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Psychological treatment for men with intellectual and/or developmental disabilities and harmful sexual behaviour

Submission date
11/05/2021

Recruitment status
No longer recruiting

Registration date
21/05/2021

Overall study status
Ongoing

Last Edited
20/11/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There is considerable public concern about men who commit sexual offences. Such men are typically offered group cognitive behaviour therapy (CBT), both in prison and in the community. This form of therapy for sex offenders has been repeatedly evaluated and most trials have found it to be effective in reducing reoffending. However, men who show harmful sexual behaviours (HSB) and have intellectual and or developmental
disabilities (IDD) have often been excluded from this form of treatment so that in the past they have rarely been offered CBT.

This proposed research project aims to evaluate the effectiveness of the SOTSEC-ID CBT group for men with IDD and harmful sexual behaviour, using the gold standard method for evaluating the effectiveness of treatments, i.e. a randomised controlled trial.

Who can participate?
Men with intellectual and/or developmental disabilities and harmful sexual behaviour

What does the study involve?
The plan is for groups of men with IDD who show harmful sexual behaviours to be assessed for sexual knowledge, victim empathy, cognitive distortions, and harmful sexual behaviours, and then the groups will be allocated randomly to be treated with SOTSEC-ID group CBT (with risk management) or TAU (treatment as usual). The men will be re-assessed at the end of six months and followed up at 1 year (all groups) and 2 years(intervention groups only).

What are the possible benefits and risks of participating?
Possible benefits include improvements (reductions) in harmful sexual behaviours, and cognitive distortions, and improvements in sexual knowledge and empathy. Risks include that this is lengthy treatment and intensive which may not suit everyone.

Where is the study run from?
University of Kent (UK)

When is the study starting and how long is it expected to run for?
From October 2021 to September 2025

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof Glynis Murphy, g.h.murphy@kent.ac.uk

Study website
https://research.kent.ac.uk/safer-idd/research/the-new-hasb-idd-trial/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291027

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 291027

Study information

Scientific Title

RCT of group CBT for men with intellectual and/or developmental disabilities and harmful sexual behaviour (HaSB-IDD)

Acronym
HaSB-IDD

Study objectives
1. To determine whether the SOTSEC-ID group CBT program, combined with risk management:
1.1. Reduces cognitive distortions in men with intellectual and/or developmental disabilities and harmful sexual behaviour
1.2. Prevents or reduces their further harmful sexual behavior
1.3. Improves their sexual knowledge, empathy, locus of control, and self-esteem, in comparison to men in the control group receiving Treatment As Usual (TAU)
2. To examine the costs and cost-effectiveness of this treatment
3. To examine therapist, carer and service user views of treatment (through smaller qualitative studies)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/01/2022, Nottingham 2 Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA; +44 (0)207 104 8169; nottingham2.rec@hra.nhs.uk), ref: 21/EM/0270

Study design
Multi-centre single-blinded cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Harmful sexual behaviour in men with intellectual and/or developmental disabilities

Interventions
This is a cluster randomized trial of a form of group cognitive behavioural treatment know as SOTSEC-ID (see https://www.kent.ac.uk/tizard/sotsec). After assessing site eligibility, sites will be randomised to Arm A or Arm B. Arm A consists of 6 months of CBT treatment (using SOTSEC-ID), plus risk management. Arm B is treatment as usual (mainly risk management). Therapists

cannot be blind to treatment. Research workers collecting assessment and outcome data will be blind to treatment.

Intervention Type
Behavioural

Primary outcome measure
Cognitive distortions measured using the Questionnaire on Attitudes Consistent with Sexual Offending (QACSO) score at baseline, 6, 12, and 24 months

Secondary outcome measures
1. Harmful sexual behaviour measured using all reports from case files, carers, police, etc at baseline, 6, 12, and 24 months
2. Sexual knowledge measured using the General Sexual Knowledge Questionnaire at baseline, 6, 12, and 24 months
3. Victim empathy measured using the Victim Empathy Scale (VES-A), adapted from Beckett and Fisher's Victim Empathy Scale at baseline, 6, 12, and 24 months
4. Locus of control measured using the Nowicki-Strickland Locus of Control Scale at baseline, 6, 12, and 24 months
5. Self-esteem measured using the Rosenberg self esteem scale at baseline, 6, 12, and 24 months
6. Service use measured using the Client Services Receipt Inventory at baseline, 6, 12, and 24 months
7. Quality of life measured using the EuroQol 5-dimension 5-level (EQ-5D-5L) questionnaire at baseline, 6, 12, and 24 months

Overall study start date
01/10/2021

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Borderline or mild intellectual disability (ie an IQ below 79) and deficits in adaptive behaviours
2. Documented history of one or more incidents of harmful sexual behavior (HSB)
3. Relatively good verbal comprehension (to be judged by clinicians)
4. Capacity to make a decision as to whether they wish to take part in trial
5. Autism, additional mental health needs (as long as this would not prevent participation in the CBT group as judged by clinicians), and criminal convictions for HSB will not be reasons for exclusion

Participant type(s)
Mixed

Age group
Adult

Sex
Male

Target number of participants
240 (30 clusters with 8 men each)

Key exclusion criteria
1. Insufficient or receptive language to take part in group CBT
2. Mental health difficulties that would prevent him from taking part in group CBT (as judged by clinicians)
3. Resident in prison or in high secure services, or on probation
4. Does not have the capacity to make a decision as to whether to take part in the trial

Date of first enrolment
01/04/2022

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kent and Medway Partnership NHS Trust
Tarentfort Centre and Brookfield Centre
Bow Arrow Lane
Dartford
United Kingdom
DA2 6PB

Study participating centre
Northumberland Tyne and Wear NHS Foundation Trust
Rosewood
Hopewood Park Hospital
Ryhope
Sunderland
United Kingdom
SR2 0NB

Study participating centre
Oxleas NHS Foundation Trust
Pinewood House
Pinewood Place
Dartford

United Kingdom
DA2 7WG

Study participating centre
Black Country Healthcare NHS Foundation Trust
Delta House
Delta Point
Greets Green Road
West Bromwich
West Bromwich
United Kingdom
B70 9PL

Study participating centre
Northampton NHS Foundation Trust
Community Team for People with Learning Disabilities
Second Floor
Newland House
Campbell Square
Northampton
United Kingdom
NN1 3EB

Study participating centre
Nottinghamshire NHS Healthcare Trust
Low Secure & Community Forensic Directorate
Wells Road Centre
Mapperley
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United Kingdom
NG3 3AA

Sponsor information

Organisation
University of Kent

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researchculture@kent.ac.uk

Sponsor type
University/education

Website
www.kent.ac.uk

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol will be published in a peer-review publication. The Statical Analysis Plan will be approved by the Trial Management Group and available from the Chief Investigator post analysis. The results of the study will be disseminated via:
1. An overall project report to the HTA
2. Six open-access publications: one on the protocol; two quantitative reports of the results; two qualitative reports; one health economics paper
3. Two papers in professional journals (e.g. the Tizard Learning Disability Review)

4. A website dedicated to the project
5. Annual ‘progress reports’ to the Seattle Club Conference on Research in Intellectual and Developmental Disabilities, which is the major UK research meeting in this area
6. End of project presentations to the International Association for the Scientific Study of Intellectual Disability (IASSID), National Organisation for the Treatment of Abusers (NOTA), BPS forensic conference and the British Association for Behavioural and Cognitive Psychotherapy (BABCP)
7. Dissemination to public bodies and charities e.g. Mencap, BILD, and CBF

Intention to publish date
01/04/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Murphy, Chief Investigator (g.h.murphy@kent.ac.uk) and Prof Lee Shepstone Lead Statistician (l.shepstone@uea.ac.uk). All data will be potentially available, all of it will be already anonymised. These will not be available until October 2027.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No