FULL PROTOCOL TITLE OF THE STUDY

Clinical and cost evaluation of intensive support teams (IST) for adults with intellectual disabilities and challenging behaviour

SHORT STUDY TITLE / ACCRONYM

The IST-ID study

Chief Investigator:

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Supported by:

NIHR HSDR 16/01/24

Sponsored by:

University College London (UCL)

Protocol version number and date:

Version 5 19/03/19.

R&D / Sponsor Reference Number(s):

16/0456

Study Registration Number:

PROTOCOL VERSIONS

Version Stage	Versions No	Version Date	Protocol updated & finalised by;	Appendix No detail the reason(s) for the protocol update
Current	**5**			**Noted some discrepancies and repetition in the sample size calculation section which have been revised accordingly (mainly grammatical). Noted formatting issues for some references which have been rectified. Added information about qualitative interview transcriptions which will be conducted by external company. No other changes have been made.**
Current	4	16/11/2018	Angela Hassiotis	Revision of sample size
	3	14/11/2018	Angela Hassiotis	Revision of service user participant exclusion criteria
	2	07/06/2018	Angela Hassiotis	IST and qualitative methodology detail added (REC request)
	1	25/10/2017	Angela Hassiotis	

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the Research Governance Framework 2005 (as amended thereafter), the Trust Data & Information policy, Sponsor and other relevant SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I (investigator) also confirm that an honest accurate and transparent account of the study will be given; and that any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature: **Date: 21/11/2018**

Print Name (in full): Angela Hassiotis

Position: Professor of Psychiatry in Intellectual Disability

On behalf of the Study Sponsor:

Signature:..... Date...../...../.....

Print Name(in full):.....

Position:.....

STUDY SUMMARY

Identifiers	
IRAS Number	239820
REC Reference No	18/LO/0890
Sponsor Reference No	16/0456
Other research reference number(s) (if applicable)	
Full (Scientific) title	Clinical and cost evaluation of intensive support teams (IST) for adults with intellectual disabilities and challenging behaviour.
Health condition(s) or problem(s) studied	Intellectual disabilities and challenging behaviour
Study Type i.e. Cohort etc	National survey and mixed methods evaluation
Target sample size	226
STUDY TIMELINES	
Study Duration/length	9 months (Phase 1) + 27 months (Phase 2)
Expected Start Date	01/09/2017
End of Study definition and anticipated date	31/08/2020
Key Study milestones	Agree contracts, REC approval, Survey Development and pilot, Survey dissemination, cluster analysis , IST models refinement, participant recruitment and assessment, follow-up
FUNDING & Other	
Funding	NIHR HS&DR
Other support	n/a
STORAGE of SAMPLES (if applicable)	
Human tissue samples	n/a
Data collected / Storage	n/a
KEY STUDY CONTACTS	Full contact details including phone, email and fax numbers
Chief Investigator	Angela Hassiotis, 02076799451, a.hassiotis@ucl.ac.uk

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also has to be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether or not he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the RE of the end of the study, including the reasons for the premature termination. Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

OTHER:

KEY WORDS

Intensive Support teams, Intellectual disabilities, challenging behaviour

LIST OF ABBREVIATIONS

CB	Challenging Behaviour
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
ID	Intellectual Disabilities
ICF	Informed Consent Form

ISTs	Intensive Support Teams
PI	Principle Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
REC	Research Ethics committee
SOP	Standard Operating Procedure
SSI	Site Specific Information
TMF	Trial Master File

CONTENTS

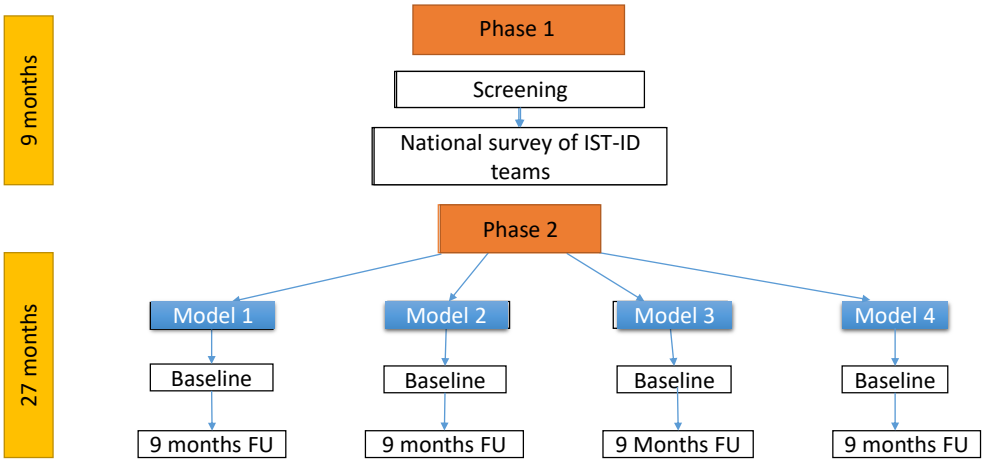
1 INTRODUCTION

Approximately 17% of adults with intellectual disabilities (ID, also called learning disabilities in the UK; constitute about 1% of the population; (Maulik, Mascarenhas, Mathers, Dua, & Saxena, 2011) living in the community present with serious challenging behaviour including aggression self-injury or other socially inappropriate behaviours (Lowe et al., 2007). As many as 100,000 children and adults are estimated to be at risk of admission to inpatient care due to the presence of such behaviours if they are not successfully managed in the community (NHSE, 2015a). There are ongoing concerns that these individuals are subject to increased rates of hospitalisation, unnecessary long term use of psychotropic medication, poorer health, abuse and exclusion (Cooper et al., 2009). Intensive Support Teams (ISTs) are specialist teams which have been advocated for many years as the right services to help people with intellectual disabilities (ID) and challenging behaviour stay in their local communities. They may be staffed by one or more professions, e.g. psychology, nursing, psychiatry, and usually deliver interventions such as positive behaviour support and accept people with ID who are in a crisis when challenging behaviour emerges or provide support when a person is admitted to a local inpatient facility. ISTs are recommended to provide high quality proactive and responsive care aimed at avoiding unnecessary admissions or reducing inpatient length of stay and supporting people in the community (Davidson, McGill, Baker, & Allen, 2015; Hassiotis, 2002). However, there is little evidence to recommend a preferred IST model and there has not been any comprehensive attempt to describe IST outcomes. NHS Commissioners require clear information about what works in order to fund appropriate services. NG11 (NICE, 2015) reports the state of evidence thus: "*It is widely recognised that locally accessible care settings could be beneficial and could reduce costs but there is no strong empirical evidence to support this*".

The proposed study will follow on from a previous phase (9 months) which includes a national survey (England) of ISTs. In phase 1 Service managers of community ID teams (CIDT) will be approached to first identify whether they have such a service locally and then a piloted and refined survey will be carried out. Outputs will include mapping the distribution of ISTs, developing of IST models and a description of the key characteristics of these models. The present project (Phase 2; 27months) includes a mixed methods evaluation of up to 4 IST models. We will collect both patient level outcomes, e.g. challenging behaviour, risk, hospitalisations, service use etc. at two assessment points (baseline and 9 months) and service level outcomes (referrer satisfaction, reach, referral numbers) over 9 months. Statistical analysis will compare outcomes across ISTs and identify which are most associated with positive outcomes (e.g. improvement in challenging behaviour). The costs of delivering the different models will be calculated and compared across all models. We shall collect qualitative data to understand the experiences and views of key stakeholders and the impact

of the different models. We shall follow with a project report and a wide range of dissemination activities, e.g. publications, contacts with NHS England and policy makers, commissioners (CCGs), clinicians etc.

In line with NHS England (NHSE) guidance in managing people with ID locally and effectively, the proposed work will provide commissioners and clinicians with the evidence they need to deliver high quality care to an under-served population group. The project maps onto principles 7 and 8 of the plan outlined in *Building the Right Support* which describes the objectives of community ID services in England (NHSE, 2015a).



2 BACKGROUND AND RATIONALE

The quality of community support for people with ID and challenging behaviour across the life span has been of concern to family carers, clinicians, researchers, and commissioners for many years. In this application we focus specifically on the support offered to adults with ID and challenging behaviour. Approximately 17% of adults with ID living in the community will present, at some point in their lives, with new onset or relapse in challenging behaviour, e.g. aggression, hyperactivity, self-injury (Cooper et al., 2009; Jones et al., 2008; NICE, 2015). These behaviours are long term and associated with younger age, comorbid disorders, e.g. autism or communication and sensory impairments (Jones et al., 2008; McClintock, Hall, & Oliver, 2003). Recent extrapolation from data collected by the Department of Health indicate that 100,000 adults with ID are at risk of being admitted to assessment and treatment units, often hundreds of miles away from home, because of challenging behaviour (NHSE, 2015b).

Such admissions are associated with poorer health outcomes, increased prevalence of abuse and of difficulties in resettlement back into the localities of origin, as the longer the patient is out of area the more likely he or she is to remain there (Perry et al., 2007). Failure to manage challenging behaviour before it reaches crisis point causes significant distress and burden to families and consequent breakdown of placements. The ID inpatient census indicates a disparity of inpatient admissions between the north and south of England confirming concerns about how care for this population group is delivered by CIDS across the country (Health and Social Care Information Centre, 2015).

Successive reports in the UK, from as early as 1993 have been advocating ISTs for the effective management of challenging behaviour in the community and to prevent inpatient admissions (Davidson et al., 2015; Department of Health, 2007; Hassiotis, 2002). ISTs are specialist services for adults, occasionally across the lifespan, with ID and challenging behaviour, aiming to treat such behaviours by applying positive behaviour support and other psychosocial interventions, thus promoting recovery and leading to reduction in severity and frequency of further episodes. Other terms such as “peripatetic teams”, “assertive outreach teams” and “specialist behaviour teams” have also been used to describe ISTs and they may also offer support for mental health crises and autism specific work.

A number of studies have investigated the impact of ISTs delivering behavioural interventions for challenging behaviour in the community. Early studies describe either demonstration projects following the closure of institutions (Lowe, Felce, & Blackman, 1995, 1996) or region wide implementation of stand-alone services (Hudson, Wilken, Jauernig, & Radler, 1995) which though report positive outcomes for service users, lack control groups. Three small randomised controlled trials (RCTs) examined 1) a stand-alone specialist support service delivering Applied Behaviour Analysis in one area in England (Hassiotis, Robotham, et al., 2009) 2) a stand-alone team delivering assertive outreach in inner London (Martin et al., 2005) and 3) an active case management model (Coehlo, Kelley, & Deatsman-Kelly, 1993). Comparator treatment was usual care in all three studies. Hassiotis et al and Coelho et al reported significant findings for the stand alone models but Martin failed to find any significant benefit. The studies were deemed to be subject to bias and the findings must be interpreted with caution. Furthermore, Inchley-Mort, Rantell, Wahlich and Hassiotis (2014), showed that positive behavioural outcomes may be achieved by an embedded IST model where a proportion of CIDS staff train in managing challenging behaviour, meet together regularly to discuss referrals, for specialist supervision and peer support. Literature from other population groups, e.g. dementia care (Toot, Devine, & Orrell, 2011) suggests that home treatment teams seemed to be effectively managing crises and reducing admissions. Wheeler et al. (2015) showed that stakeholders have a number of expectations from crisis resolution teams and this

is likely to be the case for ISTs in the field of ID. So far, there has been limited reporting on stakeholder experiences of ISTs (Inchley-Mort & Hassiotis, 2014; Robotham, King, Canagasabey, Inchley-Mort, & Hassiotis, 2011) which shows that service users and paid and family carers find the involvement of IST staff and frequency of contact helpful and acceptable.

Whilst there may be a rationale for stand-alone ISTs, there is no substantial evidence on long term outcomes. This has led to scepticism that ISTs simply offer good care and that devoting large amount of resources to specialist services will detract from offering good quality care universally, especially as emerging evidence suggests that alternatives, e.g. embedded teams, may also be effective (Inchley-Mort et al., 2014). Given the short term follow ups reported in published literature, it is possible that gains made during engagement with the IST are not maintained after discharge or after transfer to other services. Furthermore, patients and their carers may face disruption and discontinuity in care due to frequent changes in service provision and may be dissatisfied with what they perceive as less "expert" service provided by CIDS (Robotham et al., 2011). There may be benefits from other model configurations including improved staff skill mix; better management of resources; continuity of care for those requiring longer term follow up; high fidelity if all workers work to the same protocol; investment from management in a particular model if seen as novel or innovative.

The IST model aspires to key functions including: input to enable people to access mainstream health and social care services and to work with mainstream services to develop their ability to deliver individualised reasonable adjustments, support to Commissioners in service development and quality monitoring, and the delivery of direct assessment and therapies (Hassiotis, Tyrer, & Oliver, 2009). However, it does not distinguish between mental health and challenging behaviour functions, nor does it give any guidance on duration of engagement with the person. Therefore, there is confusion about whether the ISTs should resemble mental health Crisis Resolution and Home Treatment Teams or Assertive Case Treatment teams. Clarification on these points is very important as it has direct consequences on how patients can be supported in the short and longer term.

Overall, we currently have no firm evidence about whether dedicated ISTs for challenging behaviour or alternative models achieve better outcomes for adults with challenging behaviours, many of whom have long standing difficulties. NHSE has prioritised ISTs and challenging behaviour services backing this England-wide policy initiative with millions of pounds. This planned expenditure demands a proper evaluation and a clear demonstration of whether a specific model of IST is optimal for treating and managing challenging behaviour in local communities. We believe that if all areas in England are to be tasked with implementing ISTs and if commissioners are to see them as worthy of long term investments,

then an inquiry into their characteristics and ability to deliver positive outcomes is an important and pressing clinical question.

The overall aim of the study is to examine the characteristics of different models of ISTs and investigate service user and service level outcomes

3 OBJECTIVES

1. To create a typology of IST currently operating in England;

2. To generate evidence on the effectiveness of different IST models which best support improved outcomes for adults with challenging behaviour;

3. To estimate the costs of different IST models and investigate cost effectiveness;

4. To understand how ISTs impact on the lives of adults with ID and challenging behaviour, their families and the local services;

5. To generate evidence to inform and support decision making on commissioning IST for adults with ID and challenging behaviour.

4 STUDY DESIGN

The present study is the second stage of a two stage mixed methods design, starting with a national survey of ISTs leading to mapping of current provision and its geographical distribution (first stage) and followed by the clinical and cost evaluation and comparison of up to four different IST models (second stage). The project will thus allow us to examine IST model effectiveness at service user and organisational levels.

For this stage we shall include up to twelve ISTs based on a maximum of four models (three ISTs per model) in order to increase the generalisability of the findings. A model will be selected if it is not specific to a particular local configuration, it has been operational for at least 12 months, there is commitment to fund it for the study duration and it can achieve the sample size estimates. Stratified sampling will ensure representation of different size teams/caseloads, rural/urban services, where possible.

4.1 Sample

We have chosen as our primary outcome the reduction in challenging behaviour measured by the Aberrant Behaviour Checklist-Community version (ABC-C; 39) (Aman, Singh, Stewart, & Field, 1985). A sample of 102 per IST model is required to detect a low to moderate (standardised) effect size of 0.45 for the primary outcome total ABC score at 9 months at the 5% significance level with 80% power, assuming an intra-class correlation of 0.01. In order to

achieve this sample size we will recruit 34 patients from three ISTs for each model, totalling approximately 100 patients per model (n=408). Current data provided by two of the co-applicants, VC and KC, indicate that the combined new referrals total to their respective ISTs is approximately 60 a year with another 60 service users on ongoing treatment. Also average caseloads are estimated at approximately 40-45 patients. Therefore, we estimate that we shall be able to recruit our suggested sample size within the 18 month recruitment timeframe. Participants will be in the study for a period of 9 months from baseline and will be seen at two time-points (baseline, 9-months follow-up)

Progress note: adjustment to sample size. Stage 1 has now been completed and the cluster analysis suggests a two cluster typology of services. Some services have also indicated that they would have difficulty recruiting as many as 34 participants. We have therefore re-estimated the required sample size, using the same parameters used previously except for a more conservative intraclass correlation (ICC) for participants within services of 0.02 (Hassiotis et al., 2018). A sample of 96 participants per service type is required to detect a difference of 0.45 standard deviations (SD) in ABC score between the two service types at the 5% significance level with 80% power and assuming an ICC of 0.02.

In addition, we wish to factor in an estimated 15% attrition rate. Therefore our final sample size will consist of 113 participants per IST model, 226 in total. This means a target of 15 participants per service (8 services per model, 16 services in total).

Participants aged 18 years and over across the ID range (mild to profound) will be recruited from the ISTs selected for stage 2. Level of ID will be recorded as that stated by services at the point of accepting eligibility of the service user to receive specialist ID services. Potential participants will be identified by each IST staff either at first assessment or from the IST services caseloads.

4.2 Outcome measures

4.2.1 Primary outcome

Challenging behaviour Aberrant Behaviour Checklist-Community version (ABC-C; Aman, 2012). This is an established and internationally used carer administered measure of challenging behaviour. It is adopted as primary outcome given that reduction in challenging behaviour is the main remit of ISTs.

4.2.2 Secondary outcomes

Mental status: Carer reported Psychopathology Assessment for Adults with Developmental Disabilities checklist (PASADD Checklist; (Prosser et al., 1998)) is useful for screening for

mental disorder but not diagnostic. However, it will provide sufficient information on potential mental health comorbidity which is often under-ascertained in adults with ID.

Risk: Threshold Assessment Grid (TAG;) measures clinical risk and previous research has found associations between perceived risk and hospital admission (Hall, Parkes, Samuels, & Hassiotis, 2006)

Quality of Life (QoL; Shalock & Keith, 1993). Management of challenging behaviour ultimately leads to improvement in individual quality of life and this is considered an important outcome. This is a widely used measure with good psychometric properties which has been developed specifically for people with ID and can be proxy completed.

Health related quality of life: EQ-5D (5 level, (Herdman et al., 2011)) is a standard measure for health economic evaluations and it is used to generate quality adjusted life years as a result of IST input. Two versions will be administered where possible. If the service user has capacity, a self-report version of the EQ-5D-5L will be utilised. If the service user lacks capacity, the proxy version of the measure will be completed by their carer. In the case of the service user having capacity the carer will also be asked to complete the proxy version and responses compared.

Service use: Client Service Receipt Inventory (CSRI; Beecham, 1995)) (adapted for the study, 3 month retrospective service use at each assessment point). The CSRI is a widely used service use questionnaire and has been validated for use in mental health and ID services research. It will be adapted specifically for the study to reflect the specific type of data to be collected.

4.3 Other:

Sociodemographic characteristics

Clinician recorded Autism and ADHD diagnosis

Adaptive Behaviour Scale – Short Form to assess level of functioning (at baseline) (Hatton et al., 2001)

Admissions to hospital during follow up period

Change in accommodation and reasons for it, e.g. placement breakdown.

Previous treatments received, by whom and outcome (at baseline)

All outcomes, will be measured at baseline and 9 months which reflects the time period expected to be required for IST involvement to have led to resolution of the behavioural issues

including implementation of behavioural plans and working towards discharge. Service-level data will be collected over 9 months.

4.4 Service level processes and outcomes

Collection of data on number of people referred and proportion who engage with IST; time to 1st assessment and delivery of management plan; other IST scope, e.g. days of training given and other engagement with local services, e.g. joint assessments with crisis teams; population reach. The latter is important as it can provide an estimate for ISTs' caseloads. The prevailing view is that small caseloads up to 15 individuals are desirable. However, previous research in Intensive Case Management did not find substantial differences between smaller vs larger caseloads (46). Therefore, it is essential to understand how caseloads and staff numbers may be interacting to provide care to those in need based on national prevalence rates of ID and challenging behaviour.

We shall map our service data onto the monthly reports from the Mental Health and Learning Disabilities Data Set (MHLDDS) over the study period which provides information on hospital admissions aggregated by IST model. This will provide a proxy measure of IST model impact on admissions.

Finally, we shall construct a short questionnaire to capture satisfaction with referral process and training/advice/in-reach provided where applicable. This will be distributed to managers of services in contact with the IST within the 12 months preceding the study and listed by the participating IST units.

4.5 Qualitative assessment

Qualitative work will allow us to investigate how IST care is experienced by service users and family carers, and to obtain a multi-perspective view of their functioning within local service contexts, based on relevant user, carer and practitioner views. Stakeholders to be included will be IST managers and professionals, professionals from referring agencies, service users, family and paid carers, and individuals who may have rejected IST care. Data will be collected using semi-structured interviews and some focus groups from services participating in Stage 2. We aim to conduct semi-structured interviews with the following groups of participants:

Service users: Eight to ten service users **per** IST model including those who may need support to communicate (provided by family or paid carers). We will also aim to interview a smaller sample of service users who have declined offers of IST contact.

Carers: Eight to ten family and same number of paid carers **per** IST model. We shall also aim to interview a small number of family carers who have recently declined IST contact.

The managers of **all** selected IST services.

IST practitioners: A maximum of 8 IST practitioners **per** IST model, selected to include a range of professional backgrounds and levels of seniority.

Practitioners from services that frequently refer to ISTs: We will aim to convene one focus group with representatives of relevant referring agencies for **each** IST service (to include in-patient services, third sector organisations, Early Intervention Services, Community Mental Teams, Transition services). If this proves logistically challenging, we will collect data via smaller group interviews or individual interviews.

Total numbers for this qualitative work will be determined by the number of IST models identified in Stage 1, heterogeneity of sub-samples and saturation of themes, with project resources allocated accordingly, such that a detailed analysis and informative write-up will be achievable.

Semi-structured interview schedules for each stakeholder group will be developed with the help of the study management group, and the service user and family carer advisory group.

Schedules for service users will avoid complex language and terminology, and will be modified on a case-by-case basis for respondents with ID (easy read formats). Across all stakeholder groups, interview schedules will be designed to explore views and experiences of the role and functioning of ISTs, and how they interface with other health and social care provision within their local context. Questions will cover the benefits, limitations and functioning of each IST model, and explore the factors that might affect these, e.g. access, unmet needs, negative outcomes (hospital admission, out of area transfer). Interviews with IST managers and professionals, and focus groups with referring professionals will explore views on emerging IST model differences, service delivery, facilitators and barriers to achieving stated IST objectives, and explanations for performance variations between ISTs.

IST managers and professionals will be interviewed relatively early in Stage 2 and their testimonies will be used to add detail to the data from phase 1. Service user and carer participants will be interviewed near the time of discharge or around the 9 month follow up, whichever is sooner. Clinical practice suggests that most of the assessments and onward referrals will have been completed by that time. We shall ask IST staff to contact service users and their family or paid carers who may have refused IST contact to ask whether they would be interested in participating. Finally, we shall identify the interface agencies of each IST in stage 2 and access their views using focus groups.

Interviews and focus groups will be audio-recorded and transcribed verbatim. Transcriptions of qualitative interviews will be conducted by a UCL-approved' specialised and reputable company external to UCL.

Data will be analysed using thematic analysis conducted using NVivo software for data handling. A staged, collaborative and primarily inductive analytic approach will be adopted, allowing us to iteratively develop a set of themes to capture key concerns and topics, as well as more abstract or underlying issues. Although numbers in stakeholder sub-groups linked to each IST model may be relatively small, triangulation of the various stakeholder perspectives will allow us to obtain a broad picture of each IST model. Thus, we will be able to compare the various IST models in terms of multiple stakeholders' views, as well as analysing the dataset as a whole to understand broadly common views and experiences of ISTs.

Analysis will involve close collaboration between the qualitative researcher, the qualitative lead and other key members of the study team. The service user and carer group will also be consulted to provide their views on emerging themes and findings.

5 STUDY SCHEDULE

Potential participants will be recruited from the IST services within each model included in the project. Staff will identify potential participants and their family or paid carers either at first clinical assessment or from the IST services caseloads. A baseline assessment will be carried out with follow-up at 9 months (+/- 4 weeks) after the baseline. Participants may withdraw from the study at any point. Qualitative interviews with IST service managers and professionals will be conducted in the early stages of the research study, whereas interviews with consenting service users and family and paid carers will be conducted near the time of discharge from IST services or around the 9 month follow up, whichever is sooner.

The end of the study will be the date of the last visit/ telephone follow up/ home visit by the last participant. We have specified a window of -/+ 4 weeks around that date. There will be a period of three months after the last assessment to conduct data analysis and draft the report.

6 CONSENT

Consent will be sought from all service users on the IST caseload, their respective carers (paid and family) and, where appropriate, their consultees.

Potential participants will be identified by each IST staff either at first clinical assessment or from the IST services caseloads. IST staff will give potential participants' carers brief verbal information about the study and those who agree to hear more about the study will have their contact details shared with the researcher.

For those service users **with** decision-making capacity, the researcher will speak to the potential participant by phone or in person and be given or sent the Service user participant information sheet (in Easy-Read format) to inform them of the reasons for doing the study, the kind of questions we will be asking their carer, also that we will ask for information from their notes to confirm details such as number of service contacts, and that we will do this twice (baseline and repeat at 9 month follow-up). If the service user agrees to take part in the study they will complete a written consent form or consent will be taken by telephone and audio-recorded for purposes of verifying consent. The researcher will then repeat the above process (using Carer participant information sheet) with the service users' paid or family carer to seek their consent to take part and complete the study questionnaires.

We anticipate that several IST services will be managing participants who are acutely mentally unwell or in crisis. At the time of referral and/or treatment, some participants will not have the necessarily decision-making capacity to consider participation.

For those service users **lacking** decision-making capacity, the researcher will approach the personal or nominated consultee for that person (using the Consultee information sheet) and seek written or recorded telephone assent to include the service user in the study.

Reasons for ineligibility and/or exclusion of eligible service-users will be documented.

7 CRITERIA

7.1 Inclusion Criteria

Service users: Eligible to receive support from IST service; mild to profound intellectual disability; aged 18 years and over;
Service: IST adheres to one of the chosen models, has been operational for at least 12 months, there is commitment to fund it for the study duration and it can achieve the sample size estimates

7.2 Exclusion Criteria

Service-users: primary clinical diagnosis of personality disorder or substance misuse; decision by clinical team that a referral to the study would be inappropriate, e.g. there is an open complaint investigation.

8 RECRUITMENT

Potential participants will be identified by each IST staff either at first clinical assessment or from the IST services caseloads. IST staff will give potential participants brief verbal information about the study and those agreeing to speak to the researcher will have their contact details shared with the researcher. The researcher will speak to the potential participant by phone or in person and be given, emailed or sent the participant information sheet. Those participants agreeing to take part in the study will go undergo written or telephone recorded informed consent with the researcher.

Reasons for ineligibility and/or exclusion of eligible service-users will be documented.

9 STATISTICAL METHODS

The primary outcome is mean total ABC and subdomain scores at 9 months. A mixed model will be used to compare the mean total ABC and subdomain scores for each IST Model. This will include a fixed effect for Model and for ABC score at first assessment, as well as a random effect for IST to take into account clustering within each IST. Mean differences and 95% CI will be presented. The assumptions of the model will be tested. If these are not met, a suitable transformation or non-parametric test will be considered.

Some patients have their first assessment later than others. To ensure the effect sizes are not reduced as a result of this, we will perform a sensitivity analysis adding a fixed effect for time of first assessment. Mean differences and 95% CI will be presented if these are different from the primary analysis.

Variables such as duration of treatment/engagement with IST will be summarised for each model using means (standard deviation) or frequency (%) as appropriate. Variables which vary between models will be adjusted for in a secondary analysis but including the variable as a fixed effect in the primary model.

The primary analysis will be repeated for the continuous secondary measures. Binary outcomes will be analysed using a random effect logistic regression.

10 ECONOMIC EVALUATION

We shall derive and report the costs of each IST service model over 9 months. To estimate the cost of each IST service model, we shall use an established building block approach to service costing (Beecham, 1995). Informed by this approach, we shall obtain a description of each IST model, disaggregated by different elements as each IST model is likely to have different parts, and for those we shall include grade and hours of staff in different professions,

number of clients or size of the caseload, including elements funded by other department budgets, in the calculation. Combining the data on the description and cost information will facilitate the calculation of the total cost of each IST model.

We shall calculate and report a comprehensive total cost of services and support provided external to the IST model and an IST–specific cost per study participant using a modification of the approach above. To calculate the IST-specific cost per study participant, organisational and staffing inputs for each study participants will be combined with the unit cost for each professional with whom the study participant made contact over the study period. Data on services and support will be obtained from the CSRI covering a retrospective period of 3 months. It will be assumed that costs will be incurred by health and social care agencies even though some individuals make co-payments. Data will also be collected on volunteer support, befriending, telephone care-line support and unpaid support to the study participant by family and friends. To service use and support data we shall attach unit costs reflecting the long-run marginal opportunity costs drawn from available public sources. Costs per unit of measurement for each service type will be taken from a national compendium of the unit costs of health and social care produced annually; the NHS Reference Costs will be used for inpatient and outpatient attendances and for community based services, not included in the compendium of the unit costs of health and social care. Costs of unpaid care will be estimated from information on volume and type of support, the opportunity cost of lost work (wage rate) for carers in paid employment, and replacement cost for those not in paid employment based on cost of a home care worker. We shall extrapolate the three-monthly costs over the nine months.

We shall examine what effect different IST models have on costs of care over the nine month period, using multivariate statistical analyses to explore variations in costs between individuals in the sample, taking account of the clustering and the characteristics of the study participants (sociodemographic, clinical, primary and secondary measures). The analyses will examine associations between costs and individual characteristics before entry to the study and at endpoint. We shall also include mediators in the modelling. For these analyses NHS and social care services and societal costs will be used as dependent variables in turn.

We shall test whether different IST service models have different outcomes by exploring the links between costs and outcomes over the nine-month period, taking into consideration clustering and skewed costs. We shall use the primary measure of outcome, ABC, secondary outcome measures and quality adjusted life years (QALYs, over nine months), the latter calculated from the EQ-5D by applying societal weights (Dolan, Gudex, Kind, & Williams, 1995) and QOL scores as the dependent variable in a series of multiple regression analyses.

The cost effectiveness analyses will be conducted from a health and social care perspective and a wider societal perspective.

The cost-effectiveness of one IST model over another will be compared by calculating incremental cost-effectiveness ratios (ICERs), defined as difference in mean costs divided by difference in mean effects. If one model had lower costs and better outcome than its comparator it will be considered dominant. Difficulties can arise if one service model is both more effective and more costly than its comparator, leaving the decision-maker to consider whether higher costs are justified by better outcomes. Cost-effectiveness acceptability curves (CEAC) (Van Hout, Al, Gordon, & Rutten, 1994) will be plotted for each cost-outcome combination to show the likelihood of one treatment being seen as cost-effective relative to another for a range of (implicit) values placed on incremental outcome improvements. Using the net benefit approach, monetary values of incremental effects and incremental costs are combined, and net benefit (NB) derived as: NB = λ x (effectb - effecta) – (costb – costa). Where, λ is the willingness-to-pay for a unit improvement in effectiveness (ABC, QALYs and QOL) and subscript 'a' and 'b' denote *IST model a* and *IST model b*, respectively. This approach allows costs and outcomes to be considered on the same monetary scale, taking account of sampling uncertainty and adjusting for baseline covariates and clustering.

11 PATIENT AND PUBLIC INVOLVEMENT (PPI)

In the course of preparing the application we have carried out a number of consultations with service users and family carers with lived experience of challenging behaviour and/or mental illness (by VC and KC during clinical consultations since January 2016 and Hassiotis on 4/8/2016). KC also gave a presentation on IST at an educational meeting for trainees and consultants in ID (8/8/2016). The feedback received from the service users and the family carers was overwhelmingly positive and ISTs are seen as the way forward to reduce admissions and also maintain service users in the community.

We have outlined plans as to how we would engage service users and family carers and they were in broad agreement with the tasks such as assisting with materials for patient information and consent, championing the study, looking at ethical considerations, taking part in the topic guide development and in the interpretation of findings and dissemination.

We have agreed that we shall present a lay summary of the project and enlist interest from the service users who wish to be members of the advisory group. We shall hold interviews to ensure that we appoint the right mix and shall carry out a 3 hour training session in research skills and tasks over the project duration using easy read formats based on NIHR guidance (http://www.nihr.ac.uk/nihr-in-your-area/mental-

health/documents/UserCarerResearcherGuidelinesMay2014_FINAL.pdf). The service user advisory group will be facilitated by two facilitators in case of illness or leave. Regarding the family carer representatives to the study, we have decided to manage that from within the research team who will seek pragmatic input from family carers through local carer groups in co-applicants' sites. The family carer input will include two family carers to be recruited via CRN and carer groups, costed as per INVOLVE budget advice for lay participation (http://www.invo.org.uk/wp-content/uploads/2014/11/10002-INVOLVE-Budgeting-Tool-Publication-WEB.pdf).

Service users and family carers did caution that they needed help in fulfilling their roles and that they should not be overburdened. We reassured them that we would provide training and support and that we have experience in working with service users in other studies, whose testimonials are very positive about the experience of being in the advisory group. The specific tasks of the service user and carer input to the SMG will be:

1. Developing participant information resources
2. Managing the research
3. Contributing to the interpretation of the findings
4. Reporting and dissemination of research

12 FUNDING AND SUPPLY OF EQUIPMENT

The study is funded by the National Institute of Health Research Health Services and Delivery Research programme (16/01/24) and is sponsored by University College London.

The study funding has been reviewed by the UCL/UCLH Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via UCLH and/or the Local Clinical Research Network.

13 DATA HANDLING AND MANAGEMENT

All aspects of data management of the study will comply with the UK Data Protection Act 1998 and Good Clinical Practice. Data will be collected electronically via an online survey (Opinio) or on paper forms which will not contain identifiable information and will only be marked with an anonymised participant ID number. The paper files from this project will then be stored on UCL premises in a locked cupboard only accessible to members of the UCL research team. We will follow all aspects of data protection as per research governance and Social Care and NHS policies. Any data stored at UCL will be registered for the purposes of data protection (as per institutional guidance) and participant records will be anonymised. Identifiable data

which constitutes the ID key to link consent forms to CRFs and audio-recordings of consent obtained by telephone will be stored in the 'Data Safe Haven' at UCL.

14 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL

Having discussed with the UCL Research Office:

- The Sponsor considers the procedure for obtaining funding from National Institute for Health Research to be of sufficient rigour and independence to be considered an adequate peer review.

15 ASSESMENT AND MANAGEMENT OF RISK

We anticipate little distress or disruption caused directly to the participants as the measures are carer administered. However, we appreciate that some of the questionnaires may cause upset due to the nature of material they cover. The interviews with carers, especially family carers, will be handled sensitively by trained researchers.

16 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

16.1 Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**, • results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect
*A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.	

16.2 Assessments of Adverse Events

Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below.

16.2.1 Severity

Category	Definition
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further procedure; it causes slight discomfort
Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further procedure, but is not damaging to health; it causes moderate discomfort
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

16.2.2 Causality

The assessment of relationship of adverse events to the procedure is a clinical decision based on all available information at the time of the completion of the case report form.

If a differentiated causality assessment which includes other factors in the study is deemed appropriate, please add/amend the following wording to specify:

It is of particular importance in this study to capture events related to the product application procedure. The assessment of relationship of an adverse event to this/these additional safety issue(s) will also be carried out as part of the study.

The differentiated causality assessments will be captured in the study specific CRF/AE Log and/or SAE form (amend as required).

The following categories will be used to define the causality of the adverse event:

Category	Definition
Definitely:	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.

Probably:	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events).
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition).
Not related	There is no evidence of any causal relationship.
Not Assessable	Unable to assess on information available.

16.2.3 Expectedness

Category	Definition
Expected	An adverse event which is consistent with the information about the procedure listed in the Investigator Brochure, SPC, manual of Operation **or clearly defined in this protocol.**
Unexpected	An adverse event which is not consistent with the information about the procedure listed in the manual of operation **or clearly defined in this protocol.**

* this includes listed events that are more frequently reported or more severe than previously reported

16.3 Recording adverse events

AEs/SAEs will be collected by the project manager. All reports of SAEs will be reviewed by the CI within 2 days of receiving the report and the review outcome will be recorded in the eCRF

16.4 Procedures for recording and reporting Serious Adverse Events

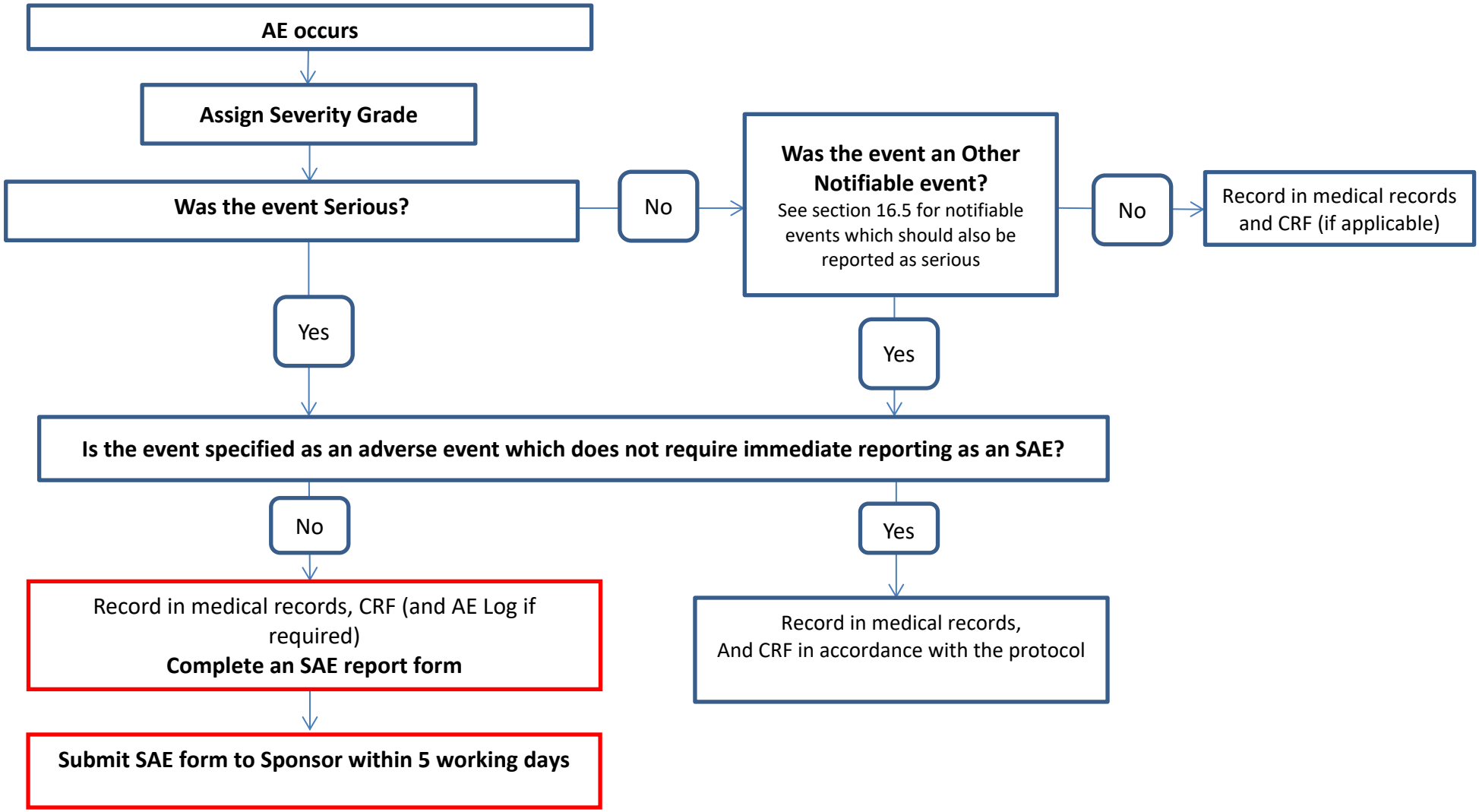
Any serious adverse events which are classed as related and unexpected will be reported to the ethics committee that approved the trial and to the sponsor.

SAEs will be reported by the CI (delegated to the Project Manager). The Chief Investigator (or their delegate) is responsible for reporting SUSARs to the ethics committee that approved the study within 15 calendar days of becoming aware of the event.

Completed forms for unexpected SAES must be sent within 5 working days of becoming aware of the event to the Sponsor

Email forms to Research-incidents@ucl.ac.uk

Flow Chart for SAE reporting



16.5 Serious Adverse Events that do not require reporting

16.6 Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/ PI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

16.7 Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The CI will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

The CI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

16.8 Trust incidents and near misses

An incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.

b. It is contrary to specified or expected standard of patient care or service.

c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.

d. It puts the Trust in an adverse position with potential loss of reputation.

e. It puts Trust property or assets in an adverse position or at risk.

Incidents and near misses must be reported to the Trust through DATIX as soon as the individual becomes aware of them.

A reportable incident is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a) It is an accident or other incident which results in injury or ill health.

b) It is contrary to specified or expected standard of patient care or service.

c) It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d) It puts the Trust in an adverse position with potential loss of reputation.
e) It puts Trust property or assets in an adverse position or at risk of loss or damage.

17 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

Study Steering Committee and Study Management Group meetings will also be scheduled regularly throughout the course of the study.

18 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files

19 INDEMNITY ARRANGEMENTS

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

20 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at UCL for the period for

the period of 10 years and in accordance with UCL policy and in line with all relevant legal and statutory requirements.

21 PUBLICATION AND DISSEMINATION POLICY

In the final stages of the study we shall produce a draft report for the funders and begin a full scale dissemination process with tailored outcomes to stakeholder groups and policy makers. We shall provide several dissemination events to share the findings and insights, with guests from the Department of Health, CCGs and NHSE. We have access to commissioners and through members of the research team to NHSE, therefore, we can arrange to hold briefings and seminars. We will write for specific service related publications, including blogs (e.g. through our connection with Mental and Learning Disability Elf), parent organisations (e.g. Challenging Behaviour Foundation) and social media (study twitter account). Further, we shall utilise wider co-applicant networks to ensure that we maximise our dissemination capacity including internationally.

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