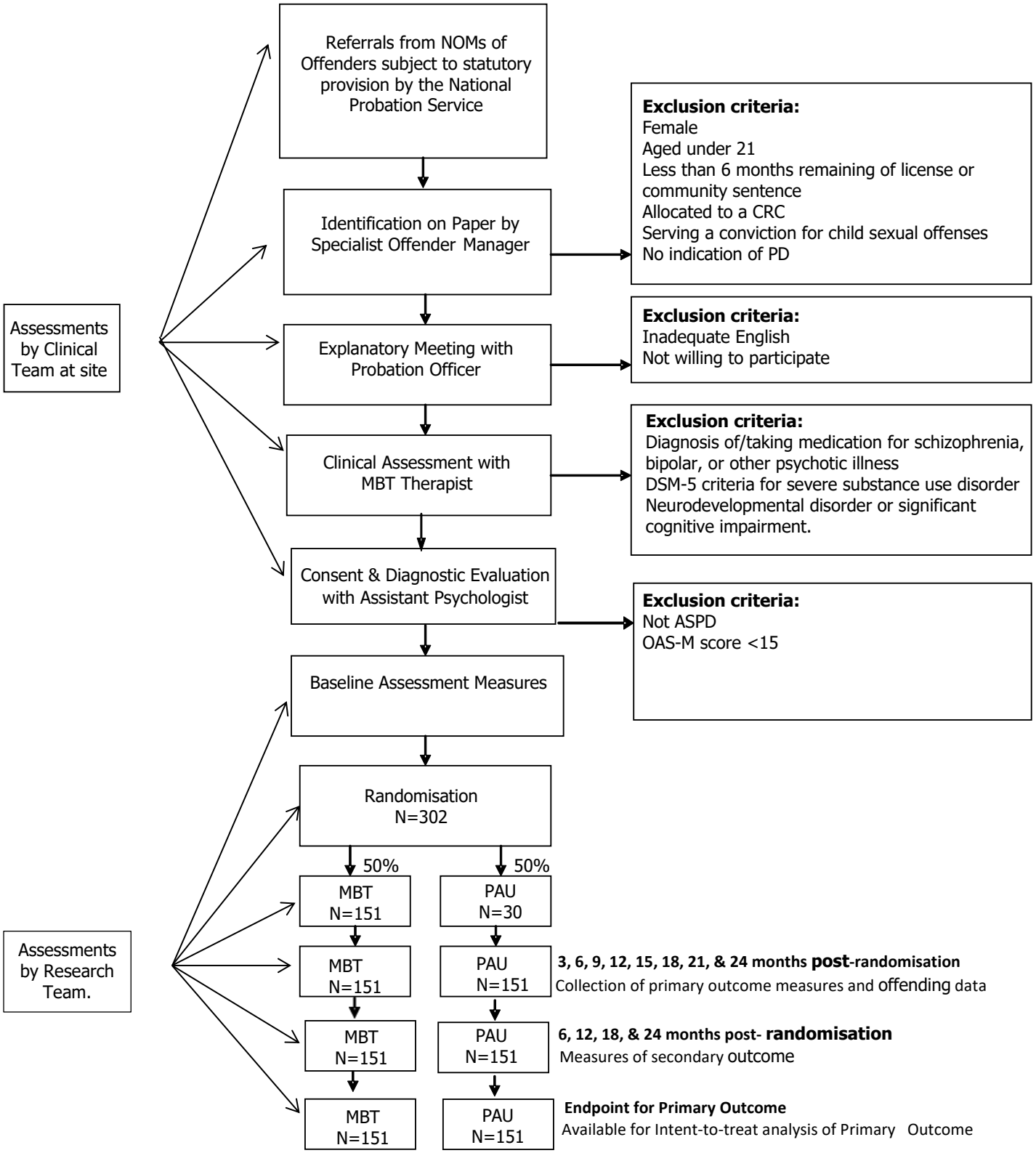
1. PROTOCOL SUMMARY

1.1. Summary of Trial Design

Title:	Mentalization for Offending Adult Males : A Randomised Controlled Trial
Short Title/acronym:	MOAM
Sponsor name	University College London (UCL)
Funder name	The Michael J Samuel Charitable Trust (Charity number: 327013) National Institute for Health Research (NIHR) (Project ID: 14/186/01)
ISRCTN no:	**ISRCTN32309003**
Design:	Randomised Controlled Trial
Overall aim:	To conduct a multi-site randomized control trial in real life NHS setting to investigate whether, in a sample of offenders under community supervision who meet DSM-5 criteria for ASPD, Probation as usual (PAU) supplemented with MBT is more effective and cost effective than the standard care pathway of PAU only.
Primary endpoint:	A reduction in the frequency of aggressive acts.
Secondary endpoints:	Measures of other offending behaviour, anxiety and depression, drug and alcohol use, self-harm and suicidal behaviour, quality of life, health and functioning, impulsivity, and beliefs. The monitoring of participants use of other services including A&E, reoffending rates and use of social services during the treatment and follow-up period
Target accrual:	*302 Participants*
Inclusion & exclusion criteria:	***Inclusion Criteria:*** • Male • Aged 21 years and over • DSM-IV-R diagnosis of ASPD (using SCID-II) • OAS-M score >15 • Evidence of aggressive acts in the 6 months prior to assessment

	• Subject to statutory provision by the National Probation Service with at least 6 months remaining of their license or community sentence ***Exclusion Criteria:*** • Convictions for child sexual offences (including child pornography) • Neurodevelopmental disorder or significant cognitive impairment. • Inadequate English or cognitive capacities to provide informed consent and participate in group therapy • Current diagnosis for schizophrenia or bipolar disorder
Planned number of sites:	13 sites
Treatment summary:	***MBT ASPD:*** Mentalization Based Therapy integrates cognitive and relational components of therapy and has a theoretical basis in attachment theory. MBT-ASPD targets mentalizing problems which lead to violence through a programme of group and individual psychotherapy. All participants randomised to this arm of the study will have an allocated psychiatrist and therapist. The treatment intervention is a one-year programme of weekly group and monthly individual sessions of MBT for ASPD. ***PAU:*** Participants randomised to receive Probation as Usual will remain under the supervision of their Probation Trust for the duration of their licence or community sentence.
Anticipated duration of recruitment:	2 year
Duration of patient follow up:	Participants will be followed up at 6, 12, 18, & 24 months post-randomisation. Primary outcome measures and offending records will be obtained every 3 months post randomisation (i.e., months 3, 6, 9, 12, 15, 18, 21, & 24).
Definition of end of trial:	24 months after the last participant is randomised.

1.2 Trial Schema



2 INTRODUCTION

2.1 Background

Personality disorder is a recognised mental disorder which is substantially overrepresented in offending populations. Multiple studies demonstrate a high prevalence of personality disorder in offenders in general (Alwin et al, 2006) and in individuals with convictions for violent offenses in particular (McMurran & Howard, 2009). Around 150,000 offenders with personality disorder are currently managed by NOMS (estimate by the DH/NOMS Offender PD Policy Team, August 2010), a high proportion of which are managed by probation (Consultation on the Offender Personality Disorder Personality Disorder Pathway Implementation Plan, DH/NOMS Offender PD Team). Along with borderline personality disorder, antisocial personality disorder (ASPD) is the most common personality disorder in criminal justice settings (DH and NOMS Offender Personality Disorder Strategy).

ASPD is characterised by failure to conform to social norms with respect to lawful behaviours, as indicated by repeatedly performing acts that are grounds for arrest; irritability and aggressiveness, as indicated by repeated physical fights or assaults; impulsiveness; consistent irresponsibility; low conscientiousness; deception; disregard for the feelings and safety of others; disregard for the safety of self and for the consequences of one's behaviour; lack of remorse (DSM-5, 2013; NICE, 2009). Prevalence has been identified as up to 3% in the general population (Coid et al., 2006; Moran et al, 2000; Robins, 1991; Torgersen, Kringlen & Cramer, 2001), although the disorder may be underdiagnosed in the community (Ogloff, 2006). Nonetheless, there is a wide disparity between its prevalence among the general population and its prevalence among the offending population: in the UK prison population, prevalence of ASPD has been identified as 63% among male remand prisoners, 49% among male sentenced prisoners, and 31% among female prisoners (Singleton *et al.*, 1998). The contribution of this disorder to violent criminal behaviour is clear: ASPD is associated with a significantly increased likelihood of committing violent behaviours (Coid et al, 2006), and is highly predictive of future violence, future reinconviction or reincarceration upon release, and recidivism severity (Hodgins et al, 1996; Wormith, Olver, Stevenson & Girard, 2007).

For society, the costs of individuals whose ASPD manifests in the form of violent criminal behaviour include direct physical and emotional damage to victims, damage to property, police time, involvement with the criminal justice system, increased use of healthcare facilities, lost employment opportunities, family disruption, relationship breakdown, childcare proceedings, gambling, and problems related to alcohol and substance misuse (Home Office & Department of Health 2002; NICE 2009). Rates of violent crime have been found to be associated with a range of negative impacts on health (Lorenc et al, 2012; Lorenc et al, 2013; Robinson & Keithley, 2010) as well as other wider societal implications (Bellis et al, 2012; Dolan *et al.*, 2005; Dolan & Moore, 2007; Dolan & Peasgood, 2007; Semmens, 2007; Shapland & Hall, 2007), and are listed as wider determinants of health in the UK Government's Public Health Outcomes Framework (2013). As an indication of the scale of the problem, over 1.5 million violent incidents were committed in the year ending December 2013 (Office for National Statistics, 2014), and 32,979 of hospital admissions in the year ending March 2013 were as a result of assault (Health & Social Care Information Centre, 2013). It is estimated that the public costs of individuals with ASPD are 10 times that of controls (Scott et al, 2001), with total costs of violence to society estimated at £29.9

billion per year (Bellis et al, 2012) and costs of treatment for those affected by violence estimated at 3-6% of the UK health budget (Burns, 2006). Finding an effective treatment to reduce violent and antisocial behaviours in individuals with ASPD holds potential for the protection of the health of the wider public against this risk of threat, and would help to alleviate the costly burden of ASPD upon the criminal justice system and other public services.

ASPD also has major public health implications in terms of its associations with comorbid psychiatric illness, drug abuse, alcoholism, suicide, early unnatural death, violent crime, unemployment, homelessness, and family violence (Martin et al., 1985; Black et al., 1996; Odgers et al, 2007; Piguero et al, 2011). More than 90% of those with ASPD have at least one other psychiatric disorder (Swanson et al, 1994), at least 50% have co-occurring anxiety disorders (Goodwin *et al.*, 2003), and 25% have a depressive disorder (Lenzenweger *et al.*, 2007). Men with ASPD are between three and five times more likely to misuse alcohol and illicit drugs than those without ASPD (Robins *et al.*, 1991a). ASPD is also associated with physical disability (Byrne et al, 2013) as well as increased mortality (Martin et al, 1985). Black et al (1996) found that young men with ASPD had a higher rate of premature death than men of the same age without the disorder, due not only to an increased risk of suicide, but also due to reckless behaviour such as drug misuse and aggression. Finding an effective treatment for ASPD holds the potential to relieve these health inequalities by improving wider determinants of health of those with ASPD through reducing avoidable mortality and morbidity and improving quality of life.

There is currently no treatment with a robust evidence base for alleviating ASPD; the paucity of high quality studies in this area is notable (Duggan, 2007; Wilson, 2014). Research into treatment for ASPD up until 2009 is covered by the NICE Clinical Guidelines for ASPD, which confirms that interventions for ASPD are poorly researched and that evidence on its treatment is scarce. In a trial comparing MBT with structured clinical management (SCM) which included problem solving and social skills, MBT was found to be more effective than SCM in patients in reducing self-harm, suicidality, hospital admissions, depression and general symptom distress in BPD patients comorbid with ASPD. Nonetheless, the effectiveness of both interventions were reduced when BPD patients with ASPD were compared with BPD patients without ASPD (Bateman & Fonagy, 2009). More recently, a pilot project collecting routine outcome data of an adapted MBT programme for ASPD in two centres in the U.K. has shown that the treatment can be learned by clinicians with only moderate levels of training and be reliably applied in different services, and that MBT treatment led to a reduction in aggressive acts, in a cohort of 20 patients (Bateman et al., 2013).

This pilot project suggests that MBT could be introduced to NHS services relatively easily and inexpensively, and that it may have the potential to enable clinicians to work with people with ASPD significantly more effectively to reduce their antisocial behaviour and offending. However, in order to allocate NHS resources appropriately and ensure that people with ASPD receive successful treatment, we need to know whether MBT is more effective than treatment as usual in probation (PAU) at reducing the frequency of aggressive acts and offending. We aim to conduct a multi-centre randomized controlled trial (RCT) comparing the effectiveness of MBT and PAU as delivered in a representative cross section of NHS clinical centres working with probation services. As well as looking at the effect of treatment on the frequency of aggressive acts, we will also study its impact on anxiety, depression, drug and alcohol use, and use of other services such as A&E.

3 TRIAL DESIGN

To conduct a multisite randomized controlled trial in real life NHS setting to investigate whether, in a sample of offenders under community supervision who meet DSM-5 criteria for ASPD, probation as usual (PAU) supplemented with MBT is more effective and cost- effective than the standard care pathway of PAU only for (1) reducing aggressive antisocial behaviour, (2) improving health status and quality of life, and (3) reducing offender, impulsivity, violence and criminal behaviour.

A multi-site, two arm, three phase pragmatic randomised controlled superiority trial, with participants randomly allocated in a 1:1 ratio to receive either PAU only or MBT plus PAU. The research will be conducted over 60 months in the National Probation Service NHS Providers at 13 sites across England and Wales.

3.1 Trial Objectives

We aim to conduct a randomised controlled trial (RCT) across thirteen sites to investigate whether MBT adapted for individuals with ASPD (MBT-ASPD) is an effective treatment for individuals with a diagnosis of antisocial personality disorder (ASPD) in the community when compared to Probation as Usual (PAU).

The primary outcome is a reduction in the frequency of aggressive acts. Secondary outcomes will include measures of other offending behaviour, anxiety and depression, drug and alcohol use, self-harm and suicidal behaviour, quality of life, health and functioning, impulsivity, and beliefs. We will monitor participants' use of other services including A & E, reoffending rates and use of social services during the treatment and follow-up period. Finally, we will conduct a cost-benefit analysis in order to determine the actual cost of service delivery in both treatment conditions and whether MBT-ASPD leads to reduction in costs compared to PAU.

Our expectation is that for individuals with ASPD, MBT-ASPD will improve their capacity to anticipate impulsive action triggered by social stressors and better manage their dysregulated affect, resulting in a reduction in the frequency of their violent and aggressive acts and improvements in general psychosocial function.

The aims to achieve the following objectives to test the primary outcome of the trial and the feasibility of progressing to a larger multi-site RCT that will enable informed decision making about the role of MBT as part of NHS service delivery for ASPD.

3.2 Trial Endpoints

Primary endpoints

A reduction in the frequency of aggressive acts.

Secondary endpoints

Measures of offending behaviour, anxiety and depression, drug and alcohol use, self-harm and suicidal behaviour, quality of life, health and functioning, impulsivity, and beliefs.

The monitoring of participants use of other services including A&E, reoffending rates and use of social services during the treatment and follow-up period.

3.3 Trial Activation

UCL will ensure that all trial documentation has been reviewed and approved by all relevant bodies and that the following have been obtained prior to activating the trial:

- Research Ethics Committee approval
- National Offender Management Approval for each site (NOMs approval)
- 'Adoption' into NIHR portfolio
- NHS permission
- Adequate funding for central coordination
- Confirmation of sponsorship
- Adequate insurance provision

4 SELECTION OF SITES/SITE INVESTIGATORS

4.1 Site Selection

In this protocol trial 'site' refers to the clinical team where trial-related activities are conducted.

Sites must be able to comply with:

- Trial treatment , follow up schedules and all requirements of the trial protocol
- MBT Service Specification Programme
- Requirements of the Research Governance Framework and the Medicines for Human Use (clinical trials) Act (SI 2004/1031 and all amendments)
- Data collection requirements, including adherence to case report form (CRF) submission timelines

4.1.1 Selection of Principal Investigator and other investigators at sites

Sites must have an appropriate Principal Investigator (PI). Other investigators at site wishing to participate in the trial must be trained and approved by the PI.

4.1.2 Training requirements for site staff

All site staff must be appropriately qualified by education, training and experience to perform the trial related duties allocated to them, which must be recorded on the site delegation log.

CVs for all staff must be kept up-to-date, signed and dated and copies held in the Investigator Site File (ISF). An up-to-date, signed copy of the CV for the PI must be forwarded to UCL upon request.

4.2 Site initiation and Activation

4.2.1 Site initiation

Before a site is activated, the UCL trial team will arrange a site initiation with the site which the PI must attend. The site will be trained in the day-to-day management of the trial and essential documentation required for the trial will be checked.

Site initiation will be performed for each site by site visit or teleconference

4.2.2 Required documentation

The following documentation must be submitted by the site to UCL prior to a site being activated by UCL trial team:

- All relevant institutional approvals (e.g. local NHS permission)
- A completed site delegation log that is initialled and dated by the PI
- A copy of the PI's current CV that is signed and dated

4.2.3 Site activation letter

Once the UCL trial team has received all required documentation and the site has been initiated, a site activation letter will be issued to the PI, at which point the site may start recruiting patients.

Once the site has been activated by UCL, the PI is responsible for ensuring:

- adherence to the most recent version of the protocol;
- all relevant site staff are trained in the protocol requirements;
- appropriate recruitment and medical care of patients in the trial;
- timely completion and return of CRFs (including assessment of all adverse events);
- prompt notification and assessment of all serious adverse events;

5 INFORMED CONSENT

The lead clinicians on site are responsible for assessing a patient's capacity to give informed consent.

Sites must ensure that all patients have been given the current approved version of the patient information sheet, are fully informed about the trial and have confirmed their willingness to take part in the trial by signing the current approved consent form

Sites must assess a patient's ability to understand verbal and written information in English. If a patient requires an interpreter, the patient should not be considered for the trial.

The PI, or, where delegated by the PI, other appropriately trained site staff, are required to provide a full explanation of the trial and all relevant treatment options to each patient prior to trial entry. During these discussions, the current approved patient information sheet for the trial should be discussed with the patient. A minimum of twenty four hours must be allowed for the patient to consider and discuss participation in the trial. Written informed consent on the current approved version of the consent form for the trial must be obtained before any trial-specific procedures are conducted. The discussion and consent process must be documented in the patient notes.

Site staff are responsible for:

- checking that the correct (current approved) version of the patient information sheet and consent form are used
- checking that information on the consent form is/ complete and legible
- checking that the patient has completed/initialled all relevant sections and signed and dated the form
- checking that an appropriate member of staff has countersigned and dated the consent form to confirm that they provided information to the patient
- checking that an appropriate member of staff has made dated entries in the patient's medical notes relating to the informed consent process (i.e. information given, consent signed etc.)
- giving the patient a copy of their signed consent form and patient information sheet

The right of the patient to refuse to participate in the trial without giving reasons must be respected. All patients are free to withdraw at any time. Also refer to section 13 (Withdrawal of Patients).

6 SELECTION OF PATIENTS

6.1 Pre-Randomisation Evaluation

Potential participants for treatment will be initially identified by the Specialist Offender Manager co-working with the MBT Therapists in each probation service. The clinical assessment will be carried out by one of the MBT Psychological Therapists over a minimum of two assessment appointments. Assessment will include history taking, establishing a clinical diagnosis of ASPD, and ascertaining the offender's ability to engage in the treatment process, particularly assessing whether he will tolerate a group setting. The assessment also includes giving the offender some psycho-education about the diagnosis and treatment model and programme. The lead clinician will assess the patient's capacity to give consent.

The Specialist Offender Manager will describe the study and, if the potential participant is interested in obtaining more information, they will provide the Participant Information Sheet. At least 24 hours later, the potential participant will be approached by the assistant psychologist at site, and if the potential participant is still interested, a meeting will be organised with an MBT therapist. At that meeting the study will be described, outstanding questions answered and the potential participant asked to sign the consent form which will be countersigned by a member of the clinical team.

The participant will then complete final screening assessments with the assistant psychologist. If they are eligible to continue, the baseline measures will be conducted with the Peer Researcher and the participant will then proceed to randomisation.

Patients must give written informed consent **before** any trial specific screening investigations may be carried out. The SCID-II and the OAS-M required to evaluate the suitability of patients for the trial. Both of these assessments will be performed by the assistant psychologist prior to any baseline measures completed so to ascertain eligibility before randomization.

6.2 Screening Log

A screening log must be maintained by the site and kept in the Investigator Site File. This must record each patient screened for the trial and the reasons why they were not randomised in the trial if this is the case. The log must be sent to UCL when requested, with patient identifiers removed prior to sending.

6.3 Patient Eligibility

There will be no exception to the eligibility requirements at the time of randomisation. Ensuring patient eligibility is the responsibility of the PI or other delegated Investigator(s). Queries in relation to the eligibility criteria must be addressed prior to calling for randomisation. Patients are eligible for the trial if all the inclusion criteria are met and none of the exclusion criteria applies. CI and TMG must review criteria carefully to ensure they are appropriate for intended purpose

6.3.1 Inclusion criteria

- Male
- Aged 21 years and over
- DSM-IV-R diagnosis of ASPD (using SCID-II)
- Evidence of aggressive acts in the 6 months prior to assessment
- Subject to statutory provision by the National Probation Service with at least 6 months remaining of their license or community sentence

6.3.2 Exclusion criteria

- Convictions for child sexual offences (including child pornography)
- Neurodevelopmental disorder or significant cognitive impairment.
- Inadequate English or cognitive capacities to provide informed consent and participate in group therapy
- Current diagnosis for schizophrenia or bipolar disorder

7 RANDOMISATION PROCEDURES

Randomisation will follow enrolment and baseline assessment and be performed by the NWORTH Clinical Trials Unit throughout the trial. Participants will be randomised to the trial treatment intervention (MBT-ASPD) or to Treatment as Usual in probation (PAU) using a stochastic minimisation programme (MINIM) balancing for:

1. **Site**
2. **Age:** 21-25; 26-39 >40 years
3. **Amount of time left on license or community sentence:** Less than 12 months; 12 months or more
4. **Type of community supervision:** Community Sentence; On Licence After Release From Prison

7.1 Randomisation

Patient randomisation will be performed off-site prior to commencement of any trial treatment/intervention. This will be conducted using a dynamic adaptive allocation algorithm accessed by a secure web portal to the system held at NWORTH Clinical Trials Unit and maintained by a statistician independent of the analysis and research teams to ensure blinding.

Following pre-treatment evaluations (as detailed in section 6.1), confirmation of eligibility and consent of a patient at a site, the randomisation form must be fully completed prior to telephoning/emailing NWORTH Clinical Trials Unit.

A trial number and treatment allocation will be assigned for the patient and the site notified by e-mail and must be recorded at site.

Randomisation telephone number:	+44 (0) 1248 388095
Randomisation e-mail address:	nworth@bangor.ac.uk

8 TRIAL TREATMENT- INTERVENTIONS

MBT-ASPD:

Mentalization Based Therapy integrates cognitive and relational components of therapy and has a theoretical basis in attachment theory. MBT-ASPD targets mentalizing problems through a programme of group and individual psychotherapy (Bateman *et al.*, 2006) (Bateman *et al.*, 2011; Bateman *et al.*, 2008b; Bateman *et al.*, 2013). All participants randomised to MBT-ASPD will have an allocated psychiatrist, a therapist who will provide individual therapy and two group therapists (one of whom will be their individual therapist). The therapist will provide a monthly 1 hour individual Mentalization Based Therapy session. Participants will also attend weekly group Mentalization Based Therapy for 75 minutes. Therapy will last for 12 months after which patients will be reassessed by a member of the trial clinical team and referred for further management if required. Each MBT group will have a maximum of 8 participants.

The main purpose of MBT-ASPD is to help participants develop an understanding of their difficulties with violence and to achieve control over their aggressive behaviour by stabilizing emotional expression. The MBT-APSD programme aims to develop a therapeutic process in which the offender's mind becomes the focus of treatment, to enable them to understand more about how they think and feel about themselves and others, and how this influences their actions and behaviours. MBT sessions will focus on identifying the thoughts and feelings associated with aggressive impulses and which may trigger aggressive or violent behaviour, with particular emphasis on (1) understanding emotional cues (2) recognising emotions in others (3) exploring sensitivity to hierarchy and authority (4) understanding others' experiences in relation to ones' own (5) clarifying threats to loss of mentalizing. Sessions will also give participants a place to discuss the difficulties they have experienced in their life which may have contributed to their violent behaviour.

Crisis and risk management, or intervening to reduce the risk of patient's urges to harm others or other offending, self-harm, actual self-harm or suicidal intent, is an important component of MBT-ASPD. When the patient is accepted for treatment a crisis plan will be agreed between the offender and the Specialist Offender Manager, based on their Pathways formulation. The crisis plan will aim to specify triggers; how the person presents when they are in crisis; and advice for other professionals on how to assist the person to manage the crisis. During office hours patients will be able to call their clinical centre and speak to a staff member. If they cannot wait for help out of hours the patient should go to A & E. If necessary the patient will be seen as soon as possible by a staff member. When the patient is seen, support will be given, necessary medical treatment arranged in consultation with a physician if required and a risk assessment made to inform a decision on referral on to local crisis services for possible admission either to a psychiatric ward or a crisis facility if available. If admitted, the therapist will maintain contact and the patient will return to the outpatient care of the therapy team as soon as possible as long as the level of risk is thought to be acceptable by the treating team Consultant Psychiatrist, the Centre Clinical Lead and the MBT Therapist. It should be noted, however, that admission to hospital is not an alternative to the criminal justice route if the patient re-offends.

Participants will be offered treatment review meetings where appropriate, including medication review, with the Consultant Psychiatrist. Medication use will be monitored carefully and only offered for co-morbid conditions according to NICE guidance. However, it should be noted that

many crises are triggered by social factors, such as changes in accommodation, and may not warrant the use of medication.

PAU:

Participants who are randomised to the PAU arm of the trial will remain under the supervision of their Probation Trust for the duration of their licence or community sentence. It is hoped that this will facilitate the participants being available for outcome measures and data collection. Participants will be free to be referred by their Probation Officer for any suitable and appropriate treatments available locally e.g. anger management programmes. However, as there are limited treatments available in the community for people with antisocial personality disorder the participants may not be able to access alternative treatments. In these cases, contact with the Probation Officer may provide an important containing and therapeutic, as well as supervisory, function.

Participants will be offered treatment review meetings where appropriate, including medication review, with the Consultant Psychiatrist. Medication use will be monitored carefully and only offered for co-morbid conditions according to NICE guidance. In order to address potential bias, site-specific strategies will be put in place to ensure that MBT principles and practice do not directly influence the management of those randomised to PAU. One strategy that will be applied to all sites is that MBT therapists and MBT supervisors will not be allowed to be in contact with participants in the PAU arm of the trial.

PAU will last for 12 months, after which participants who still have time remaining on their licence or community sentence will remain under the supervision of their Probation Trust for the duration of their licence or community sentence. It is hoped that this will facilitate the participants' availability for outcome measures and data collection

8.1 Who will deliver the interventions?

Staff providing individual therapy will have a basic clinical training (e.g. psychology, medical, nursing), and will have undergone an introduction to MBT and treated at least one patient using MBT under appropriate supervision for 6 months. Those providing group therapy will in addition have acted as a co-therapist for 6 months in a supervised MBT group in which the main therapist is an experienced MBT practitioner.

Supervision sessions will be conducted by trained supervisors, expert in the provision and supervision of MBT and occur monthly for one hour. Issues arising in both individual and group therapy will be discussed. A proportion of individual and group sessions will be video/audio-recorded and the recordings played and discussed in supervision. Participants will sign consent forms for video/audio recordings.

MBT sessions will be video or audio recorded and the recordings rated by observers to assess the degree to which therapy provided adheres to the treatment model of MBT. The rating scale used will be that devised by Karterud et al. (2012). In addition, reports from supervisors on each therapist will assess, using a tested rating scale, adherence to model. Therapists found not to reach an accepted level of adherence will be provided with additional training. Group therapy model

adherence will be monitored using video/audiotaped recordings of therapy sessions and reports from co-therapists.

Participants who are randomised to the PAU arm of the trial will remain under the supervision of their Probation Officer for the duration of their licence and may be referred to another suitable treatment available locally by trained professionals.

9 ASSESSMENTS

9.1 Screening Assessments

SCID-II

This will be administered to provide a DSM-IV diagnosis of ASPD

OAS-M

The will be administered to provide a measure of aggression in the community.

9.2 Pre-treatment Assessments

Measures

Measures will be administered at baseline, and at 6, 12, 18, and 24 months post-randomisation. Except for the primary outcome measure (Overt Aggression Scale Modified; OAS-M); the MacArthur Community Violence Instrument; Revised Conflict Tactics Scale and State-Trait Anger Expression Inventory which will be administered every 3 months and the ASPD section of the SCID-II which will be administrated 12 and 24 months post-randomisation. The measures administered at 12 months might include people who are no longer subject to statutory supervision. We will evaluate whether the end of their supervision and, therefore, their attendance being more voluntary, is connected to dropout.

- **Overt Aggression Scale Modified** (OAS-M; Coccaro et al. 1991): 7-item, clinician administered, semi-structured interview with three domains, including Aggression, Irritability, and Suicidality. For the aggression domain, there are four subscales of behaviour: verbal aggression, aggression against objects, aggression against others, and auto-aggression. For the irritability domain there are two subscales: global irritability and subjective irritability.
- **MacArthur Community Violence Screening Instrument** (MCVSI; Steadman et al., 1998; 2000): 18-item semi-structured interview to measure the frequency with which individuals have been subject to and/or have engaged in particular violent behaviours. Items start with the least severe acts and gradually progressing toward the most severe acts. Adapted to include four additional behaviours (shouting angrily at others, threatening harm to others, causing damage to property, and self-harm).
- **State-Trait Anger Expression Inventory-2** (STAXI-2; Spielberger, 1999) will be used to investigate the experience, expression of anger and control of anger. It is a 57-item self-report measure comprising of six subscales, including state anger, trait anger, anger expression-out, anger expression-in, anger control-out and anger control-in, and anger expression index.

- **Revised Conflict Tactics Scale short form** (CTS2S; Murray and Douglas, 2004) will be used to investigate levels of intimate partner violence**.** It is a 20 item self-report measure comprising of five subscales, including negotiation, psychological aggression, physical assault, sexual coercion and injury.
- **Euroqol-5** (EQ-5D Soeteman *et al.*, 2008); Standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. It takes only a few minutes to complete and has been used to assess the burden of disease for people with personality disorder.
- **Symptom Checklist-90 Revised** (SCL-90-R) Derogatis, 1993), Self-report screening instrument used to assess the psychological symptom patters of the participants. Nine primary symptom scales: Somatization, Obsessive-Compulsive, Interpersonal Sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation, and Psychoticism.
- **Alcohol Use Disorders Identification Test** (AUDIT) (Saunders *et al.*, 1993): A simple 10-question test developed by the World Health Organization to determine if a person's alcohol consumption may be harmful.
- **Drug Use Disorders Identification Test** (DUDIT; Berman et al., 2007): 11-item test developed as a parallel instrument to the AUDIT for identification of use patterns and various drug-related problems.
- **Secure Facilities Service Use Schedule** (SF-SUS; Barrett & Byford, 2007): Able to collect meaningful individual-level service use information for the economic evaluation of services provided within secure facilities. The schedule includes information on the service user's accommodation, including time spent in a secure facility such as prison or secure NHS unit, use of all health, social, voluntary sector services, psychotropic medication and contact with the police, lawyers and the courts.
- **Service Engagement Scale** (Tait et al, 2002): 14-item clinician-rated measure consisting of statements that assess client engagement with services. The scale has high internal consistency and retest reliability, including discrimination between criterion groups, in an assertive outreach team (Tait et al, 2002).
- **Self-Harm Inventory** (SHI; Sansone, 1998) and the **Suicidal Behaviours Questionnaire–Revised** (SBQ–R; Osman et al., 2001), will be used to assess self-harm and suicidal behaviour. The SHI is a 22-item, yes/no, self-report questionnaire based on self-harm behaviours. The SBQ-R is a brief 4-item self-report measure of suicidal behaviour and past attempts.
- **Personality Inventory for DSM-5 Brief Form** (PID-5-BF; Krueger, Derringer, Markon, Watson & Skodol, 2013) is a 25-item self-rated personality trait assessment scale. It assesses 5 personality trait domains including negative affect, detachment, antagonism, disinhibition, and psychoticism, with each trait domain consisting of 5 items.
- **Brief reflective function Questionnaire (**BRFQ; Luyten, under development): 8-item self-report scale to measure mentalization capacities with regards to self and others. Higher scores would indicate greater impairment in Reflective Function.

- **Antisocial personality disorder section of the Structured Clinical Interview for DSM disorder** (SCID-II, Gibbon et al., 1997) a 22 item structure clinical interview to identify antisocial personality diagnosis.
- **The Redemption and Condemnation Self-Narrative Scale (RCSN Scale) Version 2** a 25 item self-report scale measuring a prisoner's self-narrative (redemption and condemnation).

**** A sub-sample of participants will complete the following: ****

- **Reflective Functioning Questionnaire-54** (RFQ-54; Luyten, under development): 54-item self-report scale to measure mentalization capacities with regards to self and others. It includes two hypothesises factors: internal others and internal self. There are two sub-dimensions for each factor: too certain mental states about self and others and too uncertain mental states about self and others. Higher scores would indicate greater impairment in RF. The measure has a good internal reliability and convergent construct validity, correlating positively with measures of allied constructs, such as mindfulness and cognitive empathy (Moulton-Perkins et al., 2011).
- **Movie for the Assessment of Social Cognition** (MASC) is a sensitive video-based test for the evaluation of subtle mindreading difficulties. This tool involves watching a short film and answering questions referring to the actors' mental states. Questions concern the characters' feelings, thoughts, and intentions.
- **Social Hierarchy** game is interpersonal exchange game in which two players make decisions that determine which player has control of a monetary endowment and one which has no control of monetary endowments across a series of interactions. The paradigm tests how participants evaluate the benefits and costs of aggressive actions, as they learn, develop, and update expectations of social partners.
- **Investor-Trustee** game is an interpersonal exchange game in which a player makes a series of decisions to either trust or repay trust in a social partner.

User Voice Peer led research

Including researchers will lived experience of the criminal justice system is a central component to the research methodology of the trial. A sub sample of MOAM participants; the User Voice peer researchers themselves; research assistants working alongside the peer researchers; offender managers who have interacted with both groups of researchers during the recruitment and follow up phase of the trial and User Voice operational staff will be approached to share their experiences. These optional interviews will aim to explore the potential impact of the User Voice peer led approach in the following areas:

- The impact of the User Voice peer led approach on the peer researchers themselves

- To understand the MOAM participants' experience of being interviewed and followed up by a researcher with lived experience of the criminal justice system
- Understand the impact of the approach on the wider research and criminal justice system.

All recruited MOAM participants will be approached at the end of their follow up visit to complete an additional 10 item questionnaire about their experiences of being interviewed by a User Voice peer researcher or research assistant.

10 DATA MANAGEMENT AND DATA HANDLING GUIDELINES

Data will be collected from sites on version controlled case report forms (CRFs) designed for the trial and supplied by UCL.

Please note that, for this trial, patients have consented to their names and addresses and phone numbers being supplied to UCL. This is to assist with follow-up visits by the research assistant.

All CRFs must be completed and signed by staff that are listed on the site staff delegation log and authorised by the PI to perform this duty. The PI is responsible for the accuracy of all data reported in the CRF.

All entries must be clear, legible and written in ball point pen. Any corrections made to a CRF at site must be made by drawing a single line through the incorrect item ensuring that the previous entry is not obscured. Each correction must be dated and initialed. Correction fluid must not be used.

The use of abbreviations and acronyms must be avoided.

Once completed the original CRFs must be sent to UCL and a copy kept at site.

10.1 Missing Data

To avoid the need for unnecessary data queries CRFs must be checked at site to ensure there are no blank fields before sending to UCL. When data are unavailable because a measure has not been taken or test not performed, enter “ND” for not done. If an item was not required at the particular time the form relates to, enter “NA” for not applicable. When data are unknown enter the value “NK” (only use if every effort has been made to obtain the data).

11 SAFETY REPORTING

11.1 Definitions of Adverse Events

The following definitions have been adapted from Directive 2001/20/EC, ICH E2A "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting" and ICH GCP E6:

Adverse Event (AE)

Any untoward medical occurrence or effect in a patient treated on a trial protocol, which does not necessarily have a causal relationship with a trial treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a trial treatment, whether or not related to that trial treatment.

Serious Adverse Event (SAE)

An adverse event or adverse reaction that

Results in death

- Is life threatening (the term "life-threatening" refers to an event in which the patient was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe)
- Requires in-patient hospitalisation or prolongs existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly or birth defect
- Is otherwise medically significant (e.g. important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed above)
- All serious adverse events will be reported in accordance with NRES reporting guidance. Serious adverse events will be monitored for 3 months after stopping the trial treatment.

Suspected Unexpected Serious Adverse Reaction (SUSAR)

A serious adverse reaction, the nature or severity of which **is not consistent** with the applicable trial treatment information.

11.2 Reporting Procedures

11.2.1 All Adverse Events (AEs)

All adverse events that occur between informed consent and 30 days post last trial treatment administration/the end of the trial (**See section 14.1 for** end of trial definition) must be recorded in the patient notes. Those meeting the definition of a Serious Adverse Event (SAE) must also be reported to UCL using the trial specific SAE Report. Also refer to section 11.2.2 (Serious Adverse Events (SAEs)).

Pre-existing conditions do not qualify as adverse events unless they worsen.

Severity

Severity of each adverse event must be determined by using the Common Terminology Criteria for Adverse Events (CTCAE) vx.x as a guideline

In those cases where the CTCAE criteria do not apply, severity should be coded according to the following criteria:

1 = Mild (awareness of sign or symptom, but easily tolerated)
2 = Moderate (discomfort enough to cause interference with normal daily activities)
3 = Severe (inability to perform normal daily activities)
4 = Life threatening (immediate risk of death from the reaction as it occurred)
5 = Fatal (the event resulted in death)

Causality

The PI, or other delegated site investigator, must perform an evaluation of causality for each adverse event.

Causal relationship to each trial treatment must be determined as follows:

None

There is no evidence of any causal relationship.

Unlikely

There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of a trial treatment). There is another reasonable explanation of the event (e.g. the patient's clinical condition, other concomitant treatments).

Possibly

There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of a trial treatment). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant treatments).

Probably

There is evidence to suggest a causal relationship and the influence of other factors is unlikely.

Definitely

There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

UCL will consider events evaluated as possibly, probably or definitely related to be adverse reactions.

11.2.2 Serious Adverse Events (SAEs)

All SAEs that occur between the signing of informed consent and 30 days post the last trial treatment administration (or after this date if the site investigator feels the event is related to a trial treatment) must be submitted to UCL by fax or email within **24 hours** of observing or learning of the event, using the trial specific SAE Report. All sections on the SAE Report must be completed. If the event is **not being reported within 24 hours** to UCL, the circumstances that led to this must be detailed in the SAE Report to avoid unnecessary queries.

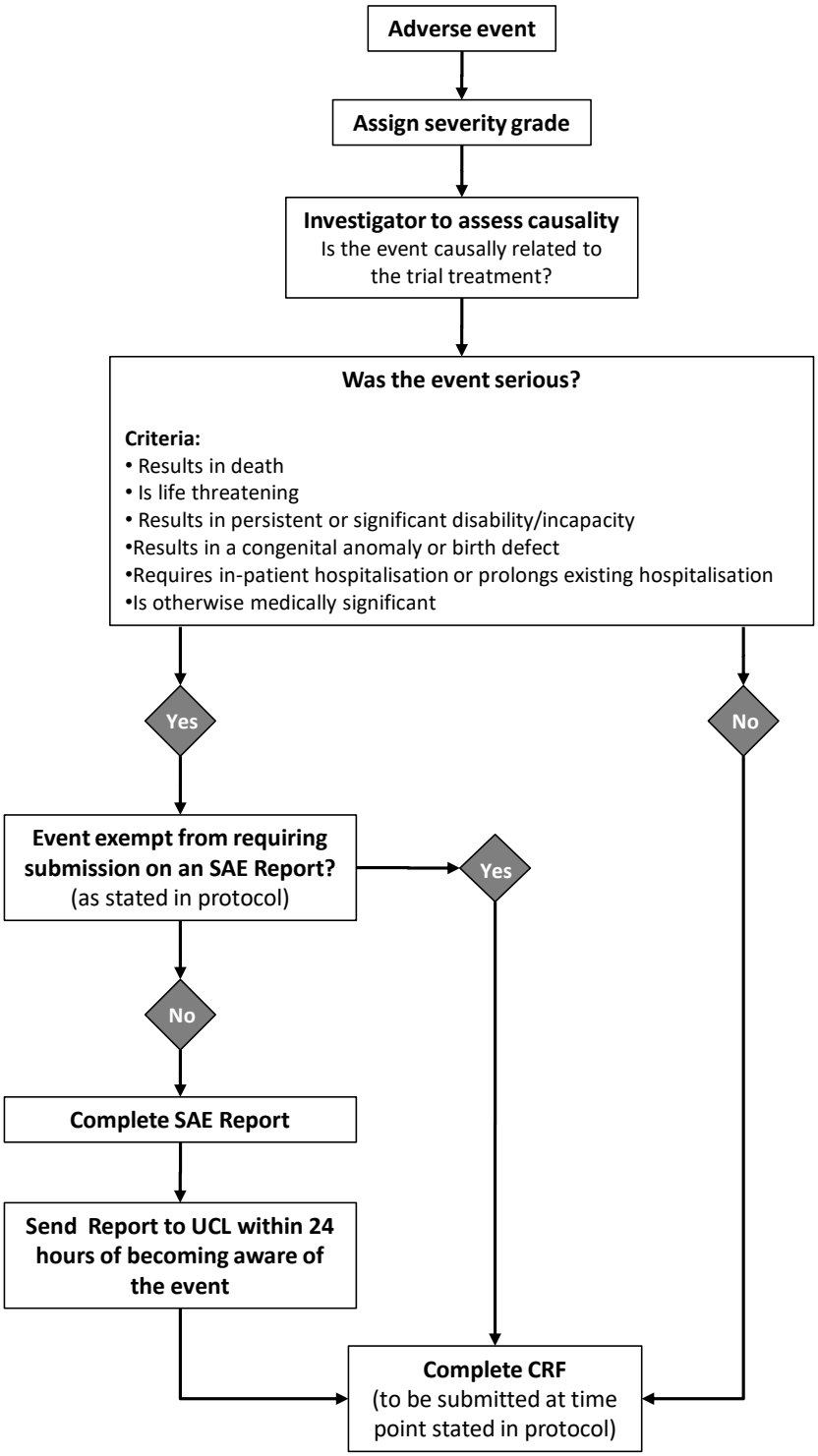
Completed SAE Reports must be faxed or emailed within 24 hours of becoming aware of the event to UCL

Fax: +44 (0)207 916 1989
E-mail: Project-MOAM@ucl.ac.uk

11.2.3 Reporting Procedures for Serious Adverse Events

A serious adverse event (SAE) occurring to a participant would be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator the event was: 'related' – that is, it resulted from administration of any of the research procedures; and 'unexpected'. Reports of related and unexpected SAEs will be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES report of serious adverse event form.

Adverse Event Reporting Flowchart



SAE Processing at UCL

On receipt of the SAE Report, UCL will check for legibility, completeness, accuracy and consistency.

The CI, or their delegate (e.g. a clinical member of the TMG), may be contacted to review the SAE and to perform an evaluation of causality on behalf of UCL. If UCL has considered expectedness difficult to determine, the CI, or their delegate, will be consulted for their opinion at this time.

11.3 Safety Monitoring

UCL will provide safety information to the TMG and the IDMC on a periodic basis for review.

Trial safety data will be monitored to identify:

- new adverse reactions to the trial treatment regimen or individual trial treatments
- trial related events that are not considered related to the trial treatment regimen.

Should UCL identify or suspect any issues concerning patient safety at any point throughout the trial, the CI or TMG will be consulted for their opinion.

12 TRIAL MONITORING AND OVERSIGHT

Participating sites and PIs must agree to allow trial-related on-site monitoring, Sponsor audits and regulatory inspections by providing direct access to source data/documents as required. Patients are informed of this in the patient information sheet and are asked to consent to their medical notes being reviewed by appropriate individuals on the consent form.

UCL will determine the appropriate level and nature of monitoring required for the trial. Risk will be assessed on an ongoing basis and adjustments made accordingly.

12.1 Central Monitoring

Sites will be requested to submit screening logs to UCL on request and these will be checked for consistency and completeness. Also refer to sections 4.2.2 (Required documentation) and 6.2 (Screening Log).

Ensuring patient eligibility is the responsibility of the PI or other delegated Investigator(s). Checks of the criteria listed on the randomisation form will be undertaken by an appropriately trained UCL staff member prior to randomisation. Also refer to section 7.1 (Randomisation).

A copy of the consent form for each patient entered onto the trial must be submitted to UCL. These will be checked for completeness and accuracy i.e. the correct version of the form has been used, patient initials in every box, patient name and signature on the form, patient personally completed date of signing, and the person taking consent has signed/dated and is listed on the delegation log as performing this duty. Also refer to section 5 (Informed consent).

12.2 Oversight Committees

12.2.1 Trial Management Group (TMG)

The TMG will include the Chief Investigator, clinicians and experts from relevant specialities and MOAM trial staff from UCL. The TMG will be responsible for overseeing the trial. The group will meet 6-monthly and will send updates to PIs (via newsletters or at Investigator meetings)

The TMG will review substantial amendments to the protocol prior to submission to the REC. All PIs will be kept informed of substantial amendments through their nominated responsible individuals.

12.2.2 Trial Steering Committee (TSC)

The role of the TSC is to provide overall supervision of the trial. The TSC will review the recommendations of the Independent Data Monitoring Committee and, on consideration of this information, recommend any appropriate amendments/actions for the trial as necessary. The TSC acts on behalf of the funder and the Sponsor.

12.2.3 Independent Data Monitoring Committee (IDMC)

The role of the IDMC is to provide independent advice on data and safety aspects of the trial. Meetings of the Committee will be held 6-monthly to review interim analyses or as necessary to address any issues. The IDMC is advisory to the TSC and can recommend premature closure of the trial to the TSC.

12.2.4 Role of UCL

UCL will be responsible for the day to day coordination and management of the trial and will act as custodian of the data generated in the trial (on behalf of UCL). UCL is responsible for all duties relating to safety reporting which are conducted in accordance with section 11 (Safety Reporting)

13 WITHDRAWAL OF PATIENTS

In consenting to the trial, patients are consenting to trial treatment, assessments, follow-up and data collection.

13.1 Discontinuation of Trial Treatment

A patient may be withdrawn from trial treatment whenever continued participation is no longer in the patient's best interests, but the reasons for doing so must be recorded. Reasons for discontinuing treatment may include

- Patient choice
- Any alterations in the patient's condition which justifies the discontinuation of treatment in the site investigator's opinion

In these cases patients remain within the trial for the purposes of follow-up and data analysis according to the treatment option to which they have been allocated.

If a patient expresses their wish to withdraw from trial treatment, sites should explain the importance of remaining on trial follow-up, or failing this of allowing routine follow-up data to be used for trial purposes and for allowing existing collected data to be used. If the patient gives a reason for their withdrawal, this should be recorded.

13.2 Future Data Collection

If a patient **explicitly** states they do not wish to contribute further data to the trial their decision must be respected, with the exception of safety data, and recorded on the relevant CRF. In this event details should be recorded in the patient's records, no further CRFs must be completed and no further data other than safety data sent to UCL

13.3 Losses to Follow-Up

If a patient moves from the area, every effort should be made for the patient to be followed up.

14 TRIAL CLOSURE

14.1 End of Trial

For regulatory purposes the end of the trial will be the date of the last assessment visit of the last participant at which point the 'declaration of end of trial' form will be submitted to participating ethical committees, as required.

Following this, UCL will advise sites on the procedure for closing the trial at the site.

14.2 Archiving of Trial Documentation

At the end of the trial, UCL will archive securely all centrally held trial related documentation for a minimum of 5 years. Arrangements for confidential destruction will then be made. It is the responsibility of PIs to ensure data and all essential documents relating to the trial held at site are retained for a minimum of 5 years after the end of the trial, in accordance with national legislation and for the maximum period of time permitted by the site.

Essential documents are those which enable both the conduct of the trial and the quality of the data produced to be evaluated and show whether the site complied with the principles of GCP and all applicable regulatory requirements.

UCL will notify sites when trial documentation held at sites may be archived. All archived documents must continue to be available for inspection by appropriate authorities upon request.

14.3 Early Discontinuation of Trial

The trial may be stopped before completion as an Urgent Safety Measure on the recommendation of the TSC or IDMC (see section 12.2.2 Trial Steering Committee (TSC) and 12.2.3 Independent Data Monitoring Committee (IDMC)). Sites will be informed in writing by UCL of reasons for early closure and the actions to be taken with regards the treatment and follow up of patients.

14.4 Withdrawal from Trial Participation by a Site

Should a site choose to close to recruitment the PI must inform UCL in writing. Follow up as per protocol must continue for all patients recruited into the trial at that site

15 STATISTICS

The primary outcome, frequency of aggressive behaviour as measured by the OAS-M score, will be analysed using a hierarchical mixed-effects linear regression with stratifying variables and baseline OAS-M score included as fixed effects, individual and therapist as random effects. Secondary outcomes will be analysed using mixed-effects linear regression (for continuous outcomes), mixed-effects logistic regression models (for binary outcomes), and mixed-effects Poisson models (for count data) as appropriate. These analyses properly account for missing outcome data when it is missing at random (i.e. the probability of missingness depends on observed covariates). If there is a significant treatment effect, we will conduct a sensitivity analysis to the data being missing not at random, using the strategy discussed in White et al (White et al., 2011).

As further secondary analyses, we will test the following as moderators for the primary and secondary outcomes: age; type of probation; length of probation; and scores on the psychopathic personality inventory-revised. We will test the following as mediators: alcohol use (scores on the alcohol use disorders identification test), drug use (scores on the drug use disorders identification test) and mood (scores on the anxiety and depression subscales of the SCL-90-R).

15.1 Sample Size Calculation

The primary outcome of the trial is frequency of aggressive acts as measured by OAS-M score. The primary null hypothesis is that there is no difference in the mean change in OAS-M score from baseline to 12 months post treatment completion between the PAU and MBT arms.

Hollander et al reported the pooled standard deviation of the change in OAS-M score from baseline to 10 weeks follow-up as being just over 9 for the pharmaceutical intervention assessed (Hollander et al., 2003). Due to our trial's longer follow-up period and the non-pharmaceutical nature of our planned intervention, we have chosen to increase the standard deviation used in our power calculation to 20. The trial's sample size is chosen to have 90% power, at a two-sided 5% significance level, to detect a significant difference between groups when the change in OAS-M score is on average 10 points greater in the MBT arm (with a standard deviation of 20) at the primary endpoint 12 months after randomisation. To take into account potential clustering by therapist in the MBT arm, with up to 6 participants per therapist group, we assume the intraclass correlation coefficient (ICC) to be 0.05. In this case, using established methods to take account of clustering [89], 95 participants per arm (190 participants overall) gives 90% power. This figure is fairly robust to higher ICC values – for example, if the ICC is actually 0.1, then the power will be 85%.

We anticipate attrition and drop out to be 37%, based on several sources including our own preliminary work and several larger data sources: a meta-analysis of attrition rate in offender treatment literature (Olver et al., 2011), a systematic review of non-completion of personality disorder treatment, and an empirical evaluation of treatment disengagement in personality disordered offenders (McMurran et al., 2010). To account for this loss, we will recruit 151 participants per arm, to end up with 95 participants per arm after attrition and drop out. Our recruitment target is therefore 302 participants across all 13 sites, equivalent to 24 participants per

site. We plan that 30 of our sample will be recruited onto our internal pilot conducted across 5 sites (equivalent to 6 participants per site), and 272 of our sample will be recruited onto the main trial. Based on our feasibility study's data which indicates that we can reasonably expect to recruit a minimum of 1 eligible consenting participant per site per month, we plan that recruitment for the internal pilot will run for 6 months and recruitment for the main trial will run for 22 months.

16 ETHICAL APPROVALS

In conducting the trial, the Sponsor, UCL and sites shall comply with all laws and statutes, as amended from time to time, applicable to the performance of clinical trials including, but not limited to:

- the principles of ICH Harmonised Tripartite Guideline for Good Clinical Practice
- Human Rights Act 1998
- Data Protection Act 1998
- Freedom of Information Act 2000
- the Research Governance Framework for Health and Social Care, issued by the UK Department of Health (Second Edition 2005) or the Scottish Health Department Research Governance Framework for Health and Community Care (Second Edition 2006)

16.1 Ethical Approval

The trial will be conducted in accordance with the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version) and in accordance with the terms and conditions of the ethical approval given to the trial.

The trial has received a favourable opinion from the NRES Committee London- South East Research Ethics Committee and NOMs.

UCL will submit Annual Progress Reports to the REC, which will commence one year from the date of ethical approval for the trial.

16.2 Site Approvals

Evidence of approval from the Trust R&D for a trial site must be provided to UCL. Sites will only be activated when all necessary local approvals for the trial have been obtained.

16.3 Protocol Amendments

UCL will be responsible for gaining ethical approval, for amendments made to the protocol and other trial-related documents. Once approved, UCL will ensure that all amended documents are distributed to sites via CSP as appropriate.

Site staff will be responsible for acknowledging receipt of documents and for implementing all amendments.

16.4 Patient Confidentiality & Data Protection

Patient identifiable data, including full name, date of birth, prison records number and NHS number will be required by the research team in order to contact the participants for follow up assessment. Participant's offending records will be obtained from the Police National Computer, with the participant's consent. UCL will preserve patient confidentiality and will not disclose or reproduce any information by which patients could be identified. Data will be stored in a secure manner and UCL trials are registered in accordance with the Data Protection Act 1998 with the Data Protection Officer at UCL.

All data will be handled in accordance with the Data Protection Act 1998 as well as the Information Security Policy and Trust Information Governance Policy of UCL. Research data will be anonymised immediately after testing and any data kept on the investigators' computers will be maintained in this anonymous format. Consent forms, demographic and medical data will be kept in locked offices to which only the investigators have access.

Only members of the research team will have direct access to the data. An on-site archive is maintained for at least five years. The list of ID and patient names will be stored securely separate from the outcomes data.

Participants will be informed that throughout their participation in the study – and also if they choose to withdraw their consent to continued participation at any point in the study - all information gathered about them will remain strictly confidential. The exception to this would be as follows: the research team would have to tell the police or another relevant authority if a participant disclosed that he/she or another person was sincerely planning to seriously harm another specific person, or that the participant was directly at risk of serious harm. In the event of a serious criminal disclosure where a court was to demand participant case records, these would have to be made available on demand for legal authorities.

All questionnaires or interview-relevant material collected from participants will not bear the participant's name or other personal identifiable data and all hard-copies as well as electronically stored data will at all times be stored securely at UCL. Personally identifiable information will be sorted separately to the research data collected in questionnaire interview, and computer tasks.

All participants – including those who withdraw at any stage of the study – should be assured that any information that they have provided at any stage will remain anonymous and that individual participants will not be identified (or identifiable) in any subsequent report or document produced. These rules apply whether or not their participation in the study was terminated early.

17 SPONSORSHIP AND INDEMNITY

17.1 Sponsor Details

Sponsor Name:	University College London
Address:	Joint Research Office Gower Street London WC1E 6BT
Contact:	Director of Research Support
Tel:	020 3447 9995/2178 (unit admin)
Fax:	020 3447 9937

17.2 Indemnity

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

18 FUNDING

The Michael J Samuel Charitable Trust is supporting the central coordination of the feasibility trial through the Anna Freud Centre. The Clinical teams have been awarded funding by the Department of Health (DoH) and the National Offender Management Services (NOMs)

The National Institute for Health Research is supporting the central coordination of the full scale RCT through University College London. The Clinical team have been awarded funding by NHS England and the National Offender Management Service (NOMs).

This study/project is funded by the National Institute for Health Research (NIHR) [name of NIHR programme **14/186/01**. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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APPENDIX 1: ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
ASPD	Antisocial Personality Disorder
CI	Chief Investigator
CRC	Community Rehabilitation Company
CRF	Case Report Form
CTCAE	Common Terminology Criteria for Adverse Events
CSP	Communicating Sequential Processes
DoH	Department of Health
DPA	Data Protection Act
DSM	The Diagnostic and Statistical Manual of Mental Disorders
IDMC	Independent Data Monitoring Committee
ISRCTN	International Standard Randomised Controlled Trial Number
MBT	Mentalization Based Therapy
NHS	National Health Service
NOMS	National Offender Management Service
NPS	National Probation Service
NRES	National Research Ethics Service
NWORTH	North Wales Organisation for Randomised Trials in Health (& social care)
PAU	Probation As Usual
PCL-R	Psychopathy Checklist Revised
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SCID	Structured Clinical Interview for DSM Disorders
SCM	Structured Clinical Management
SUSAR	Suspected Unexpected Serious Adverse Reaction
RCT	Randomised Controlled Trial
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UCL	University College London

APPENDIX 1: PROTOCOL VERSION HISTORY

Protocol:		**Amendments:**		
Version no.	**Date**	**Amendment no.**	**Protocol Section (no./title)**	**Summary of main changes from previous version.**
2	07.01.2016	1		Expansion of the four site pilot site to a full scale RCT across 13 sites.
3	06.04.2016	2	Front page Protocol summary page 5	ISRCTN study ID added **Amendment not acted on by study team**
4	28.07.2016	3	Front page Page 2 Page 5 Page 17 Page 21-22	ISRCTN study ID added Members of trial research team updated ISRCTN study ID added Stratification wording Introduction of two new measures (CTS2S and STAXI-2) and new follow up time point for ASPD section of the SCID-II
5	30.10.2018	4	Page 23	Inclusion of one new measure RCSN scale version 2
6	02.12.2018	5	Page 23	Inclusion of additional optional interviews for User Voice peer led research