Evaluating the effectiveness and cost effectiveness of BSL (British Sign Language) IAPT (Improving Access to Psychological Therapies)

Study protocol

Start date: 1st March 2014

Proposed end date of the funded project: 1st March 2016

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Outline of funding

This study is funded by NIHR Health Services and Delivery Research Programme (project reference number 12/136/79).

Link to the summary of the project on NIHR website

A summary of the research and the abstract are available in plain English and British Sign Language on the NIHR website: www.nets.nihr.ac.uk/projects/hsdr/1213679.

Contents

Background

Being Deaf as a cultural-linguistic identity was recognised by the UK government in 2003[1]. Deaf people are therefore afforded the status of other minority groups whose access to services should not simply be protected, but actively promoted under the provisions of the Public Sector Equality Duty 2011, following the Equality Act 2010. The population is estimated to be between 80 and 100,000 in England[2]. 'Deaf' does not refer to the larger population of people who might lose their hearing through the life-course, who use spoken language or who define deafness as a primarily medical condition requiring rehabilitation. This study only concerns Deaf people who use BSL (British Sign Language).

Deaf people experience significantly poorer mental health than the hearing population, with the prevalence of some common mental health problems being up to twice as high[3,4]. In only a minority of cases is mental ill-health and deafness causally connected i.e. where the aetiology of deafness is co-incidental with organic origins of mental illness/neurological impairment. Of greater significance is how early childhood deafness interferes with the usual processes of language acquisition and psychosocial development. The incidence of mental health problems in deaf children/young people is around 1.5 times greater than amongst hearing counterparts[5]. In adulthood, whilst the incidence of major psychoses is broadly consistent with that amongst hearing people, the prevalence of depressive disorders and anxiety is significantly higher (33% of the Deaf population in comparison with around 20% of the hearing population)[6].

Studies have demonstrated the inaccessibility of health services to Deaf British Sign Language users[2,3,4,7,8], including mental health services, resulting in late diagnoses and loss of benefit from early preventative interventions[8]. Poor access to information about health-related matters in BSL results in poor awareness amongst Deaf community members of mental health issues, including personal support strategies, help-seeking behaviours, routes of referral and treatment options. Deaf people are often users of mental health services only when a difficulty has escalated to the point where secondary/tertiary care intervention is required[3,7,8].

The DH (Department of Health) review of mental health services for Deaf people[7] resulted in significant strategic investment in NHS specialist services to address this health inequality. The latest is in primary care: IAPT (Improving Access to Psychological Therapies).

IAPT is a national (England) NHS programme for rolling out NICE-approved psychological interventions to manage mental health problems (principally depression and anxiety) in primary care[9.10]. BSL-IAPT[11] (known as BSL Healthy Minds) is an adapted version to meet the cultural and linguistic needs of Deaf people who use British Sign Language. BSL-IAPT is delivered by sign

language users (mostly Deaf) and uses the IAPT standard assessment and outcome measures, translated into BSL (British Sign Language) and tested for reliability[12]. Originally offered in two Health Authorities, since April 2013 this service has been offered in five areas. However, service accessibility has been declining since April 2014 as a result of new commissioning arrangements. To date almost 800 patients have used this service.

BSL-IAPT has three components:

1. Standard assessment instruments (PHQ-9, GAD-7 and WSAS) that are translated into BSL and their internal reliability for use with Deaf people established by the applicants[12];
2. Deaf people trained as Psychological Well-being Practitioners (PWPs) to deliver the IAPT programme in BSL;
3. Self help guidance that is culturally adapted[11].

Throughout the rest of England, Deaf people access Standard IAPT. These Standard IAPT services do not involve practitioners who are Deaf and who share the same linguistic and cultural identity. Service organisation is not culturally Deaf-specific in its delivery model. Assessments used have not been standardised on Deaf population norms and usually do not use a fixed translation with established reliability. It is estimated that there are around 150[13] (Standard) IAPT services in England, although it is not known how many Deaf people have used these services.

It is not possible to determine whether the current investment in specialist services (BSL-IAPT) is justified and should be extended nationally. This is because it is unknown whether it confers any benefit for Deaf people over and above accessing Standard IAPT services. The cost-effectiveness of BSL-IAPT has not been investigated. Rigorous examination of effectiveness and cost-effectiveness is needed to guide decision-making about longer term sustainability and appropriate targeted primary care intervention for this notoriously hard to reach group.

A natural experimental situation currently exists because, in at least five areas in England, there have been or currently are BSL-IAPT services whereas in the other regions, Deaf people access Standard IAPT services. The number of Standard IAPT services that Deaf people have accessed is currently unknown. A trial is therefore ethically possible comparing BSL-IAPT with Standard IAPT as accessed by Deaf people, without withholding NHS services which have been specifically designed for a population with ‘protected characteristics’ under the Equality Act 2010/Public Sector Equality Duty 2011.

Data from all IAPT patients is uploaded centrally allowing for comparisons to be made by service provider and individual patient characteristics collected through universal KPIs and the IAPT

minimum data set. This presents a major research opportunity because: (i) internationally most evidence concerning Deaf people's mental health is drawn from hospital inpatient/outpatient population studies with very limited evidence from primary care, (ii) whilst the internal reliability of the BSL-IAPT tools has been determined, validation of clinical cut-offs require analysis based on a clinical sample, (iii) The effectiveness of BSL-IAPT depends on its culturally perceived acceptability, not just its linguistic accessibility, requiring investigation of the service delivery process.

This study will be the first step in determining whether BSL-IAPT is justified for Deaf people. Importantly, the study will provide valuable information to inform the need for and design of follow-on research to assess the effectiveness and cost-effectiveness questions. Although the proposed project concerns Deaf people specifically, it is an example of an important comparison relevant to many service sectors within the NHS: namely, what is the difference in terms of benefit, if any, between standard services made linguistically accessible to particular cultural-linguistic groups of patients, and adaptations of standard services designed specifically around the cultural identity and language preferences of specific groups.

Aims and objectives

Overarching research questions:

1. Is BSL-IAPT more effective than Standard IAPT for Deaf people with anxiety and/or depression?

2. Is any additional benefit from BSL-IAPT worth any additional cost to provide it?

Design

This current research addresses only Phase I (modelling and preparatory work) and Phase II (feasibility study). It specifies the stop points and the criteria for progression from Phase I to Phase II and subsequently to a full trial (which would be the subject of a separate proposal if justified).

Phase I Modelling and Preparatory Work (months 1 -12)

This phase addresses:

Acceptability of Randomisation: Deaf people are rarely provided with a service matched to their linguistic/cultural needs. The possibility of being randomised into or out of a service regarded as specialist may be an impediment to adequate recruitment.

Instrument preparation: there is no BSL version of the EQ-5D currently and clinical cut-offs for the BSL versions of the IAPT standard instruments have not been established.

Service Delivery Modelling: Standard IAPT, when accessed by Deaf people, has not been modeled: there are a range of potential variations in how it is delivered to sign language users that require investigation and standardisation. The potential de-centralisation of the BSL-IAPT provision to delivery by a range of service providers indicates a need to model what had previously been thought to be the same service.

Therefore in this phase we aim:

(i) To investigate the acceptability of randomisation amongst Deaf service users using focus groups in BSL

(ii) To map likely numbers of users of BSL-IAPT and Deaf users of Standard IAPT who would be eligible for recruitment

(iii) To compare the previous outcomes of Deaf people using BSL-IAPT to estimate the discrimination (AUC) for a (i) cut-off and (ii) recruitment targets should a full trial be indicated

(iv) To explore the population characteristics of BSL-IAPT service users including demographic characteristics, referral routes, adherence and outcome

(v) To establish the clinical cut-offs for the BSL-IAPT assessment tools (PHQ-9, GAD-7, WSAS) for patients with anxiety and/or depression

(vi) To produce replicable descriptions of 'Standard IAPT' *when implemented with BSL users* and BSL-IAPT

(vii) To translate and test the reliability of a BSL version of the EQ-5D 5L

(viii) To identify key items of service use and develop data collection forms for economic analysis

(ix) To estimate recruitment targets should a full trial be indicated.

Stop point: The research study will stop at the end of Phase I if it demonstrates randomisation is not acceptable **AND one or more of the following apply:**

(i) The number of Deaf people accessing either Standard IAPT or BSL-IAPT is shown to be too small for a comparative/two arm study to be feasible

(ii) The degree of variability in service delivery to Deaf people accessing either Standard IAPT or BSL-IAPT is too great to model it as a coherent intervention

(iii) The populations of Deaf people using BSL-IAPT and Standard IAPT are not comparable.

The research study will continue to implement Phase II if **all** of the following apply:

(i) The number of Deaf People accessing Standard IAPT and BSL-IAPT is shown to be great enough for a comparative matched case control design to be feasible
(ii) The degree of variability in service delivery to Deaf people accessing standard IAPT and BSL-IAPT can be modelled and accounted for
(iii) The populations of Deaf people using BSL- IAPT and Standard IAPT are comparable.

Phase II Feasibility Study (months 13-24)

If Phase I indicates an RCT design is acceptable to Deaf people, we will implement a pilot trial to explore whether an RCT is feasible and can be successfully carried out. If Phase I indicates an RCT is not acceptable, we will implement a pilot study to explore whether a non-randomised design is feasible. This will use a matched case control design whereby the two groups of participants (Deaf users of BSL-IAPT and Deaf users of Standard IAPT) will be matched across relevant demographic covariates. In both instances the objectives remain the same. We will recruit 30 patients to each arm of study and:

(i) Test the feasibility of recruitment and retention of participants and centres
(ii) Determine whether recruitment targets required for a full trial/scaled up evaluation can be met within an acceptable timescale
(iii) Refine the sample size and power calculation for a large scale study/trial by estimating the attrition rate
(iv) Investigate the acceptability and adherence to data collection protocols in the diversity of settings associated with both BSL-IAPT and standard IAPT through investigating fidelity to protocol
(v) Use trial and model-based analyses to explore the potential cost-effectiveness of BSL-IAPT and identify key cost drivers.

The results of phase II will indicate whether a full RCT or scaled-up case-matched evaluation study is justified, either of which would require a separate application.

Phase I, study 1: Qualitative exploration of the acceptability of individual randomisation

Aims

This study will:

- Investigate the acceptability of randomisation amongst Deaf BSL users

Through this process we will also:

- Explore the language/terminology in BSL for randomisation and other concepts that support informed consent
- Prepare pilot recruitment materials to be used in the feasibility study (Phase II).

Rationale

The BSL-IAPT service is not England-wide therefore some Deaf people ordinarily would not have access to it as it is dependent on geographical location. The acceptability, at an individual level, of randomisation to BSL-IAPT or Standard IAPT with reasonable adjustments requires exploration of the influence of geographical conditions currently associated with access and also of attitudinal conditions linked with access.

Geographically, randomisation would create four potential conditions whose influence is unknown:

A. Randomisation to BSL-IAPT and living in an area where BSL-IAPT is provided (= usual care);
B. Randomisation to BSL-IAPT but living in an area where it is not provided (= access to a previously unavailable service);
C. Randomisation to Standard IAPT and living in an area where Standard IAPT is usually provided (= usual care);
D. Randomisation to standard IAPT and living in an area where usually BSL-IAPT is provided (= access to a service usually not available).

Attitudinally, there are three factors associated with the acceptability of randomisation.

(i) whether BSL-IAPT and Standard IAPT with modifications for linguistic access are perceived to be equivalent;

(ii) whether randomisation is perceived as acceptable on the basis of no current evidence whether one is more effective than the other;

(iii) whether ethically the issues concerning the rights to access to a service delivered directly in own language take precedence over the right to access a service mediated through an interpreter. Within the law, British Sign Language still has no legal protection (i.e. there is no legal obligation for the services to be provided in a way that is fully culturally and linguistic accessible) although Deaf people are placed within the category of disability in the ‘protected characteristics’ under the Equality

Act 2010 and therefore may expect 'reasonable adjustments' which can include interpreters to access a standard service.

Key concepts such as 'randomisation' are likely to be unfamiliar in the Deaf community. Evidence suggests that many concepts associated with research might be unfamiliar to the general public and care needs to be taken in how they are explained and explored[14,15]. However, there are additional issues for Deaf people. In general, Deaf people have poor access to incidental information over a life time resulting in smaller funds of general knowledge[16]. They have fewer opportunities to gain information to scaffold understanding because so little information is available in BSL. Also, low levels of literacy in written languages are common[17]. Finally, there is no simple word for sign translation (into BSL) of words such as randomisation, trial, effectiveness and equipoise. A conceptual translation is required based on a primarily visual approach to linguistic expression, such as that recently piloted in our research group for terminology associated with genetic counselling[18].

Methods

Sample: 20-30 Deaf people, some living in BSL-IAPT areas and some living in Standard IAPT areas.

Inclusion criteria: that a person is: over 18, audiologically deaf, BSL user, living in England, has capacity to consent. Previous IAPT service users can take part.

Exclusion criteria: If currently an IAPT service user; if unable to consent as per the research provisions of the Mental Capacity Act, 2005.

Recruitment: through usual Deaf community media such as Facebook, email groups, word of mouth/hand, advertisement in Deaf community magazines/online bulletin boards.

Data generation: A broadly community-participatory qualitative design guides the data collection.

Data will be generated through focus groups, each of which will contain between 5 and 7 people. There will be eight focus groups of Deaf people in total. Two groups will meet on two occasions in a BSL-IAPT area and the other two groups will meet on two occasions in a Standard IAPT area. This division is made to ensure the geographical issues identified can be discussed without additional confusion for participants. Groups will last three hours with a short break halfway through.

First meeting: this will establish current understanding of key terms and concepts such as randomisation, consent, informed choice, trial etc. previously established to be problematic in lay hearing communities.

Second meeting: this will tackle issues of personal preference, concern and influences on recruitment should a trial take place.

Groups will be facilitated by a researcher and a co-researcher both fluent in BSL who are culturally Deaf. A range of techniques to support participation and discussion will be used such as a short video trigger for discussion to explore perceived advantages/disadvantages of taking part in an RCT, concerns and satisfaction. Using a video is an approach that has been shown to be culturally appropriate in other studies involving lay members of the Deaf community.

Data capture: Data will be filmed to keep a visual record in BSL of the signs that participants use for terminology and concepts as the discussions progress. This will be useful later for the production of recruitment and information materials. Two or three cameras will be used to ensure the full group is covered and gives the option of later synchronization of the video recordings on a split screen. BSL is a language with no written form. It is therefore important to visually capture the creativity and spontaneity of the group in how they communicate key information in a culturally appropriate way, and to capture the most linguistically appropriate ways to express concepts.

Data analysis: Data will be analysed with the assistance of the CAQDAS (computer-aided qualitative data analysis software) tool NVIVO 10. The last three versions of NVIVO have allowed coding tags to be added to visual data, allowing coding of signed language data directly without the need for translation into a written language such as English. This will allow a thematic approach to support the aims of investigation of the factors affecting acceptability and feasibility of randomisation. It will also support a linguistic analysis of conceptual production in BSL to assist in the design of future materials and aid best practice in explanation and recruitment.

Ethical approval: As study participants do not lack capacity, are not being recruited through clinical services and are not commenting on clinical service experience, we will apply for ethical approval through the University of Manchester Research Ethics Committee for this part of the project.

PPI group: Participatory approach to the design of recruitment materials

Method: A participatory research approach will be used to engage the study's PPI group of Deaf people to assist in the design of the recruitment and information materials which will be used in phase II.

Sample: At least six Deaf BSL users (three of those will have taken part in the study on the exploration of acceptability of randomisation, and at least three will have not taken part in that study). In this way, by involving some participants from the acceptability of randomisation study, we will include some Deaf people who will have background knowledge and understanding about the key terms and concepts in this topic.

Recruitment: through the usual Deaf community media as well as inviting the participants from the acceptability of randomisation study.

A series of two workshops will take place to develop the study information and recruitment materials.

First meeting: this will involve working collaboratively: the group will work with the researchers to support the design, intelligibility and content of potential recruitment and consent materials. This will ensure cultural appropriateness, in order to scaffold understanding based on the work done in the previous meetings. In detail, this involves: (i) introduction and explanation of recruitment materials to be signed; and (ii) production of draft materials with the group for pilot testing.

Second meeting: refinement of materials following pilot testing with the wider PPI group.

The workshops will be facilitated in BSL by researchers who are native BSL users, precluding the necessity for mediated communication through an interpreter. The workshops will be filmed to capture ideas fully, including discussion points and visual drafts of materials. As detailed above, it is important to visually capture the creativity and spontaneity of the group and their suggestions regarding how to communicate key information in a culturally and linguistically appropriate way. We have successfully utilised this participatory approach to the design of recruitment materials in other studies involving hearing people with aphasia[15]. Final copies of participant information sheets and consent materials would be produced in BSL and made available online and in DVD format as part of the phase II feasibility study. The research team in which this study is based has extensive experience of the production of such materials for many studies.

Phase I, study 2: Secondary data analysis of patient numbers and outcome data

Aims

(i) To map likely numbers of users of BSL-IAPT and Deaf users of Standard IAPT who would be eligible for recruitment

(ii) To compare the previous outcomes of Deaf people using BSL-IAPT to estimate the discrimination (AUC) for a (i) cut-off and (ii) recruitment targets should a full trial be indicated

(iii) To explore the population characteristics of BSL-IAPT service users including demographic characteristics, referral routes, adherence and outcome

(iv) To establish the clinical cut-offs for the BSL-IAPT assessment tools (PHQ-9, GAD-7, WSAS) for patients with anxiety and/or depression

Analysis of number and characteristics of patients

Rationale

The number of Deaf people accessing Standard IAPT services is not known and needs to be established. Numbers of those using BSL-IAPT since January 2012 are higher than first thought at almost 800 people. These parameters are essential to establishing recruitment targets for any future trial and to establishing its feasibility. The comparability of the populations of BSL-IAPT users and Deaf users of Standard IAPT needs to be established in order to test whether any future trial would engage similar populations of patients. The referral, adherence and outcome data of BSL-IAPT users will assist with the design of the feasibility study.

Method

BSL-IAPT users

From 01/01/12 to 31/10/14 we know, from publicly available summary data, that BSL-IAPT had served 687 patients. As an IAPT service provider, BSL-IAPT is permitted to hold records of its patients, characteristics, adherence and outcomes in accordance with the IAPT recommended data fields and patient data security arrangements. The service provider is also permitted to add to those fields for its own internal use. The monthly upload to central IAPT data management services has fewer fields and less data than those a service provider is permitted to retain. Until mid 2013 the national system (Omnibus) only required the upload of specified KPIs: since mid 2013 the data upload is to the HSCIC (Health and Social Care Information Centre). Whilst the HSCIC have data that is more extensive than that previously required, it does not include within its minimum dataset key features such as preferred language.

We will therefore seek permission for data transfer of pseudo-anonymised patient data from the BSL-IAPT service provider for purposes of secondary data analysis in this study. We are aware that the BSL-IAPT service does not have any data transfer protocols therefore we will write a Standard Operating Procedure and seek ethical approval for its use as part of this study.

Inclusion criteria:

- Deaf sign language users who have accessed BSL-IAPT services since January 2012 and received a tier 2 and 3 service, whether or not they have completed the full course of treatment.
- A minimum of two contacts with a therapist
- Patients who have completed the PHQ-9, GAD-7, WSAS and risk assessments.

Exclusion criteria:

- Deaf people who are not BSL users (this might mean they are primarily spoken language users or that they use a different sign language such as Irish Sign Language)
- Deaf people who access the IAPT service but who are subsequently assessed as unsuitable on first contact
- Deaf people unable to complete the required IAPT initial assessment(s) e.g. because they are found to lack the capacity to consent to treatment
- Deaf people who have fewer than two contacts with the IAPT service.

Testing the data: We will test the reliability of these data by mapping our study inclusion/exclusion criteria against the referral and service protocols of BSL-IAPT to estimate the degree of confidence we can have in the numbers of patients identified in this way.

This mapping will be supplemented with discussion with Healthy Deaf Minds, the providers of BSL-IAPT, to understand any predicted changes in potential numbers of service users as a result, for example, of service expansion/change in commissioning arrangements.

We will verify that records use the most recent versions of the PHQ-9 BSL, GAD-7 BSL and WSAS BSL i.e. those whose reliability has been demonstrated and which is available in a fixed translation online/DVD.

Exploring the data: We will summarise clinically relevant information from the Deaf patients' records and establish the population characteristics of the BSL-IAPT patients.

<u>Deaf BSL users of Standard IAPT</u>

The population of Deaf people accessing Standard IAPT **cannot** be identified from data uploaded to the Health and Social Care Information Centre. Although language is a recommended field in the data collected by service providers it is not a required field for the data uploaded to the national repository. The previous national data repository, Omnibus, only required the upload of more limited KPIs which also did not include the language field. There is within the HSCIC-mandated IAPT dataset a field code for disability which indicates that a person has a disability in hearing (disability code 02) and/or in speech (disability code 10). Neither of these can be used to extrapolate that an individual is a Deaf BSL user.

We will therefore seek to estimate the numbers of Deaf BSL users accessing IAPT by other means. As a first stage in this process, we have established that the patient management system IAPTus, used by 80 of the 147 IAPT service providers, is able to run a query through its system which would

identify how many patients had been tagged with the language field code 007 (the code for BSL) across all services who had uploaded data using their system. It would also be able to strip away from that number those patients who had been provided with services through BSL-IAPT, leaving an estimated number of Deaf people accessing Standard IAPT in those services where IAPTus is the patient management system. This process would not require any patient data transfer nor access to any personally identifiable patient records. Only a raw total number would be provided to the research team. We will also request the same query is run through the PCMIS system, housed at the University of York, which is the second largest patient management system used by IAPT service providers. In this case there would be no need to strip out those patients seen by BSL-IAPT because that service does not use PCMIS. No identifiable patient data will be transferred, but both IAPTus and PCMIS will inform the users of their service of our enquiry by emailed letter, which we will supply. They will be required at a service level to confirm consent for the data management systems to run the anonymous query on their patient data uploads.

As a result of these two queries we will be able to estimate the number of Deaf people who have accessed Standard IAPT services since 01/01/12, although we will have no data on their characteristics or outcomes. This estimate will nonetheless:

- provide a benchmark in considering the feasibility of the second stage of the larger research project
- indicate whether numbers of Deaf users of Standard IAPT justify effort (through Study 3 below) to identify specific patients and seek consent for access to patient data
- assist with the calculation of recruitment and sample sizes required should a full trial be indicated.

Establishing clinical cut-offs

Rationale

Standard IAPT and BSL-IAPT utilise the same assessments, PHQ-9, GAD-7 and WSAS, recording baseline, outcome and follow-up scores. Although our previous work has translated these assessments into BSL and established the reliability of the BSL versions[4], their clinical cut-offs cannot be assumed to be the same as those used for the hearing population. Cultural factors are known to influence clinical cut-offs of standard assessment instruments when translated into languages other than their origin[21]. We need to establish the clinical cut-offs for the BSL-IAPT instruments in order to make meaningful assessments of clinical effectiveness of BSL-IAPT in comparison with Standard IAPT when accessed by Deaf people.

Method

Data generation:

Pre-existing data on 85 Deaf people with no mental health difficulties who completed the BSL versions of the IAPT assessment tools (PHQ-9, GAD-7 and WSAS) in our previous study[12] will be compared with data from Deaf service users (Deaf people with mental health difficulties who have used BSL-IAPT and who have completed the same BSL-IAPT assessments). Current information suggests a pool of almost 800 people in the latter group. The pre-existing data of Deaf people without mental health issues, which was collected in 2011/2012, is currently stored at the University of Manchester. We will be able to evaluate a preliminary clinical cut-off for each instrument by combining the data from these two sources.

Data analysis:

Parameter estimates (i.e. sensitivity, specificity) will be used to provide a sample size estimate based on the precision of AUC, for a future full evaluation of BSL-IAPT. For each test, we will calculate an AUC value, sensitivity, specificity, positive predicted value (ppv) and negative predicted value (npv). Bootstrapping of the sample will estimate variability (i.e. 95% CI) for the cut-off values and for the AUCs, and we will obtain details of the clinical cut-off and AUC from previously published work on IAPT for comparison. We will establish whether there is a statistically significant difference between the clinical cut-off values (e.g. BSL-PHQ-9 vs PHQ-9; BSL-GAD-7 vs GAD-7, BSL-WSAS vs BSL-WSAS).

Sample size considerations for Phase I: Based on a study of using PHQ-9 scores as a cut-off for depression in 93 patients[19], a sensitivity of 91.7% and specificity of 78.3% was observed. Assuming a prevalence rate of 33% for anxiety and/or depression[11] and the same specificity and sensitivity, in order to estimate a 90% CI for an AUC to within +/-0.1, we would require a sample size of at least 117 (39 depressed and 78 not-depressed patients). This calculation suggests that the patient numbers in the retrospective datasets are sufficient to estimate a preliminary cut-off for BSL-IAPT in Deaf patients.

Ethical approval:

We will apply to NHS NRES for ethical approval for this part of the study. This will include seeking access to both the pseudo-anonymised dataset from BSL Healthy Minds and the numbers of Deaf BSL user of Standard IAPT sought through the calculation carried out by IAPTus and PCMID. If needed, we will apply for local R&D approval for each of the local IAPT services to gain access to their recorded information of patients who are BSL users.

Phase I, study 3: Modelling BSL-IAPT and Standard IAPT as accessed by Deaf people

Aim

- To produce a replicable description of 'Standard IAPT' and 'BSL-IAPT' *when implemented with BSL users*

If indicated by sufficient numbers of Deaf users of Standard IAPT established through Study 2:

- To identify the patient characteristics and clinical outcomes of Deaf users of Standard IAPT in selected services contacted as part of Study 3

Rationale

As a national programme, IAPT has an established protocol for referral, assessment and therapy and standardised approaches to training/qualification of therapists and standards of service delivery[1]. When Deaf people access Standard IAPT, a range of variables come into play despite this standardization. These variables require identification if a replicable description of Standard IAPT as accessed by Deaf people is to be established for later stages of the research project. For example, whether an interpreter is used and, if so, at what level of qualification; whether the reliability-tested BSL versions of the IAPT tools are used or whether an interpreter translates the English 'live'; the extent of Deaf awareness and Deaf cultural competence of the therapist; whether the Deaf person participates in IAPT in English through lip-reading rather than through their first language.

BSL-IAPT was initially delivered in a controlled and consistent manner through one service provider who had also trained the Deaf PWPs recruited to the service. Since changes in commissioning arrangements, access to BSL-IAPT has declined in the specific areas of operation relevant to this service provider with the growth instead of IFRs (individual funding requests) as the route to potential service access. In addition, individual Deaf practitioners are now offering, in a limited number of areas, a direct IAPT service in BSL separate from that provided by the original organisation promoting BSL-IAPT. The originating BSL-IAPT service provider submitted an application to DH for National Specialist Commissioning status, but this has been rejected to date. Given these changes and uncertainties, it is not known whether there are any significant variations in consistency of service provision and adherence to service standards as a result. Consequently, BSL-IAPT and its potential variations also require modelling.

Method

<u>Standard IAPT</u>

Sample: Registered IAPT practitioners who work wholly or partially outside of the BSL-IAPT service. From the information provided on the IAPT website, it is estimated that there are at least 150 IAPT services in England, with a number of practitioners working in each of these services.

Inclusion criteria: Practitioners from IAPT services who do not practice according to BSL-IAPT procedures.

Exclusion criteria: Practitioners who practice exclusively within BSL-IAPT service protocols.

BSL-IAPT

Sample: IAPT practitioners who practice either exclusively within BSL-IAPT services or following BSL-IAPT service procedures in delivering IAPT services to Deaf people. It is estimated that at least ten practitioners are working within BSL-IAPT services. It is unknown how many may be practicing elsewhere.

Inclusion criteria: Practitioners from the BSL-IAPT service and/or Deaf people who are qualified PWPs and practicing in other IAPT services directly in BSL without interpreters and seeing Deaf patients.

Exclusion criteria: Deaf practitioners (PWPs) working with hearing patients with interpreters; Deaf practitioners not working in BSL; hearing practitioners (PWPs) using BSL to work directly with Deaf patients without interpreters; hearing practitioners (PWPs) seeing Deaf patients with interpreters.

Recruitment: Information about the survey and study will be sent out to all potential participants in various ways including post and email and utilising IAPT networks. We will also advertise the survey and its purpose in the IAPT magazine and on the IAPT website as well as through websites for counsellors and professional e-groups which are accessed by IAPT practitioners. Finally, we will advertise through our website for this project, through SORD networks and to practitioners within BSL-IAPT services, where all information will be made accessible in both English and BSL.

It will be made clear in the information sheet that all participants in this study are free to withdraw from the study at any time, without explaining their reason for doing so. Participant consent (typed name will be used as a signature) will be obtained online prior to completing the questionnaire and their identification information will be stored separately from their response data, using SelectSurvey software to store the information on the consent form. The link to SelectSurvey will be hosted on our project website, and will be made accessible in both BSL and English. This will be stored separately from their responses to the questionnaire to minimise the risk of identification. The data will be stored within a University of Manchester secure server, which will also automatically encrypt it. A paper-based survey will also be made available which can be distributed to practitioners.

Data generation/Data capture:

Standard IAPT practitioners

A written/electronic survey will be sent to all registered IAPT practitioners. A filter question will establish whether the practitioner is a BSL-IAPT practitioner and if so, they will be directed to a different data collection protocol. This filter is required because of the possibility now of some BSL-IAPT practitioners working within Standard IAPT services rather than working exclusively within BSL-IAPT as a standalone service. A telephone/email prompt to each Standard IAPT service and registered practitioners will follow three weeks later.

The survey will ask practitioners to respond to questions outlining a range of variables associated with the delivery of IAPT to Deaf people. We will ask practitioners either to respond according to their own experience if they have had a client who was Deaf or respond according to what they would do within their context/centre if they had a client referred who was Deaf. The survey will also establish basic information about their professional background and experience as well as the context and structure of the service in which they work.

Data generated from the survey will be mostly quantitative, based on responses to closed questions. A sample of practitioners from the Standard IAPT services who responded will be invited to take part in a short interview to clarify further responses either form the survey overall or their response in particular. We estimate that 20% of respondents will be contacted for interview, but the final proportion will depend on the range of issues about which we will seek further information. We expect these to concern, for example, choices and variations in supporting communication during delivery of IAPT; choices in use of which language or languages to use for the assessments; approach to cultural competence of IAPT practitioners; basis of decision-making in supporting access to IAPT services.

Additionally, in the survey, practitioners who have indicated that they have provided a service to any Deaf BSL users will be asked whether their service has retained patient records within their service in such a way as to be able to identify these Deaf patients. The language field (in which 007 specifies BSL user) is a recommended, but not a required field for patient records. Some services will retain their own detailed records which they are permitted to do at a service level, some will only record and retain the KPIs they are required to report (which do not record specific language use). Our work in study 2 will have provided an estimate of the size of the potential population of Deaf users of Standard IAPT and whether the specific targeting of individual services to obtain detailed patient records (with appropriate consents and ethical approval) would be justified.

If both the potential numbers of records of Deaf users of Standard IAPT is sufficient AND the feasibility of accessing those records from individual services (revealed by responses to the survey) is

demonstrated we will seek ethical approval to do this. We will then apply to these patient records the same analyses of outcomes, effectiveness and clinical and patient characteristics outlined in study 2 for the BSL-IAPT patient group. This will provide us with comparative data on the two populations of BSL-IAPT users and Deaf users of Standard IAPT. This will further inform our sample size calculations for the main trial and our recruitment approach for the feasibility study (Phase II). It will also assist in the decision to proceed to Phase II based on our stop criteria at the end of Phase I.

BSL-IAPT practitioners

We will interview, whether in person or remotely, all current BSL-IAPT practitioners in order to clarify the protocols and practices they use in the delivery of IAPT in BSL to Deaf people and to test the extent to which there is standardisation across services as well as across individual practitioners. The inclusion of all registered practitioners in our survey will capture those qualified Deaf PWPs who may be practicing outside of the BSL-IAPT service provider. Those practicing as part of the BSL-IAPT service will be known in any case.

Data analysis: Quantitative data will be analysed using descriptive statistics. Qualitative data arising from responses to a few open questions will be considered for recurring themes/issues using a simple content analysis approach. Analysis from both sources will be combined to produce a replicable description of Standard IAPT and BSL-IAPT that accommodates the points of variation in each (if any), the acceptable and unacceptable deviations, and records differences in practice (if any).

Ethical approval: This will be sought through IRAS (proportionate review) as it will involve potentially the transfer of pseudoanonymised data as well as non-specific professional comment on service protocols and practices.

Phase I, study four: EQ-5D 5L in BSL

Aim

- To translate and test the reliability of a BSL version of the EQ-5D 5L

Rationale

The EQ-5D is a standardised instrument for use as a measure of health outcome. There is currently no BSL version of the EQ-5D 5L. We have already gained permission from the EuroQol group to produce a BSL version http://www.euroqol.org/. EuroQol are actively supporting this work and will host the BSL version on their EQ-5D 5L online system to make it available for other users in the future. We will build on our previous work on the translation and reliability testing of standard instruments in BSL[12,23] and apply our technique to this project.

Method (Translating the English version of EQ-5D 5L into BSL)

We will translate EQ-5D 5L into BSL following the translation procedure as outlined by the guidelines developed by the EuroQol Group. There will be some additional minor adaptations to the protocol as BSL is a visual (non-written) language. In a previous study we have established the adaptations required for the translations of standard assessments into BSL[12]. This includes, for example, adaptations to the protocol to include an operationally equivalent version (which will not be in written/print version) and the need to undertake forward and back translations.

The aim is to ensure that the target language (BSL) will be as semantically equivalent as possible to the English version. There are five stages:

(i) *Forward translation* (two forward translators independently translate the EQ-5D 5L into BSL (*first draft*), meet with research project manager, produce the *second draft* of the BSL version and produce a report on the forward translation process to EuroQol Executive Office);

(ii) *Back translation* (two back translators independently translate back into English, comparing the back translation versions with the original version, produce a report on the back translation process, produce the *third draft* of the BSL version and produce a full report on the process to the EuroQol Executive Office);

(iii) *Respondent testing* (the *third draft* of the BSL version of EQ-5D 5L is tested by a sample of 8 lay Deaf respondents as outlined by the EuroQol group – including both healthy people and patients. This will involve interviewing them);

(iv) the *fourth draft* is produced, taking into account comments from the respondent testing and incorporating comments from the EuroQol translation review team;

(v) a final draft (*fourth draft*) is ready for *reliability testing*.

For the *respondent testing*, the 'patient' will be those who self-reported that they are currently experiencing physical health difficulties in, for example, mobility, self-care, daily activities, pain/discomfort, and/or mental health difficulties such as anxiety/depression.

Running parallel to the work on respondent testing, we will also carry out a small study with bilingual Deaf people [n=10], who will test out the BSL (*third draft*) and English versions of EQ-5D to show the agreement of both versions when the same user takes both tests.

Method (Establishing the reliability of the BSL version of EQ-5D 5L)

Sample: At least 75 Deaf people, living in the UK

Inclusion criteria: Over 18, audiologically deaf, BSL user

Exclusion criteria: not deaf, not BSL user, not living in the UK

Recruitment: Members of the Deaf community will be invited to take part to test out the BSL version of EQ-5D 5L via email, Facebook, word of mouth/hands, advertisement in Deaf-related magazines and online message boards.

Data generation/Data capture: Demographic information will be included in the data collection (e.g. as age, gender, hearing status of parents), as well as a self-report of current difficulties (if any) with their physical health and/or mental health. The BSL EQ-5D 5L will be tested for reliability by inserting the BSL version in a bespoke website. This remote data capture technique is time and cost efficient and appropriate for a geographically dispersed, small linguistic community[12,18]. Consent will be obtained online prior to completing the BSL assessments.

Deaf people will also be asked to complete CORE-10 BSL and CORE-6D BSL to examine the convergent validity of the EQ-5D BSL. The BSL version of Clinical Outcomes in Routine Evaluation – Outcome Measure has been developed from the previous study by some of the applicants from this study[23]. There are ten items in CORE-10, and six items from CORE-6D, both of which are from the full version of CORE-OM. Two items in CORE-10 and CORE-6D are the same and will not be duplicated. Therefore for the analysis of CORE-10 and CORE-6D we will use a total of 14 items. CORE-6D is used to establish the QALY weightings.

One week later, Deaf people will be asked to complete the EQ-5D 5L BSL again. They will be prompted to do this by email and/or SMS.

Data analysis: Within the test-retest of EQ-5D one week later, the intra-class correlation coefficient (ICC) of at least 0.7 will be used to establish the reliability. A sample size of 51 would allow a 95% confidence interval for an ICC of 0.75 to be estimated to within plus or minus 0.1. We will therefore aim to recruit 75 people in case of incomplete data. We have previously demonstrated that this sample size, using this method of recruitment, is entirely feasible[12,23].

For the convergent validity of the EQ-5D 5L BSL, CORE-10 BSL will be used as the psychopathology measure to correlate with the EQ-5D BSL. CORE-6D will be used as a health economic measure to correlate with the EQ-5D 5L BSL.

Ethical approval: We will apply for ethical approval through the University of Manchester Research Ethics Committee for this part of the project.

Phase I, study five: Exploratory economic evaluation

Aims

- To identify key items of service use and develop data collection forms for economic analysis
- To explore the potential costs of health and social care and quality adjusted life years (QALYs) of managing anxiety and/or depression for Deaf people
- To compare BSL-IAPT and Standard IAPT

Rationale

Little is known about the costs and cost effectiveness of health care services for Deaf people in general and for mental health problems in particular. The rationale for this preliminary economic modelling work is to explore the range of possible differences in health service use, effectiveness and cost effectiveness of BSL-IAPT compared to standard IAPT. The results of the economic modelling exercise will be used to inform assessments of the need for an evaluation of BSL-IAPT. The results will also be used to inform the range of effectiveness and service use parameters that may be important to measure in any future evaluation.

Method

An economic model will synthesise data from several sources (described below) to explore the potential costs of health and social care and quality adjusted life years (QALYs) of managing depression for Deaf people. The model will be used to compare BSL-IAPT and Standard IAPT. The economic model will estimate costs and benefits from the perspective or viewpoint of the NHS and social care and patients. The perspective determines the scope of costs and benefits included in the economic model. This means that we will estimate the costs of health and social care services and the costs of time and expenses incurred by patients/family. We will also estimate the health benefits to patients. These are the primary factors that incur costs for or benefit from the provision of BSL or Standard IAPT services. The model will use a one year time horizon for the primary analysis. Longer time horizons of five and ten years will be explored in sensitivity analysis, along with a life-time horizon. Time horizons longer than one year will be discounted using the rate recommended by NICE at the time of the analysis (currently 3.5%).

The analysis of the longer time horizons will take into account the long term and recurrent nature of depression and explore the longer term costs of managing side-effects of depression treatment as well as management for associated co-morbidity (e.g. NHS health care services in primary and secondary/tertiary care settings; residential, rehabilitation and social support provided by formal public, voluntary and 3rd sector services; informal care provided by family and friends). The primary measure of health benefit for the patient will be quality adjusted life years (QALYs).

Costs will be presented in UK pound sterling. Data for the model will be synthesised from:

- a systematic, focussed economic literature review to identify published evaluations and accessible databases that include relevant service use, cost and outcomes data for the economic model;
- It may also be possible to estimate service use for all IAPT services used by Deaf people from the secondary outcomes database described above. These data will be used to estimate the range of cost estimates for Standard IAPT, recognising that this may also include the costs associated with BSL-IAPT services for some people.

Health status and QALYs will be estimated from the EQ-5D 5L data generated by the development of the BSL version of the EQ-5D 5L (see above). These data will be synthesised with data from the systematic, focussed economic literature review and databases of population norms. Together, they will be used to estimate the likely range of EQ-5D 5L utility values and QALYs associated with mental health problems for Deaf people and model the potential impact of BSL-IAPT services on estimated utility and QALYs.

The model structure will be developed and validated from the literature and the qualitative and descriptive analyses described above and in discussion with experts in the research team. A decision tree structure will be drafted in the first instance to inform the need for alternative model forms (e.g. Markov model or discrete event simulation). The model will use Monte Carlo simulation in probabilistic sensitivity analysis (PSA) to explore uncertainty in the data for the primary and one way sensitivity analyses. This approach takes into account the uncertainty inherent in each of the estimates of the probability, cost and outcomes associated with the model events and pathways. Monte Carlo simulation with 10,000 iterations will be used to estimate the (expected) costs and outcomes for the PSAs. The Monte Carlo simulation samples from the distribution of possible values for each parameter in the decision model so that mean costs and outcomes, and measures of variance (standard deviation and 95% percentiles) can be estimated to assess the uncertainty inherent in the data used for the model. All the variables in the model will be assigned an estimate of the mean or most likely value and a distribution of possible values for the Monte Carlo simulation.

One way sensitivity analyses will be used to explore structural uncertainty due to model design decisions and formulation of research questions. These will include:

- Alternative time horizons;
- Different measures of patient benefit (e.g. CORE-10);

- If there are several sources of data for key parameters, the primary analysis will use an average of these. The one way sensitivity analysis will identify whether the results differ if single sources of data are used;

- Simplifying assumptions made to implement the economic model.

Other issues may need to be explored using one way sensitivity analysis and these will be determined by discussion with the experts in the research team and the Manchester Centre for Health Economics, University of Manchester. The primary and sensitivity analyses will be used to identify the likely range of services used and costs, key cost drivers, the impact of mental health problems and treatment on EQ-5D 5L health status and associated QALYs.

The primary and sensitivity economic analyses will estimate incremental cost effectiveness ratios, cost effectiveness acceptability curves and net benefit statistics of BSL-IAPT compared to usual care only. This is an approach recommended by the National Institute for Health and Care Excellence (NICE) for health technology appraisals[20]. The approach re-values effects or outcomes in monetary terms.

However, in the UK there is no universally agreed monetary value for the types of outcome measures used in cost effectiveness analyses. An approach used in health care is to ask the question: what is the maximum amount decision makers are willing to pay to gain one unit of outcome? An analysis of decisions made by NICE suggests a range of implicit values between £15,000 and £30,000 for the amount a decision maker is prepared to pay to gain one QALY[21]. However, this also depends on the level of uncertainty around the ICER. For example, an intervention with an ICER over £20,000, where there is low uncertainty about the likelihood of the result, may be seen as more favourable than an intervention with a lower ICER which is associated with high levels of uncertainty.

For this analysis, the outcomes will be re-valued using a range of maximum willingness to pay values from £1 to £30,000 to gain one unit of outcome. These reflect a range of hypothetical willingness to pay thresholds (WTPT) from decision makers being willing to pay £1 to gain a one unit increase in outcome to their willingness to pay £30,000 to gain a one unit increase in outcome. The unit of outcome for the primary analysis is the QALY, the measure used to define the range of hypothetical values implied by NICE decisions. However, some of the sensitivity analyses will use alternative measures of outcome, such as reduction in depression symptoms. Decision makers may not be willing to pay the same to gain other types of outcomes measured as they would to gain one QALY.

The data for the cost effectiveness acceptability curve are derived by first re-valuing each of the 10,000 net outcomes from the simulation by a single WTPT. This is repeated for each WTPT. A net

benefit statistic (NB) for each pair of simulated net costs and net outcomes for each WTPT can then be calculated as:

*NB = (O * WTPT) – C, where O = net outcome score and C = net cost.*

This calculation will be repeated for each WTPT. Cost-effectiveness acceptability curves plot the proportion of simulations where the net benefit of an intervention is greater than zero for each WTPT.

Ethical considerations in Phase I

Confidentiality

There is a possibility that the participants will know or be known to individuals in the research team because of the Deaf community being small. This may raise concerns about confidentiality, an ethical issue common to many research studies with Deaf people[16]. To preserve confidentiality, files and data will be stored on the University server where the research team has a secure data storage facility; the issue will be addressed directly in consent materials which will include the names of exactly who will have access to the data within the research team.

Anonymity

Video data of sign language users, for example from the focus groups, means that it is impossible to separate the identity of the participant from the data itself. The research team are used to this issue and have protocols such as informing participants as part of the consent process and strict guidelines on where data is viewed and by whom as well as remote secure storage arrangements for video data. This is well established within the University of Manchester from previous grants. The video-recorded data will be destroyed following the end of the project and the written data will be stored securely for five years before being destroyed.

For the online surveys, to protect anonymity of the data itself, the identification information of the participants will be stored separately from the data itself. A unique ID number will be allocated to each participant for both the data that contains identification information and also the data itself. The method of online data capture potentially raises concerns about the level of data security and storage. Our previous work has established the required IT protocols.

Regarding the secondary data analysis of the BSL-IAPT dataset, only pseudoanonymised data will be transferred, it will be stored securely at the University of Manchester and the researchers will not have the ‘key’ to unlock the pseudoanonymisation.

Concerns raised from the data in mental health assessments

It is possible that during the data collection, a response from a person who completes the BSL versions of EQ-5D 5L and CORE-10, raises a concern for their wellbeing and safety. In the CORE-10, there is a statement regarding whether the individual is a risk to oneself (plans to end one's life). It will be explained in the information sheet that we will contact their GP if their responses raise concerns about their well-being. Participants will be asked to respond to each question on the consent form to indicate that they have understood the purpose of the study and agree for us to contact their GP should there be any concerns from their response to the questions. Participants will also be asked to provide us with their GP contact details. For those participants whose responses have raised a concern, their GPs will receive the information that their client has taken part in our study and that we have concerns about their response to the mental health assessment. The letter to GP will enclose information to signpost them to culturally appropriate mental health services that might be available to Deaf participants.

Disclosure of mental health difficulties

It is vitally important that participants are clear about the limitations of the study. There is a risk that professionals and/or Deaf users of IAPT services expect that their involvement in the study will lead directly to accessible and appropriate mental health services for deaf people. The study information will therefore involve clear messages about what the research project can and cannot do and the boundaries of the researchers' role.

We will, however, be able to furnish potential and actual participants with information about accessible services such as SignHealth (a charity that provides counselling for Deaf people) and BSL-IAPT. This information will be freely available to anyone who contacts us about this study, and will be on the project's website. This will be particularly useful for those who might experience distress while completing the assessment tools.

Phase II - Main Methods

If Phase I indicates an RCT design, we will implement a pilot trial to explore whether an RCT can be successfully carried out. If Phase I indicates an RCT is not feasible, we will implement a pilot of a non-randomised study using a matched case control design whereby the two groups of participants (Deaf users of BSL-IAPT and Deaf users of standard IAPT) will be matched across relevant demographic covariates.

Aim

Whether Phase II progresses with a randomised or a non-randomised design, its **overall aim** is:

- To test out whether recruitment, retention and adherence is feasible in both the BSL-IAPT group and Standard IAPT accessed by Deaf people.

Phase II therefore largely consists of a pilot study to check whether the methods to be employed in a full RCT, or a non-randomised design, will work in practice and justify further investment of time and resources.

The specific **objectives of Phase II** (regardless of whether a randomised or non-randomised design is indicated) are to:

(i) test the feasibility of recruitment and retention of participants and centres;
(ii) refine the sample size and power calculation for a large scale study/trial by estimating the attrition rate;
(iii) determine whether recruitment targets required for a full trial/scaled up evaluation can be met within an acceptable timescale;
(iv) investigate the acceptability and adherence to data collection protocols in the diversity of settings associated with both BSL-IAPT and Standard IAPT;
(v) use trial and model-based analyses to explore the potential cost effectiveness of BSL-IAPT and identify key cost drivers.

Phase II, Study One: Piloting of recruitment and allocation systems

We have a close working relationship with BSL-IAPT. This will facilitate making potential participants aware of the study by providing information to service users who would then contact the study team (or not). Our Phase I service modelling work (study 3) will have provided an indication of how disparate BSL-IAPT services might be if not provided through the one original service organisation and will have provided contact information for Deaf PWPs practising elsewhere who meet our study definition of 'BSL-IAPT'. The BSL-IAPT service (and other services who provide BSL-IAPT) will be registered as Patient Identification Centres (PICs).

More complexity exists in the system of recruitment from Standard IAPT locations and ensuring that practitioners make any potential participant aware of the study. We will use the contacts established in Phase I amongst Standard IAPT practitioners (through study 3 service modelling) and provide them with recruitment packs for our study to be distributed to individual patients who are referred to them. Dependent on the results of Phase I study 2's identification of numbers of BSL users of Standard IAPT and our follow up work in study 3 (service modelling), it is likely that we will, in the first instance, target those Standard IAPT services with the highest density of previous Deaf patients before turning to other Standard IAPT services, if required, to reach our recruitment targets.

The recruitment packs will contain information about the study and how to make contact with a Deaf researcher in our team if they are interested in participating. The Deaf researcher will make individual contact with patients who express an interest in the study, for purposes of recruitment. Information independent of the researcher and in BSL will be on the study website. We will also provide a short information sheet to GPs to alert them to the study should they refer a Deaf person to IAPT. This sheet will request that they alert the study team to the service/centre who will be receiving the referral (not the name of the individual). The IAPT service/centre will be contacted by the research team with a request to pass on the recruitment pack to the patient. We will not contact the patient unless they respond to us directly having viewed/read information in the recruitment pack.

If piloting a randomised design, we will use an external process of randomisation through the MAHSC (Manchester Academic Health Sciences Centre) Trials Coordination Unit, to allocate participants to each arm of the trial. If piloting a non-randomised design, we will do the case-matching against a pre-determined set of covariates. These reflect, in part, characteristics of the specific population (Deaf sign language users) as well as variables known to be associated with mental health outcomes more generally. Candidates for the set of covariates include:

1. age
2. gender
3. whether living alone or with others
4. deprivation (at postcode level)
5. duration of mental health problems
6. previous mental health admissions or contact with mental health services
7. employment status (a disproportionately high number of Deaf people are unemployed in comparison with the general population)
8. highest educational qualification (the pattern of educational attainment amongst Deaf people does not mirror that of the general population but is skewed at the lower end)
9. whether BSL is the only signed language that a participant knows/uses (use of more than one signed language e.g. American Sign Language, Irish Sign Language etc. is not uncommon and can be used as a proxy for wider social experience and flexibility of linguistic usage)
10. hearing status of parents

The final set of key variables will be identified in Phase I from analysis of statistical associations between personal characteristics and outcomes in the study 2 analyses of the BSL-IAPT data set.

Phase II, study two: Piloting the process of service provision and retention of participants

If a randomised design is indicated, we will also pilot the process of service provision for those allocated to each arm of the trial. This is made more complex because BSL-IAPT is not provided England-wide but only in a limited number of geographical locations. This was previously in two regions, North West and South Central, but with changes in clinical commissioning at primary care level, this is likely to become more fragmented. It is possible that a picture might emerge from the Phase I work that shows a large number of individual BSL-IAPT practitioners working across a disparate geographical area and/or the retention of the BSL-IAPT core service coordination and provision through one organization, but working in a greater number of CCGs as a result of IFRs (individual funding requests). Originally, it had been expected that there would be four conditions associated with randomisation:

- A: Randomisation to BSL-IAPT and living in an area where BSL-IAPT is provided
- B: Randomisation to BSL-IAPT but living in an area where it is not provided
- C: Randomisation to Standard IAPT and living in an area where Standard IAPT is usually provided
- D: Randomisation to Standard IAPT and living in an area where BSL-IAPT is usually provided

Each of these events has consequences which potentially affect the delivery of service provision, retention of those randomised and costs of service provision, as a direct result of the research.

Condition A: Living in a BSL-IAPT area and being randomised to BSL-IAPT: cost neutral, service accessed and provided as would usually be expected;

Condition B: For those not living in a BSL-IAPT area who are randomised to BSL-IAPT this will entail a BSL-IAPT practitioner travelling to their location and it is not clear how this might affect the consent of the individual and/or service and retention. We have asked for NHS support costs to provide the clinical service outside of the BSL-IAPT boundaries;

Condition C: Living in non BSL-IAPT area and being randomised to Standard IAPT: cost neutral, service accessed and provided as would usually be expected;

Condition D: For a participant living in a BSL-IAPT area who is randomised to Standard IAPT, there are unlikely to be any additional travel costs or inconvenience associated with Standard IAPT provision because it will be available as it is to the general population in their area. There will be

some additional costs associated with access via interpreting provision because in these areas health services would usually expect a Deaf person to access BSL-IAPT and therefore would not be obligated to cover interpreting costs for access to Standard IAPT. These costs are included in our budget.

Our Phase I work will indicate whether there are additional conditions associated with randomisation that we have not considered consequent on commissioning changes outlined above and which will also be considered within this study.

If Phase II follows a non-randomised design, we will nonetheless need to pilot the retention of participants and the fidelity of service provision.

Retention of participants can in part be identified through the analysis of data uploaded to the HSCIC (Health and Social Care Information Centre) database in respect of those recruited to the study and their identifiers (attendance at sessions and length of retention in service are KPIs on which all IAPT services are required to report).

We will also evaluate if participation in a research study had an effect on continuation in the IAPT process, therefore, participants will be asked to complete a short survey on leaving their IAPT service. This survey, which will be available in BSL, is in addition to that usually carried out by IAPT services on patient satisfaction.

Sample Size: Phase I will have established the sample size and recruitment targets required for a full definitive study. Phase II will test out the feasibility of achieving these. We will implement a pilot over a six month period, recruiting participants to each condition (BSL-IAPT or Standard IAPT) and monitoring attrition. At this stage we use the convention for pilot studies of a sample size of 30 in each arm[22], but this will be refined as data from Phase I becomes available. The estimate will incorporate our knowledge of current throughput of clients in BSL-IAPT services on a monthly basis.

Phase II, Study Three: Data quality assurance

All demographic and assessment data for participants, whether in BSL-IAPT or Standard IAPT, follows a standard protocol and is uploaded to the Health and Social Care Information Centre data base for IAPT. These data are limited for purposes of this study. None of the variables associated with Deaf people's access to Standard IAPT (which we will have modelled in Phase I study 3) will be centrally recorded as they fall outside of both KPIs and the information likely to be recorded at service provider level. For example, whether an interpreter was used and of what standard; whether the BSL reliable assessments were used or the standard versions of PHQ-9, GAD-7 and WSAS in English or with a live translation etc. An additional data collection sheet developed from Phase I will

be distributed to practitioners working with the 30 Deaf people in the Standard IAPT arm (to be completed by the practitioner). In this pilot, we will establish the feasibility of its accurate completion and fidelity to actual conditions. When the recording sheet is returned to us, we will interview the practitioner by telephone to check the answers given and understand the thinking behind them. This checking is for purposes of accuracy because a non-specialist might incorrectly complete the questionnaire because of their lack of experience or make assumptions which are untested and incorrect. For example, it is common for hearing people to assume a Deaf person does not need an interpreter if they seem to be able to express themselves in spoken language, without testing out the individual's language preference, rather than communication abilities. It is a common assumption that as reading does not require hearing, then no adaption for access to an assessment is required for a Deaf person, without understanding the impact of deafness on literacy[17].

Phase I Study 3 will have modelled BSL-IAPT in order to agree a consistent definition of the intervention and its protocols. Although BSL-IAPT was set up to mirror Standard IAPT and adhere to its national protocols, the fragmentation of BSL-IAPT from a single service to a potentially distributed provision at individual practitioner level raises issues of fidelity. Therefore, the modelling of BSL-IAPT in phase I will result in a protocol checklist. In this study, individual Deaf PWPs who have delivered BSL-IAPT will be contacted to ascertain fidelity to the BSL-IAPT service protocols by completion of the checklist after each patient session and for the contact with the patient overall.

Phase II, Study Four: Economic evaluation

The economic model and literature review in Phase I will be used to develop service use data collection forms and identify the method of administration. These will be tested to assess whether they are:

- feasible to implement (participants/researchers able to complete the forms; completion rates/level of missing data)
- able to accurately identify the range of services actually used by participants in the pilot study.

It is anticipated that two types of data collection form will be used. The first is a form completed by the Deaf person. This will ask for information about whether the person has used any hospital inpatient or outpatient services in the last six months. If they have, they will be asked to record the name of the hospital and type of service used. The Deaf person will also be asked to record whether they used any community-based and primary care services. If they have, they will be asked to record

the number of visits over the last six months. The second form will be completed by researchers. If the Deaf person reports use of hospital inpatient or outpatient services, the researcher will review relevant hospital case notes to identify frequency and intensity of the Deaf person's use of those services. We will ask the participants to complete the service use questionnaire prior to the assessment appointment. Following the assessment appointment, we will interview the Deaf person by video phone or in person to check the answers given and prompt the person to complete any missing information. These data will be used to assess whether it is feasible to use self-report service use forms or whether they should be completed by interview with the Deaf participant.

The data from the pilot will be used in the economic model (developed in Phase I) to run an additional analysis, to assess whether the potential cost effectiveness of BSL-IAPT differs in the pilot participants and explore possible reasons for this.

Sample size considerations for Phase II outcomes

The results of the pilot trial in Phase II will determine whether it is feasible for a full trial to be implemented with sufficient recruitment and retention of participants to demonstrate with 80-90% power (5% level of significance) that BSL-IAPT is more effective (i.e. different clinical cut-off values) than standard IAPT for a Deaf population.

Ethical approval: Phase II

Phase II will be subject to a separate ethical approval application dependent on the outcome of Phase I. This will also be made through NRES as it will involve the recruitment of 60 people who are users of either BSL-IAPT or Standard IAPT. The main issues concerning informed consent for randomisation will have been investigated in Phase I and through the PPI group in Phase II. We will have established the most culturally meaningful and linguistically effective ways to produce information and recruitment materials in BSL. If Phase II is based on a non-randomised design, then access to BSL-IAPT or Standard IAPT is in fact access to usual treatment. Consent issues are confined to the recording and use of the data.

Statement of indemnity

Subject to ethical approval(s), a copy of the Ethics Insurance Form will be completed and submitted to the insurance office at the University of Manchester.

Second potential stop point

There will be no grounds for considering progression to a full trial if:

1. we have been unable to recruit and retain sufficient numbers to both BSL-IAPT and Standard IAPT to make achievement of estimated sample size required for a full trial feasible

AND

2. the fidelity of data collection associated with the variability in Standard IAPT as accessed by Deaf people and/or BSL-IAPT cannot be assured

Dissemination and projected outputs

Although this is a two phase study which will determine whether a full trial is justified, it will produce results at each stage which are of direct clinical and academic relevance in their own right i.e. there are significant products even if the research does not progress to a full trial.

- A BSL version of the EQ-5D with established reliability and validity will be produced. It will be the first version in any sign language in the world. EuroQol group are actively supporting this work and will host the BSL version on their EQ-5D online system to make it available for other users. An academic paper will also result.

- Secondary analysis of the BSL-IAPT patient data records and potentially those associated with a smaller number of Deaf people accessing Standard IAPT services will provide, for the first time, large scale population level data about depression and/or anxiety in the Deaf population which will assist in the targeting of current and future clinical practice. An academic paper will also result.

- Determining the valid clinical cut-offs for the BSL versions of the PHQ-9, GAD-7 and WSAS will enhance clinical practice in the future and enable meaningful comparisons to be made between outcomes of IAPT interventions for Deaf people and for the general population. The BSL versions of the instruments are already hosted on a free to access web site and distributed without charge. An academic paper will address the validation of clinical cut-offs in line with other language versions of the instruments which are available on a world wide basis. It will follow the STARD checklist for reporting diagnostic accuracy.

- Consultation with Deaf community members on how best to convey in a visual language concepts such as randomisation, trial, and treatment allocation, and the production of a culturally acceptable version of standard information and recruitment materials for a trial, will assist future RCTs involving BSL users. An academic paper will result. The translations of key terminology

in BSL within a form of web-based glossary shared on a free to access basis for other researchers will also result.

- Preliminary evaluation of the cost effectiveness of BSL-IAPT and whether it confers benefit over and above standard IAPT. An academic paper will result. The results will be conveyed through clinical commissioning groups on an England-wide basis as well as being reported to national IAPT.

- The overall design of the study tests an issue that is of wider relevance to the delivery of NHS services to other minority language communities i.e. whether there is any significant difference in terms of clinical outcome and cost effectiveness between a standard service made linguistically accessible through a third party interpreter and a standard service reconfigured to be delivered by practitioners sharing a culture and language with the users of the service. We will disseminate the findings at conferences focussed on the health and well-being of minority communities in the UK more broadly than only the Deaf community.

- The strength of the results of the study will vary depending on whether a randomised or non-randomised design is used in Phase II and whether progression to a full trial is indicated. In a field with a poor evidence base for the effectiveness of primary mental health care interventions with Deaf BSL users, its results will nonetheless assist in future NHS investments and decision-making for this population.

Plan of investigation and timetable (Phase 1 only at present, subject to further discussion about a shortened Phase 2)

STUDY	ORIGINAL MILESTONE	REVISED MILESTONE AT FIRST INTERIM REPORT	CURRENT SITUATION	PROPOSED COMPLETION MILESTONE
Study 1: Acceptability of randomisation	Months 4 – 8	Months 7 – 11	Recruitment complete; data collection complete; analysis underway; writing not started.	Month 15 (end of June)
PPI involvement in the design of the recruitment materials for phase II	During phase II	Months 7 – 11	This was originally moved into phase I, but as it is dependent on completion of study 1 it has not yet been started. The PPI group have been recruited and kept informed. It would be possible to start this group before final analysis complete of study 1 e.g. month 13.	Month 13
Study 2: (i) comparisons of outcomes and patient characteristics between Standard IAPT and BSL IAPT (ii) establishing clinical cut offs for BSL IAPT instruments	Months 4 – 6	Months 9 – 11	(ia) We have the BSL IAPT data and are calculating outcomes/outcome patterns against national Standard IAPT statistics; we are calculating patient characteristics against outcomes. (ib) We have established a means of identifying numbers of Deaf users of Standard IAPT (not individual patient data) for the purposes of calculating feasibility of recruitment. Permission requests started for data release, but returns slow (remedial action taken).	(ia) Month 13 (April) (ib) Month 13 (April)

			(ic) Unable to gather individual level patient data for Standard IAPT users within original study 2 boundaries. (ii) All data gathered for use in clinical cut-off calculations and being analysed now.	(ic) this could be put into a reworked study 3 if agreed (ii) Month 12 (March)
Study 3: modelling of Standard IAPT for Deaf people	Months 4 – 8	Unknown because of change in protocol	Ethics and R&D applications started Month 11 for the original intention of modelling Standard IAPT for Deaf people plus the revised intention of modelling BSL IAPT.	Month 18 (September)
Study 4: validation of a BSL EQ-5D	Months 4 – 6	Months 2 – 9	Translation complete; pilot respondent testing complete and satisfactory; all data collection complete; analysis complete, unable to say yet if changes will or will not be needed to the items; final version yet to be confirmed and uploaded to Euroqol website. Data for validation of the CORE-OM 6 collected; Analysis complete.	Month 14 (May)
Study 5: Economic modelling	Months 7 – 12		Literature review complete; Modelling will be continued using data from studies 2,3,4 from Month 13 onwards when available.	Month 18 (September)

Patient and Public Involvement

The main focus of service user involvement during the study is to enhance the feasibility and cultural appropriateness of recruitment, information and consent materials to be used in the pilot study which forms Phase II of the study. A PPI group of Deaf patients/former patients and Deaf people who have not used mental health services will work with the research team to produce linguistically and culturally appropriate information and recruitment materials. The research team has long-standing experience of working in the Deaf community, the trial manager is a Deaf native BSL user, there are other Deaf members of the team and hearing members who are fluent signers, but we do not presume this linguistic knowledge and culturally 'insider' status is enough to be able to fashion meaningful information for potential research participants. The perspective of those not used to research language and research concepts is vital to ensure that the correct 'register' is used in the BSL information we provide. In addition, key terms such as 'randomisation', 'cost-effectiveness' or 'trial' do not have any easy word to sign equivalence in BSL. Trying out conceptual equivalents within a visual (non-written) language will be vital for accurate and culturally meaningful transmission of information to aid understanding and informed consent.

We have budgeted for three three-hour sessions with the PPI group including travel expenses, refreshments and payment for time/expertise in accordance with INVOLVE guidelines. Details of our participatory research approach and the content of the sessions are in the main body of the proposal. Additionally, two representatives from the PPI group will sit on the advisory group of the project for its duration. We will also invite PPI group members to participate in the dissemination of the terminology we finally identify as appropriate in BSL for trial-related language. We intend this to be available to other researchers through free online access via the SORD (**So**cial **R**esearch with **D**eaf people) website at the University of Manchester.

Outside of this direct involvement in the research itself, SORD has a history of user-related public involvement in research and has run an annual free one day conference with lay members of the Deaf community to explore our research and, more recently, the greater involvement of Deaf people in the research process – see:
http://www.nursing.manchester.ac.uk/research/researchgroups/socialcareandpopulationhealth/sord/issue5.pdf

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