HASB-IDD trial

RCT of group CBT for men with intellectual and/or developmental disabilities and harmful sexual behaviour: the HaSB-IDD trial

Version	1.2
Date	19/05/22
Sponsor	University of Kent
Trial registration	ISRCTN Study ID no: ISRCTN21187053
NRES #	291027

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FUNDED BY

NIHR | National Institute for Health and Care Research

Authorisation: Chief Investigator

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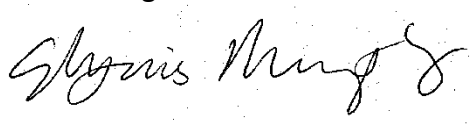
Role	Chief Investigator
Signature	
Date	27.06.22

Authorisation: CTU Director or Representative

Name	Matt Hammond
Role	CTU Deputy Director
Signature	
Date	22.06.22

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1 Administrative information

This document was constructed using the Norwich Clinical Trials Unit (NCTU) Protocol template Version 4. It describes the HaSB-IDD trial, sponsored by University of Kent and co-ordinated by NCTU.

It provides information about procedures for entering participants into the trial, and provides sufficient detail to enable: an understanding of the background, rationale, objectives, trial population, intervention, methods, statistical analyses, ethical considerations, dissemination plans and administration of the trial; replication of key aspects of trial methods and conduct; and appraisal of the trial's scientific and ethical rigour from the time of ethics approval through to dissemination of the results. The protocol should not be used as an aide-memoire or guide for the treatment of other patients. Every care has been taken in drafting this protocol, but corrections or amendments may be necessary. These will be circulated to registered investigators in the trial. Sites entering participants for the first time should confirm they have the correct version through a member of the trial team at NCTU.

NCTU supports the commitment that its trials adhere to the SPIRIT guidelines. As such, the protocol template is based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2012 Statement for protocols of clinical trials [1]. The SPIRIT Statement Explanation and Elaboration document [2] can be referred to, or a member of NCTU Protocol Review Committee can be contacted for further detail about specific items.

1.1 Compliance

The trial will be conducted in compliance with the approved protocol, the Declaration of Helsinki (2008), the principles of Good Clinical Practice (GCP) as laid down by the Commission Directive 2005/28/EC with implementation in national legislation in the UK by Statutory Instrument 2004/1031 and subsequent amendments, the UK Data Protection Act, and the UK Policy Framework for Health and Social Care Research, and other national and local applicable regulations. Agreements that include detailed roles and responsibilities will be in place between participating sites and NCTU.

Participating sites will inform NCTU as soon as they are aware of a possible serious breach of compliance, so that NCTU can fulfil its requirement to report the breach if necessary within the timelines specified in the UK Clinical Trials Regulations (currently 7 days). For the purposes of this regulation a 'serious breach' is one that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects in the trial, or
- The scientific value of the trial.

1.2 Sponsor

University of Kent is the trial sponsor and has delegated responsibility for the overall management of the HaSB-IDD trial to the Chief Investigator and NCTU. Queries relating to sponsorship of this trial should be addressed to the Chief Investigator or via the trial team.

1.3 Structured trial summary

Primary Registry and Trial Identifying Number	ISRCTN Study ID no: ISRCTN21187053
Date of Registration in Primary Registry	21/05/21
Secondary Identifying Numbers	● IRAS number: 291027 ● NIHR: 128550
Source of Monetary or Material Support	NIHR (HTA stream)
Sponsor	University of Kent
Contact for Public Queries	g.h.murphy@kent.ac.uk
Contact for Scientific Queries	Glynis Murphy, Professor of Clinical Psychology & Disability, Tizard Centre Cornwallis North East University of Kent, Giles Lane Canterbury Kent CT2 7NS Email: g.h.murphy@kent.ac.uk Tel 01227 823960
Short Title or Acronym	RCT of group CBT for men with IDD and harmful sexual behaviour (HaSB-IDD)
Scientific Title	RCT of group CBT for men with intellectual and/or developmental disabilities and harmful sexual behaviour: the HaSB-IDD trial
Countries of Recruitment	England
Health Condition(s) or Problem(s) Studied	Harmful sexual behaviour in men with intellectual and/or developmental disabilities
Intervention(s)	Arm 1: Group Cognitive Behaviour Therapy (CBT) using the Sex Offenders Treatment Service Collaborative – Intellectual Disabilities (SOTSEC-ID) model, plus risk management. The CBT is specifically adapted for men with IDD. It consists of six months of sessions (two sessions per week). Arm 2: Treatment As Usual (mainly risk management)
Key Inclusion and Exclusion Criteria	Essential inclusion criteria for participating men are as follows: a) Adult men (aged 18 yrs+), with borderline or mild intellectual disability (ie an IQ below 80) and deficits in adaptive behaviours, with or without autism b) A history of one or more incidents of harmful sexual behaviour (HSB) in the last 5 years, regardless of whether convicted

	c) Relatively good verbal comprehension (to be judged by clinicians). d) Has capacity to provide informed consent. Exclusion criteria for men: a) Major mental health difficulties that would prevent participant from taking part in group CBT b) Resident in prison or in high secure services, or on a probation order, with a sex offender treatment requirement. c) Has completed CBT for HSB in the preceding three years A Carer will be recruited, one for each man. They may be a family member (e.g. a parent) or a paid carer. They must know the man well.
Study Type	Cluster randomised, single-blinded, controlled trial of the effectiveness and cost effectiveness of community or secure unit delivered group CBT for harmful sexual behaviour in men with IDD with an internal pilot and embedded process evaluation.
Date of First Enrolment	1st April 2022
Target Sample Size	240
Primary Outcome(s)	Cognitive distortions, as measured on the QACSO (Questionnaire on Attitudes Consistent with Sex Offences) measured at 12 months. This will be measured at baseline (time 1); after the intervention (time 2, six months after baseline); and at two follow-ups (time 3, i.e. 12 months after baseline, and time 4, i.e. 24 months after baseline).
Key Secondary Outcomes	Changes from baseline of: 1. Further harmful sexual behaviour (from carers' report) 2. Men's Sexual Knowledge, as measured on the General Sexual Knowledge Questionnaire (GSKQ) 3. Men's Victim empathy (using the Victim Empathy Scale – Adapted (VES-A) 4. Men's Self-esteem on the Rosenberg Scale 5. Men's Locus of control, using the Nowicki-Strickland Locus of Control Scale 6. Health care and other service use by participants, from a variety of sources including a modified CSRI, and from carers' report 7. Men's Quality of Life, using the EQ-5D-5L These will also be measured at baseline (time 1); after the intervention (time 2); and at two follow-ups (time 3 and time 4).

1.4 Roles and responsibilities

These membership lists are correct at the time of writing; please see terms of reference documentation in the TMF for current lists.

1.4.1 Protocol contributors

Name	Affiliation	Role [individuals who contribute substantively to protocol development and drafting should have their contributions reported]
Glynis Murphy	University of Kent	Prof of Clinical Psychology & Disability, responsible for the first draft of protocol and ethics form, and for finalisation of both
Lee Shepstone	Norwich CTU	Prof of Medical Statistics, drafting sections 9 to 11 of protocol
John Rose	University of Birmingham	Prof of Clinical Psychology, responsible for the qualitative studies and contributed to second draft of protocol and ethics form
Peter Langdon	University of Warwick	Prof of Clinical and Forensic Psychology, advised on outcome measures and contributed to second draft of protocol and ethics form
David Turner & Adam Wagner	Norwich CTU	Health economists, responsible for the health economics section of the protocol
Erika Sims	Norwich CTU	Contributed to the second draft of the ethics form and protocol

1.4.2 Role of trial sponsor and funders

Name	Affiliation	Role [in trial design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities]
NIHR (HTA)	NIHR	Funder.
Nicole Palmer	University of Kent	Sponsor.

1.4.3 Trial Team

Name	Affiliation	Role and responsibilities
Glynis Murphy	University of Kent	Prof of Clinical Psychology & Disability, Chief Investigator, responsible for the conduct and management of the trial
Lisa Richardson	University of Kent	Trial Manager (Joint with Nadjet Salima El-Mehidi)
Nadjet Salima El-Mehidi	University of Kent	Trial Manager (Joint with Lisa Richardson)
Josephine Collins	University of Kent	Research Assistant
Lee Shepstone	Norwich CTU	Prof of Medical Statistics, lead for the statistical aspects of the trial
John Rose	University of Birmingham	Prof of Clinical Psychology, lead for the qualitative studies and PI for north and west Midlands
Peter Langdon	University of Warwick	Prof of Clinical and Forensic Psychology, PI for South Midlands and East
David Turner	Norwich CTU	Health economist, lead for the health economics aspects of the trial.

John Taylor	University of Northumbria	Prof of Clinical Psychology, PI for the North
Andy Inett	Kent & Medway Partnership Trust	Forensic psychologist, PI for South East
Viv Cooper	Challenging Behaviour Foundation	Lead for PPI and chair of carers' advisory group
Regi Alexander	Broadland Clinic, Hertfordshire Partnership NHS Trust	Consultant Psychiatrist and advisor on psychiatric issues.
Martin Pond	Norwich CTU	NCTU Head of Data Management

1.4.4 Trial Management Group

Name	Affiliation	Role and responsibilities
Glynis Murphy	University of Kent	CI
Peter Langdon	University of Warwick	PI
John Rose	University of Birmingham	PI
John Taylor	University of Northumberland	PI
Andy Inett	Kent and Medway Partnership Trust	PI
Regi Alexander	Hertfordshire Partnership University NHS Foundation Trust (HPFT)	PI
Adam Wagner	Norwich CTU	Lead for Health Economics
David Turner	Norwich CTU	Health Economics
Lee Shepstone	Norwich CTU	Lead for statistics
Martin Pond	Norwich CTU	Data Management
Lisa Richardson	University of Kent	Trial Manager
Nadjet Salima El Mehidi	University of Kent	Trial Manager
Josephine Collins	University of Kent	Research Assistant
Viv Cooper	Chief Exec, Challenging Behaviour Foundation	Lead for PPI
Erika Sims/ Matthew Hammond	Norwich CTU	Research Lead, Trial Operations Group

1.4.5 Trial Steering Committee

Name	Affiliation	Role and responsibilities
Nigel Beail	Sheffield University	Independent clinical psychologist & Chair
Claire Hughes	National Autistic Society	Independent stakeholder rep
Victoria Allgar	University of Plymouth	Independent Statistician
Eirini Saloniki	University College London	Independent Health economist

2 people with IDD/ carers		PPI
Glynis Murphy	University of Kent	Chief Investigator
Kate Theodore	Royal Holloway	Independent clinical psychologist
Lisa Richardson and Nadjet Salima El Mehidi	University of Kent	Trial managers, observers
Erika Sims/ Matthew Hammond	Norwich CTU	Observer and representative from Norwich CTU

1.4.6 Data Monitoring Committee

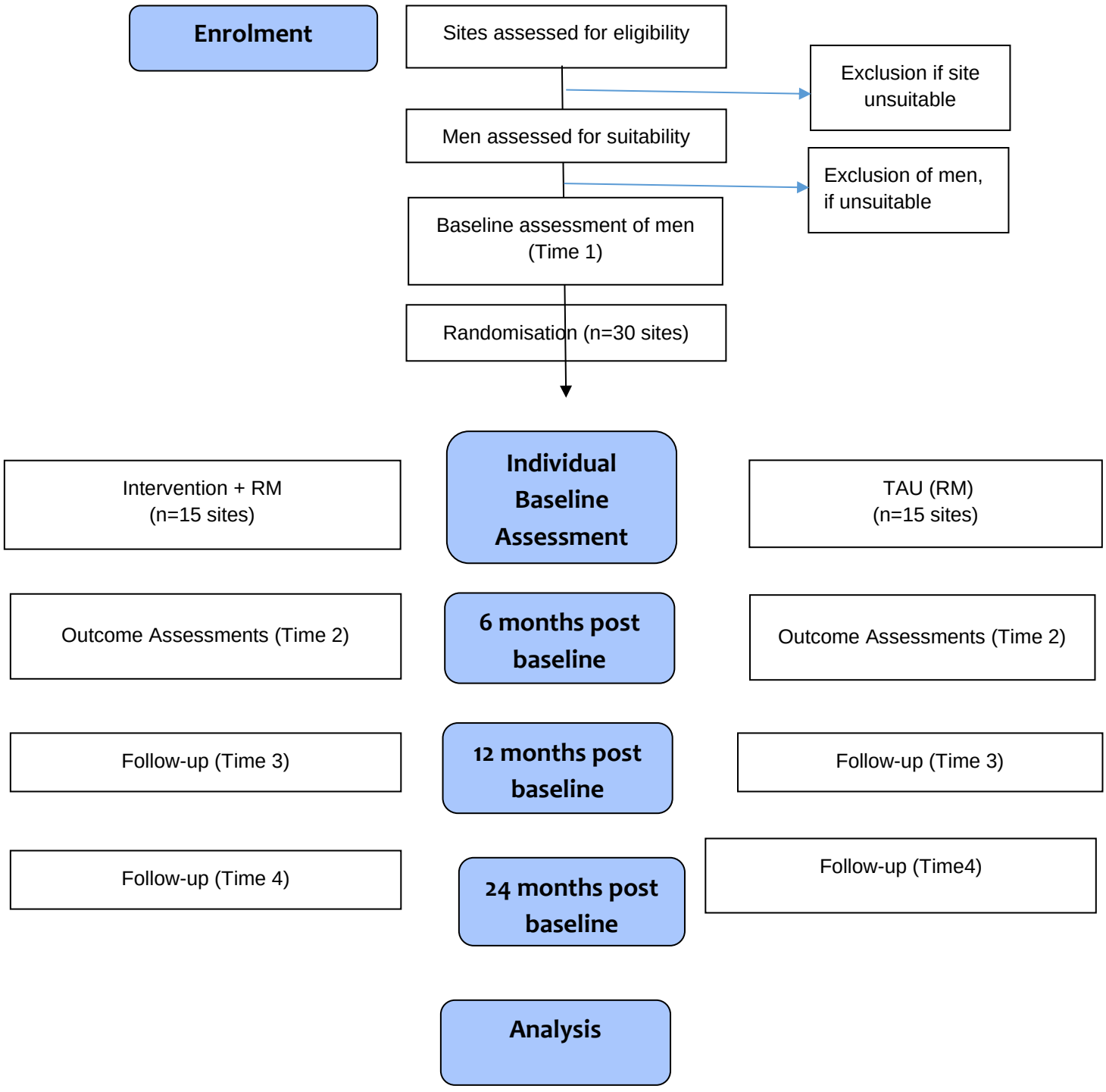
[Delete as appropriate]

Name	Affiliation	Role and responsibilities
David Felce	Emeritus Prof at Cardiff University	Independent Statistician(chair)
Andrew Jahoda	University of Glasgow	Independent psychologist
Tim Croudace	University of Dundee	Independent Triallist

1.4.7 Other Trial Oversight Groups

Name	Affiliation	Role and responsibilities
Viv Cooper	Chief Exec of Challenging Behaviour Foundation	Chair of carers group
Other members:		Carers (group of four)

2 Trial Diagram



3 Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CBT	Cognitive Behaviour Therapy
CF	Consent Form
CI	Chief Investigator
CPS	Crown Prosecution Servicer
CSRI	Client Services Receipt Inventory
CRF	Case Report Form
DMC	Data Management Committee
DSUR	Development Safety Update Report
EQ-5D-5L	EuroQoL 5 dimension, 5 level questionnaire
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority
HSB	Harmful sexual behaviour
IC	Informed consent
ID	Intellectual Disability
IDD	Intellectual and/or developmental disabilities
IPA	Interpretative Phenomenological Analysis
ITT	Intention to Treat
NCTU	Norwich Clinical Trials Unit
PI	Principal Investigator
PID	Participant Identification Number
PIS	Participant Information Sheet
PROMS	Patient Reported Outcome Measures
QA	Quality Assurance
QACSO	Questionnaire on Attitudes Consistent with Sexual Offending
QC	Quality Control
QMMP	Quality Management and Monitoring Plan
RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
RM	Risk Management
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SOTSEC-ID	Sex Offenders Treatment Service Collaborative – Intellectual Disabilities
SSA	Site Specific Approval
TA	Thematic Analysis
TMF	Trial Master File
TMG	Trial Management Group
TMT	Trial Management Team
ToR	Terms of Reference
TSC	Trial Steering Committee
UEA	University of East Anglia
VES-A	Victim Empathy Scale - Adapted

4 Introduction

4.1 Background and Rationale

What is the problem being addressed?

There is widespread and well-recognised public concern about sexual offending, partly in the wake of scandals surrounding high profile individuals (such as Jimmy Saville), and partly because of the apparently poor treatment of victims by organisations as diverse as Social Services departments, the police and the church. Meanwhile, though the public are aware that most such offenders are men, they seem less aware of the possibilities of treatment for these offenders. However, there is a growing body of research, including randomized controlled trials, suggesting that group cognitive behavior therapy (CBT) for sex offenders is effective in reducing recidivism (Gannon et al, 2019). Nevertheless, men with intellectual and/or developmental disabilities (IDD – defined below) have been largely excluded from this research. In this project we will evaluate the effectiveness of this treatment for men with IDD who show harmful sexual behaviour (HSB). Not all of these men will have convictions for their behaviour because the police are often reluctant to charge men with IDD and the Crown Prosecution Servicer (CPS) is often unwilling to proceed to court.

Why is this research important to public/NHS?

Men who have IDD and HSB often do not receive treatment and so may continue to engage in harmful sexual behaviours, creating more victims. This project will investigate the effectiveness of the SOTSEC-ID intervention programme (Sex Offenders Treatment Service Collaborative – Intellectual Disabilities; see www.kent.ac.uk/tizard/sotsec), specifically designed for men with IDD and HSB. SOTSEC-ID was first developed about 20 years ago and has become internationally known. Training has been provided for over 700 therapists in its use, and this has included therapists in England, Wales, Eire, Switzerland, Spain, New Zealand and Japan. The programme is internationally known and probably the best researched programme in the world for men with IDD and HSB. It has already shown considerable promise in terms of outcome, including resulting in better sexual knowledge, better victim empathy, fewer cognitive distortions, and low rates of further HSB for treated men (Murphy et al, 2007b; SOTSEC-ID, 2010; Heaton & Murphy, 2013) but no controlled trials have been completed and the intervention is still not used widely in the UK

Typically, men with IDD and HSB receive one of three criminal justice/health outcomes: (a) conviction and a custodial sentence or (b) admission to a secure unit or (c) intensive risk management in the community. All three alternatives are expensive. Prison costs are over £35K annually per place (Ministry of Justice 2016); secure mental health NHS services often cost between £150-200k per bed annually (Department of Health, 2015) and very close risk management will often require constant supervision by staff, which is extremely costly.

In addition to the direct costs of care for perpetrators of HSB, there are also the outcomes for victims to be considered. Victims include children, and other people with intellectual disabilities

themselves, who sometimes share facilities with perpetrators (and, less often, victims may be non-disabled adults). Frequently, sexual abuse leads to poorer mental health, often life-long difficulties with close relationships, and extensive personal psychological trauma, resulting in greater health care needs and/or challenging behavior for victims with and without intellectual disabilities themselves (Murphy et al, 2007a; Rowsell et al, 2013). These increased care needs and mental health difficulties can be lifelong and result in huge human and financial costs.

Review of existing evidence

Research on treatment for non-disabled men who have HSB has been very extensive (see reviews Hanson et al, 2002; Aos et al, 2006; Kenworthy et al, 2006; Schmucker & Losel, 2015; Kim et al, 2016; Gannon et al, 2019) and has shown that CBT is effective in reducing re-offending. There is much less research for men with IDD. This may be because: (a) men with IDD and HSB are not always convicted (Green, 1992; Brown et al., 1995), (b) their offending is more hidden from view, often occurring in intellectual disabilities settings (Brown et al, 1995; McCarthy & Thompson, 1997), and (c) a belief that men with IDD may not benefit from psychological interventions (Bhaumik et al., 2008). Nevertheless, it is known that men with IDD are responsible for about half of the sexual abuse perpetrated against victims who themselves have IDD (44% in Sobsey & Doe, 1991; 53% in Brown et al., 1995). Estimates of the prevalence of such behaviour amongst men with IDD are in the region of 4% to 6% of men with IDD (Swanson & Garwick, 1990; Thompson & Brown, 1997).

As regards the form of treatment, group CBT has been favoured as the treatment of choice for non-disabled men with HSB and, although there have been some disagreements about the effectiveness of this therapy (Kenworthy et al. 2004; Marques et al., 2005; Dennis, 2012, Mews et al, 2017), meta-analyses have mostly provided encouraging results (Hanson et al. 2002; Craig et al 2003; Schmucker & Losel 2015; Kim et al, 2016; Gannon et al, 2019). In the most recent meta-analysis of CBT interventions for over 40,000 offenders (Gannon et al, 2019), the predictors of successful programmes were analysed. The factors related to successful treatment included the presence of a qualified psychologist as treatment provider (this has not been the model for treatment in prisons where prison staff are trained to provide a manualised intervention); group rather than individual treatment for the men; staff supervision; arousal conditioning and no use of polygraphs. The men treated in community settings also did better.

The intervention in this trial, SOTSEC-ID, includes four of these factors: a qualified psychologist delivering the treatment; group treatment (as opposed to individual treatment); with staff supervision; no polygraph use. Furthermore about 50% of participants are expected to be from community settings (as in SOTSEC-ID 2010), and none from prisons (where it seems some of the issues of ineffectiveness are at present, see Schmucker & Losel, 2017; Gannon et al, 2019).

As regards men with IDD and HSB, early studies of CBT mainly involved small case series (e.g. Lindsay & Smith, 1998; Lindsay et al. 1998; Rose et al. 2012; Murphy et al. 2007a) or uncontrolled modelling or feasibility trials (e.g. Bremble & Rose 1999; SOTSEC-ID, 2010). Several older reviews (e.g. Wilcox 2004; Craig & Hutchinson, 2005) and three recent reviews (Cohen & Harvey, 2016; Jones & Chaplin, 2017; Marotta, 2017) have since concluded that: (a) treatment with CBT for

these men was associated with positive outcomes, (b) longer follow-up periods were needed, and (c) proper randomisation was needed, since none of the studies reviewed had a randomised controlled trial design. Hence several researchers have recommended that it is time for a randomised controlled trial (Heaton & Murphy, 2013; Jones & Chaplin, 2017).

4.1.1 Explanation for choice of comparators

None of the research on the effectiveness of CBT for men with IDD and harmful sexual behaviours has included a control group, and there are no randomised controlled trials (RCTs). Therefore, we cannot be certain that CBT is effective for these men. The HaSB-IDD trial will be the first such RCT, with the experimental group receiving the SOTSEC-ID model of CBT across six months, alongside risk management, and the control group receiving treatment as usual (TAU), which will include risk management. Full details about the SOTSEC-ID treatment group and about TAU are given below.

4.2 Aims

We aim to determine whether the SOTSEC-ID group CBT programme, combined with risk management:

- reduces cognitive distortions in men with IDD and HSB,
- prevents or reduces their further harmful sexual behaviour, and
- improves their sexual knowledge, empathy, locus of control, and self-esteem,

in comparison to men in the control group receiving Treatment As Usual (TAU).

We also aim to examine the costs and cost effectiveness of this treatment, as well as examining therapist, carer and service user views of treatment (through smaller qualitative studies).

4.3 Trial Design

This is a single-blinded, cluster-randomised, controlled trial of a group CBT intervention and risk management (SOTSEC-ID), for men with intellectual and/or developmental disabilities and harmful sexual behaviours, delivered in the community or secure unit, and where the control is treatment as usual with risk management.

Our experience (based on our previous studies with SOTSEC-ID, see SOTSEC-ID, 2010 and Heaton & Murphy, 2013), is that each NHS Trust rarely has more than eight untreated eligible men at any one time, hence a parallel design would not be feasible. Further, and also based on our previous work, in such a design there is a risk of contamination, as once the intervention begins within an area, clinicians may augment their practice or resist allocating participants to a control arm, as they wish for them to receive treatment as quickly as possible. In order to counter some of these difficulties, a cluster randomised trial is more appropriate. Thirty sites will be recruited and they will be randomly allocated to receive either SOTSEC-ID treatment (with risk

management) **or** TAU (including risk management).

4.3.1 Internal Pilot Phase

A six month internal pilot has been designed to allow an assessment of stop/go criteria for progression to a full trial. At the end of pilot, a decision will be made by the funder, in consultation with the TSC and IDMC, on whether or not to proceed with the trial. Recruitment will continue (and those recruited will continue in the trial) while data on patients in the internal pilot are analysed and reviewed by the TSC and IDMC and a funder decision is obtained. As an internal pilot, all data collected on study participants will be included in the further analyses.

The objectives of the internal pilot phase (to be evaluated at the end of month 12 of the project) are to confirm feasibility of:

1. Site recruitment
2. Acceptability of site randomisation
3. Participant recruitment (5-10 per site)

The stop/go criteria are:

1. Site recruitment and set-up – 10 sites contracted, randomised and intervention programme or TAU set up by month 12.
2. At least 70% of eligible participants recruited to the study, with no site recruiting less than 5 men.

5.0 Study proposed

5.1 Site Selection

The trial sponsor has overall responsibility for site and investigator selection and has delegated this role to the CI.

5.1.1 Study Setting

The sites will be in community-based teams or in-patient health settings for people with intellectual disabilities, in 4 areas of the UK (North, Midlands, East Anglia, South East), including NHS, voluntary and private healthcare sector (including low or medium secure services). Social services may be involved in these teams but are not the lead providers of this treatment. Each area covers multiple teams and settings. We anticipate that some of these sites will involve Community Learning Disability Teams some low and medium secure services. We have extensive experience of running the intervention across a mix of settings including, in some groups, mixtures of legally restricted men and unrestricted men, in any one setting. High secure services, prisons and probationary services are excluded.

5.1.2 Site/Investigator Eligibility Criteria

Once a site has been assessed as being suitable to participate in the trial, the trial team will provide them with a copy of this protocol.

To participate in the HaSB-IDD trial, investigators and trial sites must fulfil a set of criteria that have been agreed by the HaSB-IDD Trial Management Group (TMG) and that are defined below. PIs in sites will be termed 'clinical PIs' to distinguish them from the academic PIs at University sites.

Eligibility criteria:

- A named clinician is willing and appropriate to take Clinical Principal Investigator responsibility
- Suitably trained staff are available to recruit participants and take consent, and provide the intervention (SOTSEC-ID or TAU)
- Sufficient clinical and/or forensic psychologists/psychiatrists, with at least 3 years experience in working with men with IDD, to lead the intervention (see section 6.1.2 for details)

Research assistants are available, and are permitted by the sites, to collect data from both suitable men and from their carers. Trial sites meeting eligibility criteria will be issued with the HaSB-IDD Site File and a pack of documentation needed by the Research and Development Department (R&D) of their Trust to enable the Trust to provide confirmation of capacity and capability to undertake the study.

5.1.2.1 Clinical Principal Investigator's (PI) Qualifications and Agreements

The investigator(s) must be willing to sign an investigator statement to comply with the trial protocol (confirming their specific roles and responsibilities relating to the trial, and that their site is willing and able to comply with the requirements of the trial). This includes confirmation of appropriate qualifications (HCPC registered clinical or forensic or counselling psychologist or psychiatrist), familiarity with the appropriate use of any investigational products, agreement to comply with the principles of GCP, to permit monitoring and audit as necessary at the site, and to maintain documented evidence of all staff at the site who have been delegated significant trial related duties.

5.1.2.2 Resourcing at site

The investigator(s) should be able to demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period (ie. the investigator(s) regularly treat(s) the target population). They should also have an adequate number of qualified staff and facilities available for the foreseen duration of the trial to enable them to conduct the trial properly and safely.

Sites will be expected to complete a delegation of responsibilities log and provide staff contact details.

5.2 Site approval and activation

On receipt of the signed investigator statement, approved delegation of responsibilities log and staff contact details, written confirmation will be sent to the site PI. The trial manager or delegate will notify the PI in writing of the plans for site initiation. Sites will not be permitted to recruit any patients until a letter for activation has been issued, following formal confirmation of capacity and capability in collaboration with the site. The Trial Manager or delegate will be responsible for issuing this letter after a green light to recruit participants has been completed.

The site must conduct the trial in compliance with the protocol as agreed by the Sponsor and HRA, and which was given favourable opinion by the Research Ethics Committee (REC). The PI or delegate must document and explain any deviation from the approved protocol, and communicate this to the trial managers at the Tizard Centre.

5.3 Participants

5.3.1 Eligibility Criteria

Men (18 years of age and over) with IDD, including an IQ below 80 and adaptive behaviour deficits, who have shown harmful sexual behavior in the last 5 years, irrespective of any conviction, will be invited to join the study, from the 4 areas of England and Wales (North, Midlands, East Anglia, South East).

Intellectual disabilities (ID) is defined internationally as an IQ below 70 and significant deficits in adaptive behavior. It used to be referred to as 'mental handicap' but more recently has been sometimes referred to in the UK as (pervasive) 'learning disabilities'. It is important to note that this is *not* the same as specific learning disabilities, e.g. dyslexia, where IQ is in the normal range. Many people with ID also have autism spectrum disorders and the term 'intellectual and/or developmental disabilities (IDD)' is widely used, to cover both. People with IDD in the UK receive services from Community Learning Disability Teams. These are provided for those with autism and intellectual disabilities, often including those with borderline disabilities (who have IQs 70-79), if they also have autism.

The men recruited for the trial will not necessarily have been convicted or even charged for sexual crimes, given the arbitrariness of police involvement for men with IDD, but there will need to be very good evidence from carers and case notes of harmful sexual behaviour. HSB will be defined as sexual behaviour in which the other person was not consenting (or was unable to consent), and the sexual behaviour would be defined as illegal (whether or not the police had been involved). Most men presenting for treatment in clinical services for this kind of behavior have a history of more than one incident. Incidents may not have been reported by the victim (who may be someone with more severe intellectual disabilities and may have very poor or no verbal communication skills). The incidents also may not have been reported to the police by professionals or someone in the community, because they realise the person has intellectual disabilities and they may think that they are not suitable to be dealt with by the Criminal Justice System.

It is anticipated that some men may be in low or medium secure health services, while some may be legally unrestricted, living in the community. Groups may include some or all of these categories (as was the case in SOTSEC-ID, 2010 and in Heaton and Murphy, 2013). It is likely that all men will also have family carers or paid carers who will be invited to take part in the research (see below for details). Men in prisons, on probation (with a sex offender treatment order) and in high secure services will be excluded. If men are imprisoned during the treatment trial (ie during the six months of treatment) they will discontinue in the treatment group but be included in the intention to treat analysis.

Men with autism will **not** be excluded as long as they also have mild or borderline ID. Though they may find group treatment difficult, the evidence is that many were included in previous group CBT research (e.g. SOTSEC-ID, 2010; Heaton & Murphy, 2013) and the men themselves

have said they found the treatment helpful (Melvin, Langdon & Murphy, 2019).

Some men engage in sexually harmful behaviour but have severe intellectual disabilities and extremely limited communication skills, and so would not be able to participate in CBT. Experience suggests that this is fewer than 20% of the total cohort of men with IDD and HSB, though there is no hard evidence to back this figure up. Experience has also shown that these men, with more severe intellectual disabilities, and very poor verbal skills, are unable to benefit from CBT once their verbal comprehension falls too low, so they will be excluded.

Carers: Most men will be living with family carers (typically parents) or with paid carers in residential homes or secure services. Occasionally men will be living in a flat alone but they will be receiving support from visiting paid carers. One carer (family member or paid carer) will be recruited for each man recruited. Their role will be to provide a historical and prospective record of the man's harmful sexual behaviour and of his resource use for the health economics data.

5.3.1.1 Participant selection

There will be **NO EXCEPTIONS** (waivers) to eligibility requirements at the time of recruitment. Questions about eligibility criteria should be addressed PRIOR to attempting to recruit the participant.

The eligibility criteria for this trial have been carefully considered and are the standards used to ensure that only appropriate participants are entered. Participants not meeting the criteria should not be entered into the trial for their safety and to ensure that the trial results can be appropriately used to make future treatment decisions for other people with similar diseases or conditions. It is therefore vital that exceptions are not made to these eligibility criteria.

Participants will be considered eligible for enrolment in this trial if they fulfil all the inclusion criteria and none of the exclusion criteria as defined below.

5.3.1.2 Participant Inclusion Criteria

Essential inclusion criteria for participating men are as follows:

a) Must be 18 years of age or over

b) Must have a borderline or mild intellectual disability (ie an IQ below 80) and deficits in adaptive behaviours, with or without autism

c) Must have a documented history of one or more incidents of Harmful Sexual Behaviour (HSB), within the last 5 years but need not have a conviction for HSB

d) Must have relatively good verbal comprehension (to be judged by clinicians).

e) Must have capacity to make a decision as to whether they wish to take part in trial.

In addition, some measures will involve the men's family carer or paid carer, depending on with whom he lives and who provides him with support. Provided the man with IDD agrees, the carer will also be asked for their informed consent.

5.3.1.3 Participant Exclusion Criteria

Exclusion criteria for the men are:

a) Severe mental health difficulties (chronic, debilitating, affecting cognitive functioning) that would prevent him from taking part in group CBT (as judged by clinicians)

b) Resident in prison or in high secure services, or on probation, with a sex offender treatment order

c) Has received cognitive behavior therapy for HSB in the preceding three years

5.3.1.4 Eligibility Criteria for Individuals Performing the Interventions

All sites will have suitably qualified, HCPC (Health & Care Professions Council) registered clinical and/or forensic psychologists, experienced in working with men with IDD, who will lead the SOTSEC-ID treatment group. Typically the treatment sessions are facilitated by one or more male and one or more female therapists (these rotate so there is always one male and one female therapist in each session wherever possible). Apart from the lead therapist, the others may be clinical or forensic psychologists or suitably qualified nurses or challenging behaviour specialists. All those providing the intervention will have been trained in the SOTSEC-ID model. This training involves three days of lectures, discussion and role play provided by the SOTSEC-ID trainers (see 6.4.1 for more details).

5.3.1.5 Screening Procedures and Pre-recruitment Investigations

Written informed consent to enter the trial must be obtained from participants after explanation of the aims, methods, benefits and potential hazards of the trial and **BEFORE** any trial-specific procedures. Where participants do not have a recent assessment for IQ, adaptive behaviour, in order to establish their eligibility to take part in the trial, these assessments will be carried out by the research team after the consent has been obtained. The assessment and recording of harmful sexual behaviour (obtained from the consenting carer), will only be collected following consent process. Any men found not to meet the trials eligibility criteria following these assessments will be excluded from the trial.

Written informed consent will be sought from both the men with HSB and the carer for each man. Participant information sheets for the men will be in Easy Read with pictures, and the clinicians taking consent will ensure the men understand the information, by explaining any difficult words. They will check the men understood by asking them to explain it back. This is a widely accepted practice in IDD services.

Carers will be assumed to have capacity to consent (as recommended in the Mental Capacity Act 2005). Their information sheets and consent forms will be in simple language and they will be able to ask the clinicians for explanations of anything about which they are unsure.

5.4 Interventions

In Arm A, participants will receive SOTSEC-ID group CBT and risk management. In Arm B, participants will receive Treatment As Usual (TAU), likely to be mainly risk management. See below for details.

5.4.1 Arm A - Intervention

The intervention we are proposing is a group CBT programme, known as SOTSEC-ID (Sex Offender Treatment Services Collaborative – Intellectual Disabilities) - see www.kent.ac.uk/tizard/sotsec, which was initially developed almost 20 years ago for men with IDD and HSB, and which has been increasingly adopted in England in health services for people with IDD. This intervention is well-established, and internationally known, with over 700 facilitators trained internationally. However, by no means all Trust in the UK offer such treatment for men with IDD and HSB. The second edition of the SOTSEC-ID treatment manual has just been completed and will be made available to all sites offering SOTSEC-ID treatment. The manual provides a session by session guide and is over 200 pages long (see Appendix for a brief summary of the contents of treatment). All therapists will receive free training in the SOTSEC-ID intervention. This is three days long and involves both didactic and practical training, including extensive role-play.

The intervention will be delivered to groups of participants (5 to 10 men per group), by therapists who have been trained in SOTSEC-ID. It is normal practice for services to maintain men with risk management until there are sufficient numbers to start a group: in a typical area of a Community Learning Disability Team (CLDT), with a general population 220,000, 2% of the population (i.e. 4,400) should have intellectual disabilities, and of these approx. 5% of the men (i.e. around 100) will have a history of current or past sexually harmful behaviour). Commonly, CLDT areas combine to provide such treatment (e.g. two or three boroughs will collaborate).

Treatment groups will last for six months (2 sessions each of 2 hrs per week, making 100 hours of treatment). In every group, each session will have two therapists present, and often services use a pool of three or four therapists who rotate on a weekly basis, in such a way that there is always some continuity from the previous session (therapists at each session will be recorded). The therapists will be led by a qualified HCPC registered clinical or forensic psychologist with CBT training or psychiatrist and other group facilitators may also be psychologists, or challenging behavior specialists or nurses, all of whom will have been trained in SOTSEC-ID and will have had some experience of CBT.

In treatment sessions, there will always be two therapists (in case one of the men in the group needs to leave and/or be escorted away). Of these therapists, one will be male and one female facilitator whenever possible (it is not always possible to guarantee this for 100% of sessions). Therapist supervision will be provided by an experienced practitioner (a long-term member of SOTSEC-ID), monthly during the treatment (in groups, by teleconferencing).

Typically, SOTSEC-ID has been delivered at a rate of one 2 hr session of treatment per week for the men, every week for a year (100 hrs of treatment). For this trial, however, we will offer twice-weekly sessions for six months; an equivalent number of treatment hours. Men who have completed SOTSEC-ID groups in the past were consulted about this change and thought that men would prefer it (as a year of treatment is a big commitment). Moreover the faster programme delivery is likely to be more attractive for services concerned about control groups

not receiving the treatment.

The SOTSEC-ID programme will thus consist of 50 sessions, each of 2 hrs in length. The sessions are arranged in six modules:

- Getting started: Group purpose; group rules; 'good lives'
- Sex education
- Cognitive model (thoughts, feelings and behaviour)
- Victim empathy
- The 4-stage model of sexual offending (thinking 'not OK' sexual thoughts; making excuses, victim blaming; planning it; doing it)
- Relapse prevention and 'Keeping Safe' plans.

Following the end of the 6 modules (after the twice weekly treatment groups), men meet for one 2hr session each six weeks, with therapists, to review (in their group) how their weeks have been going and to support the men to adhere to their 'Keeping Safe' plans.

In addition to the men's sessions, there are three sessions for carers (which run in parallel with the men's sessions) and are run by one of the therapists. There is one carer's session at the start of the intervention, one at mid-way and one at the end. This allows carers to understand the plan for the men's treatment and to be able to support the men outside their sessions.

Men will also receive risk management (RM) which typically consists of environmental adjustments, designed individually for each man, to lower his risk of re-offending. Examples of the kinds of adjustments include: ensuring the participant is accompanied by staff when out in the community; reducing the likelihood of him meeting vulnerable people who could be potential victims; avoiding various settings in the community (e.g. schools, day services). For men in secure services, these restrictions can be enforced but for men who are not legally restricted they have to remain voluntary. Research assistants will collect data to provide a thorough description of the RM element for each man, including data on the extent to which the men stick to their risk management strategies (from self-report and staff/carer report).

It is important to note that all NHS Trusts and independent health settings have risk management policies that they apply for all service users with risky behaviour, whether or not they are involved in treatment trials. Both the TAU group (see below) and the intervention group will receive risk management, according to the local policies. For the intervention group these are likely to be much better informed and targeted since, as part of the intervention, the specific risky settings and/or dynamic risk factors for the men emerge, and they will inform part of their risk management plans.

5.4.2 Arm B – Usual Care

Given that we propose a cluster randomised design, some sites will be randomly allocated to receive Treatment as Usual (TAU) only. In our experience, TAU may consist of medical interventions (such as anti-androgens or anti-psychotics, though these are rarely used nowadays), nurse-delivered interventions, or counselling and risk management. Typically, the

latter involves environmental adjustments (for example, being asked not to go out except with staff, being asked not to walk past schools where vulnerable children might be seen, or being asked not to attend day services with vulnerable individuals, etc). These restrictions normally form part of an individualised risk management strategy. Those in the TAU groups will not receive individual or group CBT interventions targeting their sexual behavior (this includes no sex education). They may receive counselling and behavioural interventions in relation to other issues (for example anger management), and associated risk management. We will collect data to provide a thorough description of TAU within this trial, using a proforma to record treatments received and risk management details.

5.4.3 Fidelity

Sites will record location and duration of each session, therapists present at each session, participants present, participants who DNA. Fidelity will be established by video-recording treatment sessions. Where participants do not consent to video recording, we would seek to audio-record the sessions, if consent for audio-recording is not given the session will not be recorded. For each treatment site, one session chosen at random in each of the CBT's six modules, with experienced clinicians rating fidelity using a pre-defined rating scale (similar to that used in the anger management trail, Jahoda et al. 2013).

5.4.4 Compliance, Adherence and Acceptability

A treatment manual will be provided for all sites running the SOTSEC-ID intervention. This is lengthy (over 200 pages) and detailed. Supervision of therapists will be provided on a monthly basis and fidelity will be checked (see above). Participants' attendance at treatment sessions will be monitored.

Acceptability will be investigated by qualitative post treatment interviews with participants and therapists.

5.4.5 Concomitant Care

All patients will receive treatment as usual for their other difficulties (i.e. those not related to harmful sexual behaviours) regardless of entry into this trial. Data about concomitant care will be collected as part of the health economics evaluation, on a proforma.

5.4.6 Protocol Treatment Discontinuation

In consenting to the trial, participants are consenting to trial treatment, trial follow-up and data collection. However, an individual participant may stop treatment early or be stopped early for any of the following reasons:

- Unacceptable adverse event, such as imprisonment
- Inter-current illness that prevents further treatment
- Any change in the participant's condition that in the clinician's opinion justifies the discontinuation of treatment such as deterioration in mental health where this is severe and debilitating
- Withdrawal of consent for treatment by the participant

As participation in the trial is entirely voluntary, the participant may choose to discontinue trial treatment at any time without penalty or loss of benefits to which they would otherwise be entitled. Although not obliged to give a reason for discontinuing their trial treatment, a reasonable effort will be made to establish this reason, whilst remaining fully respectful of the participant's rights.

Participants who discontinue protocol treatment, for any of the above reasons, should remain in the trial for the purpose of follow up and data analysis where possible.

5.5 Outcomes

Following the baseline assessment (Time 1), participants will be assessed at six-months post-baseline (Time 2), and then again at both 12-months post baseline (Time 3), and 24-months post-baseline (Time 4) - see flow chart.

5.5.1 Primary Outcomes

The primary outcome measure will be the score on the Questionnaire on Attitudes Consistent with Sexual Offending (QACSO, Broxholme & Lindsay, 2003; Lindsay et al 2006; Lindsay et al, 2007) at 12 months post-baseline (i.e. Time 3).

It might be thought desirable to use further harmful sexual behaviour as the primary outcome measure. However, the trial is relatively short, with only a two-year follow-up, and such behaviours are rare. It has therefore been decided that the primary outcome measure will be the QACSO, a well-validated measure of cognitive distortions for use with men who have IDD (see below for details). A recent review has reported that treatment programmes of the SOTSEC-ID type for men with IDD and HSB produce considerable change in cognitive distortions, with a large effect size (Patterson, 2018). Furthermore, a review by Hammond and Beail (2020) of the relationship between behaviour and cognitions in people with IDD has concluded that there is good evidence that for, sex offenders with IDD, cognitions and behaviour are related such that the QACSO is an appropriate measure.

The QACSO was developed by Bill Lindsay and colleagues in the early 2000s for the precise purpose of measuring cognitive distortions in men with intellectual disabilities who had engaged in harmful sexual behaviour (Broxholme & Lindsay, 2003; Lindsay et al 2006; Lindsay et al, 2007). It has been accepted since the late 1980s that non-disabled sex offenders engage in cognitive distortions, i.e. offence-supportive beliefs, and that these worsen as their offending continues. Moreover, there is ample evidence than non-offending men do not share these beliefs and it has long been argued that altering these beliefs is a central task in treatment. There is considerable evidence that treatment results in a reduction in these beliefs alongside reduced offending for men without disabilities (see review by Ward et al., 1997), as would be predicted by the cognitive behavioural model.

Similar evidence exists for men with IDD who have harmful sexual behaviour, most of this

evidence being based on findings using the QACSO as the measure of cognitive distortions. The QACSO is completed directly with the men; it has over 60 items and assesses cognitive distortions across seven different offence types: rape; voyeurism; exhibitionism; dating abuse; homosexual assault; paedophilia; stalking and sexual harassment. The QACSO discriminates well between sexual offenders and non-offenders with intellectual disabilities, and the sub-scales differentiate men with different offence types (Lindsay et al 2006). It has good levels of test-retest reliability (Broxholme & Lindsay 2003) and other psychometric properties (Keeling et al, 2007) and has been very widely used in research on sexual offending in men with intellectual disabilities (Murphy et al, 2007; Langdon et al, 2007; Rose et al 2012; SOTSEC-ID 2010; Heaton & Murphy, 2013), the evidence being that the men's cognitive distortions reduce with treatment alongside their reduced offending.

5.5.2 Secondary Outcomes

Secondary outcome measures will be undertaken at baseline, 6, 12 and 24 months post baseline. Most of these measures will be completed with the men themselves, and some will be completed with their carers (see Table below). The measures are as follows:

5.5.2.1 Clinical outcome measures

QACSO score (only at 6 and 24 months post-baseline).

Sexual knowledge scores, victim empathy scores, locus of control and self-esteem at 6 months, 12 months and 24 months post baseline, using the following questionnaires:

General Sexual Knowledge Questionnaire (GSKQ): It is known that men with IDD have less sexual knowledge than men without disabilities, and previous studies have shown their knowledge increases with SOTSEC-ID treatment (SOTSEC-ID, 2010; Heaton & Murphy, 2013). Sexual knowledge will be measured on the GSK, developed by Talbot & Langdon (2006). This was designed for men with intellectual disabilities and has good internal consistency and split-half reliability. There are 63 items, covering physiology (with pictures), sexual intercourse, pregnancy, contraception, sexually transmitted diseases and sexuality. The maximum score is 110, with men with ID scoring around a mean of 45, allowing sufficient room for improvement.

Victim Empathy Scale-Adapted, (VES-A), was adapted for men with IDD from Beckett and Fisher's Victim Empathy Scale (Beckett and Fisher, 1994) for men without intellectual disabilities who had committed sexual offences (Keeling, Rose & Beech, 2007; Murphy et al, 2007). The original scale was already relatively accessible, so few changes were needed: the wording was simplified in places and a visual analogue was added to assist in the response scale. The resultant measure has 30 statements asking men how they felt and how their victim felt in various ways, in relation to the man's own offence. The responses are ratings of degree of agreement or disagreement on a four point scale. Lower scores indicated better empathy. For this adapted measure, which has been widely used for men with intellectual disabilities and harmful sexual behavior (Murphy et al 2007; SOTSEC-ID 2010; Heaton & Murphy, 2013; Langdon et al, 2007;

Rose et al 2002), Cronbach's alpha was 0.91 (Langdon et al 2007).

Nowicki-Strickland Locus of Control Scale (Nowicki, 1976): the intervention is intended, in part, to help the men understand their own responsibility in their offending (so that they do not simply blame it on their victims). Several previous studies have employed a measure of locus of control, the validated Nowicki-Strickland Locus of Control Scale in recognition of this issue (eg Rose et al 2002; Rose et al, 2012).

Self-Esteem: for the men themselves, it is important to assist them to maintain their own self-esteem, which is often very low, at the start of treatment. At times, the intervention may threaten their self-esteem, partly because it helps them understand their responsibility for their behavior. At other points the intervention will help them build their self-esteem, by recognizing how they are progressing towards 'good lives'. It is known that self-esteem correlates with good mental health so it is important to be sure that overall self-esteem rises with treatment, rather than falls, and for this reason a well-established measure of self-esteem adapted for people with IDD and with good psychometric properties (Dagnan & Sandhu, 1999; Keeling et al, 2007) will also be used at all time points.

Harmful Sexual Behaviour Schedule : Incidences of harmful sexual behavior that have occurred during the 6 months prior to baseline, and then between baseline and 6 months, 6 and 12 months and 12 and 24 months will be recorded at baseline, 6, 12 and 24 month follow-up time points, respectively, using information from patient and carer report, case notes, police interviews, court appearances, and court convictions. Research assistants will report such incidents to the local clinician. Clinicians/professionals working with the participants have a responsibility and duty of care to report any safeguarding concerns or crimes, including sexual abuse, to the relevant authoritative body (local Safeguarding Board), when they are made aware of these during the trial.

5.5.2.2 Heath Economic Outcome Measures:

Client Services Receipt Inventory (CSRI): Use of health, social and CJS resources used by participants will be collected from routine records where possible, supplemented by use of a modified CSRI with participants and their carers; this will allow the cost of service use to be estimated.

The EuroQol quality of life measure, EQ-5D-5L, a validated quality of life measure comprising of five questions or dimensions and a visual analogue scale will be completed to evaluate changes in quality of life.

5.5.3 Qualitative Study/Process Evaluation

A purposive sample of patients, therapists and carers (who provide support to the participants but are not directly involved in the intervention), will be interviewed about their experiences of the SOTSEC-ID groups and how the experience has made an impact: these data will be analysed qualitatively using Interpretive Phenomenological Analysis (IPA) or Thematic Analysis (TA) (see

below). Some interviews of patients, therapists and carers may be conducted online, using web-based meeting platforms. Where interview participants do not wish to be video recorded, they can switch off their cameras.

a) Service Users
A sample of service users (and their carers, see below) will be interviewed after the intervention to gain an understanding of their experiences of participating. This part of the research is not hypothesis driven but aims to gain an 'insider's perspective' from which a theoretical framework regarding the subjective experiences of service users can be developed. The chosen analysis for this data is Interpretative Phenomenological Analysis (IPA). IPA attempts to reduce the complexity of experiential data through vigorous and systematic analysis in a transparent and plausible manner (Smith, 1996). It has a specific psychological focus and is suitable for data collected from relatively less articulate/forthcoming participants (Rose et al, 2019). A small number of participants is required: about one service user will be randomly sampled from each of the participating intervention groups (so that we achieve up to N=15).

b) Therapists
One, randomly selected, therapist from each group (approximately N=15) will be invited to participate post-intervention in order to investigate their experiences of the groups, and their impressions of the 'climate' within the group and the impact of the group on the wider service. The focus of this evaluation is on the therapists' personal, subjective experiences and therefore IPA will again be utilised as the most appropriate qualitative analysis. Both service user and therapist interviews will be conducted according to a semi-structured interview schedule, containing questions which encourage the participants to focus on 'personal meaning' and making sense of their experiences of the therapeutic process.

c) Carers
A sample of carers including the participants' key workers who work in the residential services where participants live, or care co-ordinators of the participants who have responsibility for managing the care of participants will be interviewed post intervention (approximately N=15). They will be asked to reflect on any changes they may have observed within individuals who they know have participated in the group. They will also be asked about the broader impact of changes observed in individuals such as in social relationships within residential and community settings. It seems likely that carers will not have such an in depth knowledge of the experience of the group. As a result it is suggested that thematic analysis is used to analyse the data from these interviews.

These studies of process will help identify which elements of the treatment package seem to have had a particular influence on individuals and may enable us to refine future versions of the intervention.

5.6 Participant Timeline

Time 1 in the table below is the baseline; Time 2 is six months later; Time 3 is 12 months after baseline; Time 4 is 24 months after baseline.

Procedure	Who with?	Screen-ing	Time 1 Baseline		Time 2 Month 6	Time 3 Month 12	Time 4 Month 24
Consent	Man with IDD and carer	+		Alloc-ation of sites to groups and then Inter-vention			
WASI	Man with IDD	+					
ABAS	Carer	+					
QACSO	Man with IDD		+		+	+	+
Record of harmful sexual behavior	Carer & case notes		+		+	+	+
Sexual knowledge	Man with IDD		+		+	+	+
Victim empathy (VES-A)	Man with IDD		+		+	+	+
Self esteem	Man with IDD		+		+	+	+
Locus of control	Man with IDD		+		+	+	+
Modified CSRI	Carer & case notes		+		+	+	+
EQ-5D-5L	Man with IDD		+		+	+	+

5.6.1 Participant Assessments

Participants' assessments will take place in their Community Team offices or in the secure unit, if they are detained there. They will be told they may bring a carer if they wish (family carer or paid carer). In our experience most men will wish to do this, as they are frequently anxious about meeting new people (in this case the research assistant). Typically the men will ask the carer to stay

for a bit, while they get comfortable with the setting and RA, and then the carer is usually able to wait outside in the waiting room. In some cases it may be necessary to conduct assessments using a web-based meeting platform (for example in the event of further restrictions due to Covid-19), though this would not be routinely offered. The men can have a carer present with them if they need support to access the web-based meeting and for other support.

The assessments on time 1, 2, 3, and 4 will take between 1 and 1.5 hours. Some men will want to do these without stopping. Some will want breaks. It will made clear to them that they may have breaks if they wish. It is anticipated that, if accompanied by a carer, it will be possible to complete the carer assessments (see Table above) after seeing each man, while the man, in turn, waits in the waiting room. Assessments are anticipated to take approximately an hour, although where short breaks are required, they make longer; they will still be completed within one day.

Research Assistants are expected to comply with local safeguarding procedures and risk assessments when undertaking assessments and interviews.

5.6.2 Early Stopping of Follow-up

If a participant chooses to discontinue their trial treatment, they should continue to be followed up as closely as possible to the follow-up schedule defined in the protocol, providing they are willing. They should be encouraged and facilitated not to leave the whole trial, even though they no longer engage in the trial treatment. If, however, the participant exercises the view that they no longer wish to be followed up, this view must be respected and the participant withdrawn entirely from the trial. University of Kent and NCTU should be informed of the withdrawal in writing using the appropriate HASB-IDD trial documentation. Data already collected will be kept and included in analyses according to the intention-to-treat principle for all participants who stop follow up early.

Participants who stop trial follow-up early will not be replaced.

5.6.3 Participant Transfers

If a participant moves from the area, making continued follow up at their consenting centre inappropriate, every effort should be made for them to be followed-up at another participating trial centre. Written informed consent should be taken at the new centre and then a copy of the participant's CRFs should be provided to the new centre. Responsibility for the participant remains with the original consenting centre until the new consent process is complete.

5.6.4 Loss to Follow-up

Where participants are lost to follow-up every effort will be made to trace their whereabouts. In our experience men with IDD and harmful sexual behaviour are very rarely lost to follow-up since they are usually on the sex offender register.

5.6.5 Trial Closure

The end of the trial is defined as 9 months following the last follow-up visit of the last patient randomised, to allow for data entry and data cleaning activities to be completed.

5.7 Sample Size

In our previous (as yet unpublished) single group study, of 109 participants, the magnitude of change following treatment in the primary outcome measure, the QACSO, was 22.5 (SD = 24), and the observed ICC was 0.15. Assuming a similar change in the intervention group in this new study and a change of no more than one fifth of this in the controls (it is unlikely to be greater given the lack of CBT intervention in this group directed at sexual behaviour), we would expect a mean difference of around 18 units in the QACSO between the two groups. This led to a proposed sample size of 164 in our first Stage 2 submission to NIHR. However, this was considered by the HTA panel to be relying on too large an expected effect size, i.e. one of 0.75 standard deviations, and consequently running the risk of an inflated Type II error. We have, therefore, revised our calculations considering smaller effect sizes. We now propose using 30 sites and a total target sample size of 240. Under the same assumptions (ICC = 0.15 and an attrition rate of 20%), this would provide statistical power of 90% for an effect size of 0.607 and 80% for an effect size of 0.525. These would translate into 14.5 and 12.6 units difference on the QASCO. In our experience in our previous studies, attrition is less than 20% and, we believe the risk of a Type II is now well mitigated against.

5.8 Recruitment and Retention

5.8.1 Recruitment

Participants will be recruited in 4 areas of England and Wales (North, Midlands, East, South East) and this will be facilitated by the PIs on the grant, one of whom is in the North (JT), one in the South East (AI), two in the Midlands (JR & PL), one of whom also has very good contacts in the East (PL). All the PIs have excellent contact with local Community Learning Disability Teams, low secure and medium secure units. This recruitment will also be facilitated by the SOTSEC-ID group, who have a record of who has been trained in SOTSEC-ID (those trained become SOTSEC-ID members). All members will be contacted and told about the trial and asked if their site would like to take part. Where further training is needed, this will be offered for free as an incentive to participate, if there are insufficient therapists already trained in SOTSEC-ID when the trial starts. In addition, the Kent, Surrey and East Sussex CRN will promote recruitment through their NHS Trust contacts. We have 20 Trusts wishing to take part (June 2021).

5.8.2 Retention

Men will be encouraged to stay in the trial, through to the end of the trial. They will receive a £10 voucher to reward them for their effort and time, at each assessment. They will also receive letters from the trial staff thanking them for their help at the four time points (see Table). In our experience men with IDD really appreciate such letters as correspondence, thanking them, is rare in their lives.

5.9 Assignment of Intervention

The trial is a cluster-randomised controlled trial.

5.9.1 Allocation

5.9.1.1 Sequence generation -

Participating sites will be randomly allocated to either the group CBT programme or treatment as usual with a 1:1 ratio of allocation. Allocation will occur after site eligibility has been established and in two tranches: the first 10 sites will comprise the pilot phase, the remaining 20 will be allocated after month 13. Sites will be randomly allocated instantaneously, 5 in each group for the pilot, and 10 to each group for the remaining trial period. Random allocation will be the responsibility of Norwich CTU. The staff responsible will be blinded to site identity.

5.9.1.2 Allocation concealment mechanism

As allocation will be instantaneous, a random sequence will be generated, using a small block length given the small sample size. The sequence will be generated by a member of the Norwich CTU data management staff.

5.9.1.3 Allocation Implementation

After the instantaneous randomisation, the allocation of each site will be communicated to the trial manager, who will communicate directly with the study sites. This allocation will not be communicated to other research team members.

5.9.2 Blinding

All researchers collecting data will be blinded to treatment arm allocation. The Chief Investigator will not be blinded. The trial manager, the local site PIs and treating therapists cannot be blinded.

5.10 Data Collection, Management and Analysis

5.10.1 Data Collection Methods

Each participant will be given a unique trial Participant Identification Number (PID). Data will be collected at the time-points indicated in the Trial Schedule.

The preferred method of data collection is direct online entry of data onto the central database, stored on servers based at NCTU by members of the HaSB-IDD trial team working within each research site. Data may be entered onto paper Case Record Forms (CRFs) prior to entry onto the database (but this is not an essential step). Staff will receive training on data collection and use of the online system (see Section 5.2).

Data collection, data entry and queries raised by a member of the HaSB-IDD trial team will be conducted in line with the NCTU and trial specific Data Management Standard Operating Procedure.

Identification logs, screening logs and enrolment logs will be kept on a secure database at NCTU. Minimal participant identifiable data will be stored on the database in the study for the purposes of

contacting participants. There will be a clear logical separation of participant identifiable data from the trial data.

All data will be handled in accordance with the Data Protection Act 2018.

5.10.2 Data Management

Data will be entered under the participants PID number onto the central database stored on the servers based at NCTU. Access to the database will be via unique, individually assigned (i.e. not generic) usernames and passwords, and only accessible to members of the HASB-IDD trial team at NCTU, and external regulators if requested. The servers are protected by firewalls and are patched and maintained according to best practice. The physical location of the servers is protected physically and environmentally in accordance with University of East Anglia's General Information Security Policy 3 (GISP3: Physical and environmental security).

The database and associated code will be developed by NCTU Data Management, in conjunction with the HASB-IDD trial team. The database software provides a number of features to help maintain data quality, including; maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure/ missing data.

After completion of the trial the database will be retained on the servers of NCTU for on-going analysis of secondary outcomes, and prepared for archiving in accordance with NCTU archiving guidance. The trial database will be archived according to Sponsor SOPs, or according to NCTU archiving guidance, where a Sponsor SOP doesn't exist.

The identification, screening and enrolment logs, linking participant identifiable data to the pseudoanonymised PID, will be held locally by the trial site. This will either be held in written form in a locked filing cabinet or electronically in password protected form on NHS/secure service computers. After completion of the trial the identification, screening and enrolment logs will be stored securely by the sites for 5 years unless otherwise advised by NCTU.

5.10.3 Non-Adherence and Non-Retention

No participant will be excluded on the basis of non-adherence to therapy according to the treatment arm. Any participant withdrawing from therapy will remain within the trial, unless wishing to withdraw, and all efforts will be made to collect study data.

5.10.4 Statistical Methods

5.10.4.1 Outcomes

The primary outcome measure will be the Questionnaire on Attitudes Consistent with Sexual Offending (QACSO) score. Secondary outcome measures are the further occurrences of harmful sexual behaviour, sexual knowledge scores, victim empathy scores, locus of control and self-esteem scores. The EQ-5D-5L will also be completed for health economics purposes. These measures at baselines, 6 months, 12 months and 24 months will be captured using the same instruments (see Table page 26).

The primary efficacy analysis will be of the QACSO at 12 months. A general linear model with baseline QACSO as a covariate will be used as the primary means of analysis. Allocated treatment group will be

included as a fixed effect. Due to randomisation being at the site level, rather than the individual level, generalised estimating equations (GEEs) will be used for parameter estimation to adjust for correlations between participants within sites. All estimates will be provided with 95% confidence intervals. Additional prognostic variables will be included in the analytical model as specified prior to any analysis, in the statistical analysis plan. Statistical significance will be set at the two-sided 5% level. All secondary outcomes will be analysed in an analogous manner.

5.10.4.2 Statistical Analysis Plan

Following Norwich CTU guidelines, we will produce a detailed statistical plan (SAP) before the end of data collection and ask for approval from data oversight committees. The SAP will follow guidance provided by Gamble et al (2017).

5.10.4.3 Additional Analyses

Currently no additional analyses (either formal interim analyses or subgroup analyses) have been planned. Any additional formal analyses will need to be pre-specified in the statistical analysis plan prior to any formal analyses.

5.10.4.4 Analysis Population

The efficacy analysis will be on the Intention-to-Treat population, consisting of all individuals randomised to the study, analysed according to the arm to which they were allocated, irrespective of the treatment received

5.10.4.5 Missing Data

The primary analysis will consist of complete cases, i.e. those with complete data available for the analytic model. Where the number of participants with missing data excluding analysis is deemed non-trivial (more than 5% and less than 50%), a formal imputation approach will be used. This will involve multiple imputation using an imputation model that will include, as a minimum, the variables included in the analytical model.

5.10.5 Economic evaluations

We will conduct an economic evaluation alongside the clinical trial from the perspective of NHS and social services. Additionally, we will collect information on other relevant resource use (e.g. use of the criminal justice system) to enable a broader social perspective to be estimated. The economic analyses will compare the SOTSEC-ID intervention to the TAU group, using two different outcome measures. The first and main health economic analysis will be a cost-utility study. We will estimate quality adjusted life years (QALYs), estimated using the EQ-5D-5L. The EQ-5D-5L will be obtained from participant self-report at baseline, 6-months, 12, months, and 24 months. QALYs will be estimated using the 'area under the curve' method assuming straight line interpolation between observations. In the second analysis, we will estimate cost-effectiveness using the primary outcome measure, QACSO, and will estimate the cost per one-point improvement in the QACSO. The time frame of the analysis will be the same as the clinical trial, i.e., 2-years. We will perform a 'within-trial' analysis. As the trial has a duration of more than 1-year we will follow national guidance on

discounting to allow for the differential weighting of costs and benefits in different time periods (NICE guidelines).

One important output of the trial will be an estimate of the costs required to provide the SOTSEC-ID intervention. This will comprise the following key components. Firstly, the SOTSEC-ID requires a 3-day training course. We will record all attendance by staff at this training to estimate staff time required. Additionally, details of staff required to provide the training will be recorded, as well as details of any consumables. Secondly, a record will be kept of the group CBT sessions provided. This will include attendance so that average numbers attending and hence a cost per attendance can be calculated. A record will be kept of the staff providing the intervention. Details will be recorded of the staff type in attendance, and, if possible, the agenda for change (AfC) band of these health care professionals. We will also ask staff to estimate any travel time required to provide the sessions. Sessions would typically be 2-hours long and there would be 50 sessions in total. Thirdly, details will be collected of the 3 sessions with the participant's carer. Again, staff required to provide these sessions will be recorded. Fourthly, after the conclusion of the intervention participants will receive 6-weekly follow-up sessions. Again, attendance and staff required to provide these sessions will be recorded.

In addition to the resources described above we will additionally record health and social care provided in order to have an estimate of the cost of health and social care of the two study groups. This will also quantify what represents TAU in the control group. As this is a pragmatic cluster randomised trial, TAU may vary between sites included in the study. Relevant resource use will be collected using two broad sources: 1) via a modified Client Services Receipt Inventory (CSRI); 2) completing a suitable case report form (CRF) based on consulting the man's notes and records. Both sources ask about use of the same resources (with some tailoring to reflect collection method).. The CSRI will be completed by means of a face-to-face interview, ideally including the participant themselves, along with a family or professional carer.. These two data sources also include relevant resource use outside the health and social care sector: for example, contacts with the criminal justice system. All resources identified will be costed using appropriate unit cost data, for example the NHS reference costs (National Cost Collection for the NHS. NHS. Accessed at: NHS England » National Cost Collection for the NHS) and Unit Costs of Health and Social Care (PSSRU, https://doi.org/10.22024/UniKent/01.02.84818). We will use the most up to date available unit cost data at the time of analysis.

5.10.5.1 Health Economic Analysis Plan

In accordance with NCTU practice we will draft a health economic analysis plan (HEAP) prior to conducting the economic analysis. This will be shared and discussed with members of the TMG and other key personnel before analysis is undertaken.

5.10.5.2 Within-trial analysis

The analysis will adopt a 'within trial' approach, i.e., up to the two-year follow-up point of the clinical trial. In line with the statistical analysis we will analyse patterns of missing data, and where appropriate, multiple imputation will be used to impute data. Decisions relating to the treatment of missing data will be made in consultation with the study CI and statistician. If data is imputed then results will be presented for both the imputed data as well as a complete case analysis (CCA). Data will

be analysed on an intention to treat basis. Costs and effects will be analysed using regression-based methods to allow for any differences in baseline characteristics (mindful of the prognostic variables identified and used in the SAP). Incremental costs and effects will be reported. Additionally, if one group is more costly and more effective than the other, we will report incremental cost-effectiveness ratios (ICERs). Non-parametric bootstrapping will be used to analyse uncertainty. Uncertainty inherent in the data will be represented by means of a cost-effectiveness acceptability curve (CEAC). Analyses will be performed in a variety of packages, these are likely to include: MS Excel SPSS; R; and STATA.

5.11 Data Monitoring

5.11.1 Data Monitoring Committee

Further details of the roles and responsibilities of the Data Monitoring Committee (DMC), including membership, relationships with other committees, decision making processes, and the timing and frequency of interim analyses (and description of stopping rules and/or guidelines where applicable) are described in detail in the HASB-IDD DMC Terms of Reference (ToR).

5.11.2 Interim Analyses

No formal interim data analyses are planned. All analyses for the Data Monitoring Committee will be descriptive in nature rather than inferential. The DMC may, however, require formal interim analyses be conducted when necessary. Any such analyses will be described in writing and agreed with the DMC before being conducted.

5.11.3 Data Monitoring for Harm

Adverse events (AEs) and Serious Adverse Events will not be collected in this trial. Instead, incidences of harmful behaviour will be collected at each time point, using the Harmful Behaviour Schedule. Incidences will be reviewed cumulatively by the DMC over the duration of the trial. As incidences of harmful behaviour are recorded retrospectively at baseline, 6, 12 and 24 months , it is not possible for researchers to act upon the information received or indeed to influence the outcome of the incident. As such, the Trial team are not responsible for following up on any events.

Carers will be required to notify social workers and police, where necessary, where the incidences warrant it.

5.11.3.6.2 NCTU responsibilities

It is the responsibility of the CI to keep NCTU informed, and NCTU will keep investigators informed, of any safety issues that arise during the course of the trial.

5.11.4 Quality Assurance and Control

5.11.4.1 Risk Assessment

The Quality Assurance (QA) and Quality Control (QC) considerations for the HaSB-IDD trial are based on the standard NCTU Quality Management Policy that includes a formal Risk Assessment, and that acknowledges the risks associated with the conduct of the trial and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on: the rights

and safety of participants; project concept including trial design, reliability of results and institutional risk; project management; and other considerations.

QA is defined as all the planned and systematic actions established to ensure the trial is performed and data generated, documented and/or recorded and reported in compliance with the principles of GCP and applicable regulatory requirements. QC is defined as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the trial related activities are fulfilled.

5.11.4.2 Central Monitoring at NCTU

NCTU staff will review Case Report Form (CRF) data for errors and missing key data points. The trial database will also include reports on errors and error rates that, subject to permissions, can be run by members of the trial team. Essential trial issues, events and outputs, including defined key data points, will be detailed in the HaSB-IDD trial Data Management Plan.

5.11.4.3 On-site Monitoring

Centralised and triggered on-site monitoring only will be detailed in the HaSB-IDD Quality Management and Monitoring Plan (QMMP). The QMMP will also detail the procedures for review and sign-off of monitoring reports. In the event of a request for a trial site inspection by any regulatory authority, NCTU must be notified as soon as possible.

5.11.4.3.1 Direct access to participant records

Participating investigators must agree to allow trial related monitoring, including audits, REC review and regulatory inspections, by providing access to source data and other trial related documentation as required. Participant consent for this must be obtained as part of the informed consent process for the trial.

5.11.4.4 Trial Oversight

Trial oversight is intended to preserve the integrity of the trial by independently verifying a variety of processes and prompting corrective action where necessary. The processes reviewed relate to participant enrolment, consent, eligibility, and allocation to trial groups; adherence to trial interventions and policies to protect participants, including reporting of harms; completeness, accuracy and timeliness of data collection; and will verify adherence to applicable policies detailed in the Compliance section of the protocol. Independent trial oversight complies with the NCTU trial oversight policy.

In multi-centre trials this oversight is considered and described both overall and for each recruiting centre by exploring the trial dataset or performing site visits as described in the HaSB-IDD Quality Management and Monitoring Plan.

5.11.4.4.1 Trial Management Team

The Trial Management Team (TMT) will be set up to assist with developing the design, co-ordination and day to day operational issues in the management of the trial, including budget management. The membership, frequency of meetings, activity (including trial conduct and data review) and authority will be covered in the TMT terms of reference.

5.11.4.4.2 Trial Management Group

A Trial Management Group (TMG) will be set up to assist with developing the design, co-ordination and strategic management of the trial. The membership, frequency of meetings, activity (including trial conduct and data review) and authority will be covered in the TMG terms of reference.

5.11.4.4.3 Independent Trial Steering Committee

The Independent Trial Steering Committee (TSC) is the independent group responsible for oversight of the trial in order to safeguard the interests of trial participants. The TSC provides advice to the CI, NCTU, the funder and sponsor on all aspects of the trial through its independent Chair. The membership, frequency of meetings, activity (including trial conduct and data review) and authority will be covered in the TSC terms of reference.

5.11.4.4.4 Independent Data Monitoring Committee

The Independent Data Monitoring Committee (IDMC) is the only oversight body that has access to unblinded accumulating comparative data. The IDMC is responsible for safeguarding the interests of trial participants, monitoring the accumulating data and making recommendations to the TSC on whether the trial should continue as planned. The membership, frequency of meetings, activity (including review of trial conduct and data) and authority will be covered in the IDMC terms of reference. The IDMC will consider data in accordance with the statistical analysis plan and will advise the TSC through its Chair.

5.11.4.4.5 Trial Sponsor

The University of Kent is the trial sponsor. The role of the sponsor is to take on responsibility for securing the arrangements to initiate, manage and finance the trial. The Sponsor is responsible for ensuring that the study meets the relevant standards, and makes sure that arrangements are put and kept in place for management, monitoring and reporting. The University of Kent has delegated some Sponsor's activities to the CI and NCTU.

6 Ethics and Dissemination

6.1 Research Ethics and Health Research Authority Approval

Before initiation of the trial at any clinical site, the protocol, all informed consent forms and any material to be given to the prospective participant will be submitted to the relevant REC and to HRA for approval. Any subsequent amendments to these documents will be submitted for further approval.

The rights of the participant to refuse to participate in the trial without giving a reason must be respected. After the participant has entered the trial, the clinician remains free to give alternative treatment to that specified in the protocol, at any stage, if s/he feels it to be in the best interest of the participant. The reasons for doing so must be recorded. After randomisation the participant must remain within the trial for the purpose of follow up and data analysis according to the treatment option to which they have been allocated. However, the participant remains free to change their mind at any time about the protocol treatment and follow-up without giving a reason and without prejudicing their further treatment.

6.2 Competent Authority Approvals

This is not a Clinical Trial of an Investigational Medicinal Product (IMP) as defined by the EU Directive 2001/20/EC. Therefore, a CTA is not required in the UK.

6.3 Other Approvals

Documentation will need to be submitted to the R&D Department at each NHS Site, or independent health care site (where relevant), in order to gain confirmation of capacity and capability prior to the study being initiated at that site. Confirmation from the site will take the form of a site agreement signed by both the Sponsor/NCTU and the relevant site.

A copy of the local R&D approval and of the Participant Information Sheet (PIS) and consent form on local headed paper must be forwarded to the co-ordinating centre before participants are randomised to the trial.

The protocol has received formal approval and methodological, statistical, clinical and operational input from the NCTU Protocol Review Committee.

6.4 Amendments

Amendments to the Protocol and other documents (e.g. changes to eligibility criteria, outcomes, sample size calculations, analyses) will be agreed by the TMG. Such amendments will be forwarded to the Sponsor for confirmation as to whether it is either substantial or non-substantial and will then be submitted to the Health Research Authority or Ethics Committee for categorisation and approval. Once the amendment has been categorised it will be sent to relevant sites for consideration in accordance with standard HRA processes and timescales. Amendments must not be implemented

until HRA approval is received and sites have either confirmed acceptance or, no objection has been received within the defined timescale. Notification will be sent by the Trial Managers to trial personnel to confirm when an amendment can be implemented.

6.5 Consent or Assent

For the participants who are men with IDD and HSB, they will be provided with an accessible Easy Read Participant Information Sheet (PIS) and given help to read it fully by their local clinical or forensic psychologist. Following a discussion with the local clinical or forensic psychologist, any questions will be satisfactorily answered and if the participant is willing to participate, written informed consent will be obtained. During the consent process it will be made completely and unambiguously clear that the participant is free to refuse to participate in all or any aspect of the trial, at any time and for any reason, without incurring any penalty or affecting their treatment.

Carers and therapists will also be provided with Participant Information Sheets and consent forms. In most instances, their consent will be taken by the PI or delegated member of staff at sites. There may be some occasions where the consent of carers needs to be taken by research assistants on the trial team. If the carers or therapists are undertaking assessments (carers only), or interviews (carers and therapists) and this is being done via a web-based meeting, then the consent process will be video or audio recorded, in lieu of obtaining a signed form. The recording will be stored electronically on secure servers at the University of Kent, separate from participant data. As soon as the recording is transferred to secure drives at the University of Kent they will be wiped from recording equipment.

Consent will be re-sought for all participants if new information becomes available that affects the participant's consent in any way. This will be documented in a revision to the participant information sheet and the participant will be asked to sign an updated consent form. These will be approved by the ethics committee prior to their use. Consent will also be re-sought in the event that a participant's carer changes.

A copy of the approved consent form is available from the CI and the NCTU trial team.

6.6 Confidentiality

Any paper copies of personal trial data will be kept at the participating site in a secure location with restricted access. Following consent, identifiable data will be kept on the trial database to allow authorised members of the trial team to contact patients in order to arrange appointments/assessments. Only authorised trial team members will have password access to this part of the database. This information will be deleted 5 years after the end of the trial.

Confidentiality of patient's personal data is ensured by not collecting patient names on CRFs and limiting access to personal information held on the database at NCTU. At trial enrolment the patient will be issued a participant identification number and this will be the primary identifier for the patient, with secondary identifiers of month and year of birth and initials.

The patient's consent form will carry their name and signature. These will be kept at the trial site, with a copy sent to NCTU for monitoring purposes. This copy will be destroyed once checks are complete. Consent forms will not be kept with any additional patient data.

6.7 Declaration of Interests

The investigators named on the protocol have no financial or other competing interests that impact on their responsibilities towards the scientific value or potential publishing activities associated with the trial.

6.8 Indemnity

University of Kent is the sponsor. University of Kent (employer of Prof Murphy, CI) will provide indemnity and insurance arrangements in relation to the management of the trial and the design of the trial.

University of East Anglia (Employer for Norwich CTU staff) will provide indemnity and insurance for Norwich CTU involvement in the trial design, NCTU involvement in trial delivery and analysis.

Harm to the participants: Some participants will be recruited through the NHS, so for them NHS arrangements will apply. Some participants will be recruited through independent healthcare, in which case the independent healthcare organisations' indemnity/insurance arrangements will apply.

6.9 Finance

The HASB-IDD trial is fully funded by an NIHR (HTA stream), grant number 128550. It is not expected that any further external funding will be sought.

6.10 Archiving

The investigators agree to archive and/or arrange for secure storage of HASB-IDD trial materials and records for 5 years after the close of the trial unless otherwise advised by the NCTU

6.11 Access to Data

Requests for access to trial data will be considered, and approved in writing where appropriate, after formal application to the TMG. Considerations for approving access are documented in the TMG Terms of Reference.

6.13 Publication Policy

6.13.1 Trial Results

All participants will receive a two page Easy Read summary of the results. Therapists who took part will also receive a two-page summary and will be offered access to the publications that result in academic/professional journals.

There will be an internal report, conference presentations, publication on the SOTSEC-ID website and academic papers.

The results of the trial will be disseminated regardless of the direction of effect.

6.13.2 Authorship

Authorship guidelines of the Norwich CTU will be followed.

6.13.3 Reproducible Research

A protocol paper will be published. Following publication of the findings, applications to access the anonymised participant-level dataset and statistical code will be made available, subject to permission from the CI and Sponsor.

7 Protocol Amendments

This is version 1.2 of the protocol. Changes made to version 1.1 are detailed below.

Document name:	HASB-IDD Protocol	**Version No.**	1.2	**Effective date:**	10.06.22
Summary of change(s)		**Reason for Change**			
1. Eligibility criteria refined in relation to previous treatment. Men will only be excluded from the trial if they have had CBT for HSB in the last three years. If they have had treatment longer than three years ago they can be included in the trial (see p. 3 & 16).		This change was prompted by a discussion at a site meeting. They had a potential participant who had received HSB treatment over ten years ago and it was indicated that further treatment would be beneficial. The TMG discussed and agreed on a cut off of three years to be most suitable and still allow the study to detect changes in the outcome measures.			
2. Typographical error corrected in relation to the age of men. Men can be 18 years old or above (see p. 14 & 15)		This is an amendment of a typographical error and has been amended to improve clarity.			
3. Economic evaluation methods have been clarified in section 5.10.5, (see p. 31).		This is not a change but seeks to clarify the sources drawn on to collect data about resource use for the economic analysis, i.e. CSRI completed with carers/ men and includes a review of case notes and documents. Using both methods will enable a full a picture as possible of the men's resource use (including where they draw on the Criminal Justice System).			
4. Trial Steering Group- amended PPI representation (p. 6). From two men with IDD to two people with IDD or carers		The two men we have approached to attend the TSC may decline to be involved and so we wish to expand who might be involved as PPI for the TSC.			
5. Lee Shepstone has been removed as a non-independent member of the DMC (p. 6)		This is on advice of NIHR.			

Changes made to version 1.0 of the protocol are detailed below.

Document name:	HASB-IDD Protocol	**Version No.**	1.1	**Effective date:**	13.05.22
Summary of change(s)		**Reason for Change**			
1. Trial team list updated (p5, table 1.4.3)		Trial managers and research assistant have joined the team			
2. Trial Management Group list updated (p6, table 1.4.4)		All PIs needed to be listed. Trial managers and research assistant have joined the team. Additional team members from NCT added.			
3. Trial Steering Committee list updated (p7, table 1.4.5)		TSC members have now been confirmed. All non-independent members added (Trial Managers and NCTU representatives). Other Trial Team members removed, although they can attend			

	by request as an observer of the TSC meetings (refer to TSC ToR document).
4. Data Monitoring Committee list updated (p7, table 1.4.6)	DMC members have now been confirmed.
5. Other Trial Oversight groups details amended	Clarified four members to the carers group. Names not provided to protect confidentiality.
6. Eligibility criteria refined. Only men on probation with a harmful sexual behaviour treatment order will be excluded from the trial. Men on probation with no such treatment order can be included. Men who have had any CBT for harmful sexual behaviour will be excluded (i.e.not just group CBT for harmful sexual behaviour). (see p 4, 17 & 19)	These changes have been made to provide further clarity to sites for recruitment of men to the trial.
7. Removed statement about sites having sufficient data management resources to allow return of data (p16).	Research Assistants employed within the trial team will collect the majority of the data.
8. Clarified psychiatrists can lead the intervention (p16 and p20)	Psychiatrists are also able to lead the intervention.
9. Deviations to the protocol should be reported to the Trial Managers and not NCTU. Trial Managers will update all colleagues as necessary (p17).	Trial Management is held at Tizard Centre. Trial Managers are not blinded and are the key point of contacts for sites.
10. Screening procedures updated to reflect that no data would be collected on participants prior to consent, including such data that determines their eligibility for the trial (p19).	This update reflects the information provided in the PIS(s).
11. Hours of treatment updated to 100 (p20 and p21)	The total treatment hours was noted as 50, this was incorrect and is actually 100.
12. Fidelity- treatment session recording will be video recorded (with consent), see p22.	The previous protocol only alluded to audio recording the treatment sessions. The ethics committee gave approval for seeking consent to video record these (with consent).
13. Some interviews for the process evaluation may take place via web-based meeting platforms (p26) and consent to video or audio record these will be sought.	The ethics committee gave approval for some interviews to be conducted via web-based meeting platforms, this update reflects this.

14. Participant assessments may (if required) take place using web-based meeting platforms (p28).	The team are seeking an ethical amendment to request to have the option to collect participant assessment data via web-based meeting platforms should the need arise. Though data will not be routinely collected in this way.
15. The Chief Investigator will not be blinded (p30).	It is not necessary for the Chief Investigator to be blinded. Making them un-blinded will mean that they can also offer supervision to therapists, supervise and establish the reliability of ratings for fidelity assessments. Being un-blinded will also mean they can attend the full TMG meeting and not have to leave for closed sessions.
16. There will be no stratification by region (see p.30).	Stratification by region is not proving feasible in relation to recruitment. In consultation with the trial statistician, it was felt sensible not to use a stratification.
17. Resources to provide risk management will not be collected; this has been removed (p33).	Data will be collected on services use via the Client Service Receipt Index for all men and will capture resources for risk management. Risk management is part of usual treatment and although is discussed as part of SOTSEC-ID treatment, it will not be possible to disaggregate this data for the cost effectiveness analyses.
18. Implementation of protocol changes notifications will be sent by the Trial Managers (p38).	This change reflects the division of responsibility for the trial.
19. Consent for carers will be collected by the PI, delegated staff at sites or a trial employed research assistant (p38).	PI's and site staff will be best placed to take consent from carers, however there may be some occasions when the trial employed research assistants may need to take consent from carers.

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9 Principal Investigator compliance statement

Principal Investigator agreement to confirm adherence to the protocol, the UK Policy Framework for Health and Social Care Research and GCP.

RCT of group CBT for men with intellectual and/or developmental disabilities and harmful sexual behaviour: the HaSB-IDD trial

I, [Insert investigator name], confirm:

1. that [insert name of site] site is willing and able to comply with the requirements of the HaSB-IDD trial;
2. that I regularly treat the target population and believe the site has the potential for recruiting the required number of suitable subjects within the agreed recruitment period (figures included in the trial recruitment plan);
3. that I have sufficient time to properly conduct and complete the trial within the agreed trial period;
4. that I have supplied an up-to-date curriculum vitae, GCP certificate and/or other relevant documentation requested by University of Kent, to demonstrate that I am qualified by education, training and experience to assume responsibility for the proper conduct of the trial at this study site;
5. that I am thoroughly familiar with the appropriate use of the investigational products as described in the protocol and in other information sources provided by the University of Kent;
6. that I have an adequate number of qualified staff and adequate facilities available for the foreseen duration of the trial to conduct the trial properly and safely;
7. that I will maintain a signature and delegation log of appropriately qualified persons to whom I have delegated trial related duties which includes confirmation that each member of staff is appropriately trained (including GCP) for the roles allocated to them, and will ensure this is made available to University of Kent in a timely manner on request;
8. a research CV for each member of staff on the delegation log will be stored in the site file according to site policy;
9. that I take responsibility for ensuring all staff delegated trial related duties are adequately informed about the protocol, the investigational product and their trial related duties and functions, and that I will continue to take responsibility for regularly updating them as new information becomes available;
10. that the [insert name of site] site has sufficient resources to manage data generated by the trial to allow prompt and complete data and query return to NCTU;

11. that I am aware of, and will comply with, the principles of GCP as given in the HaSB-IDD protocol compliance statement and the applicable regulatory requirements, and that a record of my GCP training is accessible and described on my current curriculum vitae;

12. that a record of GCP training is accessible for all staff delegated responsibilities in relation to the HaSB-IDD trial and who are named and approved on the site signature and delegation of responsibilities log and that individual training evidence will be saved in the site file, for all staff, according to trust policies;
13. that I will permit routine and for-cause monitoring and auditing by University of Kent, and inspection by the appropriate regulatory authorities, including the provision of direct access to source data and other participant notes and files as required; and
14. that I agree to archive and/or arrange for secure storage of HaSB-IDD trial materials and records for a minimum of 5 years after the close of the trial unless otherwise advised by the NCTU.

Agreement: Principal Investigator

Name	[insert name]
Signature	[insert wet signature]
Date	[insert date]

(Please return a copy of this signed agreement (only pages 47 & 48) to the HaSB-IDD team at *g.h.murphy@kent.ac.uk* / *trialmanagershasbidd@kent.ac.uk*)