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

Study protocol

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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] and in Scotland in 2015 its legal position was further strengthened by the passing of the BSL Bill[2]. 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[3]. '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[4,5]. 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[6]. 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)[7].

Studies have demonstrated the inaccessibility of health services to Deaf British Sign Language users[3,4,5,8,9], including mental health services, resulting in late diagnoses and loss of benefit from early preventative interventions[9,10]. 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[4,8,9].

The DH (Department of Health) review of mental health services for Deaf people[8] 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[11,12]. BSL-IAPT[13] (known as BSL Healthy Minds by the service provider who delivers it,

SignHealth) 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[14]. 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 subsequent to the transformation from a PCT structure in England to CCG (clinical commissioning groups) instead.

BSL-IAPT has three core 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[14];

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[13].

However, there are likely to be other components to BSL-IAPT which have not been described, but which play a part in making the service culturally and linguistically well-matched for Deaf BSL users. Where a BSL-IAPT service does not exist or is not commissioned, Deaf people access Standard IAPT. These Standard IAPT services were not set up with the inclusion of 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. The range of adaptations, if any, made by Standard IAPT services to meet the requirements for Deaf BSL users are not known. It is estimated that there are around 150[15] (Standard) IAPT services in England, although it is not known how many Deaf people have used these services. A second effect of the commissioning changes has been that a small number of Deaf PWPs are now working freelance or within otherwise Standard IAPT services. These changes mean that it may no longer be appropriate to consider BSL-IAPT as defined solely as one service provided by BSL Healthy Minds. It may be necessary to describe the crucial components of BSL-IAPT, independent of provider.

It is not possible to determine whether the current investment in a core specialist service (BSL-IAPT as provided by BSL Healthy Minds) 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, particularly given the range of potential adaptations for Deaf people to the Standard IAPT service which are in existence and whose effectiveness is also unknown. 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.

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 (Key Performance Indicators) and the IAPT minimum dataset. 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 the modelling and preparatory work required prior to any future trial or large-scale observational study to answer the research questions above. It specifies the necessary outcomes that would allow decisions about progression to a full trial or large study of another research design (which would be the subject of a separate proposal if justified). In addition, there are specific outcomes to each study within the research that have independent value and implications for future research, clinical services and available information for commissioners of IAPT services in the future. The preparatory and modelling work has five components:

(i) 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.

(ii) Instrument preparation: there is no BSL version of the EQ-5D-5L currently and clinical cut-offs for the BSL versions of the IAPT standard instruments have not been established for the Deaf population in the UK.

(iii) Modelling: Standard IAPT, when accessed by Deaf people, has not been modelled: there are a range of potential variations in how it is delivered to sign language users that require investigation. Furthermore, the growing decentralisation of the BSL-IAPT provision to delivery by a range of service providers indicates a need to model BSL-IAPT as well although previously it had been considered an homogenous intervention defined in part by a sole service provider.

(iv) Secondary data analysis of patient outcome data: in order to gauge the relative effectiveness of Standard IAPT and BSL-IAPT for Deaf people, which will assist with evaluation of whether a larger scale trial would be feasible in terms of establishing the effect size required or whether a different research design would be justified

(v) Economic modelling: the development of an economic model is required for any further investigations of the cost effectiveness of IAPT provision with respect to Deaf people.

Therefore the research aims are:

(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 and GAD-7) for patients with anxiety and/or depression
(vi) To produce replicable descriptions of 'Standard IAPT' *when implemented with BSL users* and of BSL-IAPT *whether delivered through BSL Healthy Minds or within a standard service setting*

(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 conduct further analyses of data collected through the project in order to establish and compare appropriate utility weights for use in future research with this population

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

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 suitable for use in a future large trial..

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[15,16]. 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[17]. 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[18]. 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[19].

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 aim of investigating 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 could be used in a future large trial.

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[16]. 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 a future large trial. The research team in which this study is based has extensive experience of the production of such materials for many studies.

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 to a large-scale study

(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 and GAD-7) 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 referred to BSL-IAPT through the BSL Healthy Minds service 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 any future study.

Method

<u>BSL-IAPT users</u>

From 01/01/12 to 01/01/15 we know, from publicly available summary data, that 800 patients had been referred to BSL-IAPT through the BSL Healthy Minds service. As an IAPT service provider, BSL Healthy Minds 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 BSL Healthy Minds 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 (BSL Healthy Minds) 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, 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 (defined as the service provided by BSL Healthy Minds) to estimate the degree of confidence we can have in the numbers of patients identified in this way.

This mapping will be supplemented by discussion with BSL Healthy 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 and GAD-7 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 (within the BSL Healthy Minds service).

Deaf BSL users of Standard IAPT

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 Healthy Minds, 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 Healthy Minds service 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 a larger research project in the future and its potential design

- 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 individual level anonymised patient data
- assist with the calculation of recruitment and sample sizes required should a full trial be indicated or another design for a follow-on study considered.

Establishing clinical cut-offs

Rationale

Standard IAPT and BSL-IAPT utilise the same assessments, PHQ-9 and GAD-7, 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[14], 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[23]. 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 and GAD-7) in our previous study[14] will be compared with data from Deaf service users (Deaf people with mental health difficulties who have used BSL-IAPT through the BSL Healthy Minds service and who have completed the same BSL-IAPT assessments). Current information (October 2015) suggests a pool of over 400 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).

Sample size: Based on a study of using PHQ-9 scores as a cut-off for depression in 93 patients[21], a sensitivity of 91.7% and specificity of 78.3% was observed. Assuming a prevalence rate of 33% for anxiety and/or depression[13] 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 users of Standard IAPT sought through the calculation carried out by IAPTus and PCMIS.

Study 3: Modelling BSL-IAPT and Standard IAPT as accessed by Deaf people

Aim

- To produce a replicable description of 'Standard IAPT' *when implemented with BSL users*
- To produce a replicable description of the core components of BSL-IAPT *differentiated from its delivery by a single service provider.*

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 standardisation. 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 modeling e.g. there may be Standard IAPT services who are delivering a BSL IAPT service – the intervention and the service are now potentially divisible for definitional purposes.

Method

Standard IAPT

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. We are recruiting as broadly as possible with the aim of producing a model that captures the widest range of diversity. Based on the previous response rate from Standard IAPT services (within study 2) and with the input of the GM CLRN, we estimate responses from up to 50% of services and up to three practitioners within each responding service i.e. 75 x 3 = 225 responses.

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, but from our contacts with the BSL Healthy Minds service and other sources of information about national IAPT services, we estimate there to be no more than five practitioners providing BSL-IAPT within other settings.

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: This will proceed through two parallel processes: a) recruitment through fora which reach potential participants by virtue of them being IAPT practitioners; b) recruitment by direct contact with IAPT services. The former is subject to ethics permission being granted. The latter is subject both to ethics permission and, in the case of NHS IAPT services, to local governance agreement through a successful R&D application for each NHS Trust.

Routes for recruitment will include:

a) Information about the survey and study will be sent out to potential participants through post and email, utilising non-NHS IAPT networks. We will advertise the survey and its purpose in magazine, websites and other media relevant to IAPT practitioners as well as through websites for counsellors and professional e-groups which are accessed by IAPT practitioners. We will advertise through our website for this project and through SORD networks.

b) Information about the survey and study will be sent direct to contacts within BSL-IAPT and Standard IAPT services by email (subject, in the case of NHS IAPT services, to a R&D application having been approved), with the request to distribute it further to staff within the service. The email will include a link to the webpage 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 provided on the consent form. This information will be stored separately from their responses to the questionnaire to minimise the risk of identification. The link to SelectSurvey will be hosted on our project website, and will be made accessible in both BSL and English. All 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 should they prefer this format.

Data generation/Data capture:

<u>Standard IAPT practitioners</u>

The written/electronic survey for use by registered IAPT practitioners will include a filter question to establish whether the practitioner is a BSL-IAPT practitioner. 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 follow-up telephone/email prompt to each Standard IAPT service already contacted 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 from the survey overall or their response in particular. We estimate that up to 15% of respondents will be contacted for interview, about 15 interviews, 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 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 retaining 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 (as indicated in study 2) AND the feasibility of accessing those records from individual services 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 (BSL Healthy Minds service) patient group. This will provide us with comparative data on the two populations of BSL-IAPT users (through BSL Healthy Minds) and Deaf users of Standard IAPT.

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 for research concerning both Standard IAPT and BSL-IAPT within this study: This will be sought through IRAS (proportionate review) as it will involve potentially the transfer of pseudo-anonymised data as well as non-specific professional comment on service protocols and practices. R&D applications will be made for each NHS IAPT service from which pseudo-anonymised data is sought (estimated to be a maximum of 20 services). R&D applications will also be made for each NHS IAPT service to allow direct recruitment by contact to the service, using a recruitment email with links to the online questionnaire and study information (estimated to affect up to a further 130 services – we will work with the Greater Manchester CLRN who have agreed to provide support and help in gaining these approvals).

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[14,25] 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[14]. 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. 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 EQ-5D 5L BSL 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[14,20]. 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[25]. 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[14,25].

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.

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 explore the potential cost effectiveness of BSL-IAPT in comparison with Standard IAPT
- To conduct additional analyses of the data collected as part of the translation and validation of the EQ-5D 5L into BSL. This will include collapsing the CORE-6D 5 level version collected for the study to the CORE-6D 3 level version (published utility weights are only available for the 3 level version) which will then allow us to generate the CORE-6D utility weights from the data and compare utility scores generated by the CORE-6D and the EQ-5D.
- To compare the utility weights generated by the CORE-6D and EQ-5D for Deaf people to those of the hearing population and explore possible reasons for any differences found.

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 explore the longer term costs and outcomes of treatment associated with the long term and recurrent nature of depression (e.g. managing adverse effects of depression and treatment (e.g. side effects of anti-depressant medicines or co-morbidity due to

depression). The primary measure of health benefit for the patient will be quality adjusted life years (QALYs).

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

- a systematic, focused economic literature review to identify published evaluations and accessible databases that include relevant service use, cost and outcomes data for the economic model;
- data collected in the previous studies (including EQ-5D utility values and outcomes from IAPT services).

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, focused 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 hybrid model structure will be used, comprising of a decision tree structure for the IAPT intervention, leading into a Markov model for longer term outcomes.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. alternative utility sources);

- 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[22]. 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[23]. 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.

In addition to the development of an economic model explained above, additional analyses of the data collected as part of the translation and validation of the EQ-5D-5L into BSL. This will involve mapping the CORE-6D 5 level data collected for the study to the CORE-6D 3 level version for which published utility weights are available. This will then allow use generate the CORE-6D utility weights from the data and compare utility scores generated by the CORE-6D and the EQ-5D. As well as providing us with another option for utility figures in the model, this also allows us to compare and discuss the implications of using different measures to estimate utility in the Deaf population.

In addition to the analysis above, the utility weights generated by the CORE-6D and EQ-5D for Deaf people will be compared to those of the hearing population and the possible reasons for any differences found will be explored. Data for the hearing population will be identified with a literature review.

Ethical considerations

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[18]. 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 pseudo-anonymised 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 pseudo-anonymisation.

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.

Dissemination and projected outputs

- A BSL version of the EQ-5D 5L 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 5L 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 and GAD-7 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 DVDs of the BSL versions of the instruments are already 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 worldwide 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.

- We will develop a specific set of resources and information for clinical commissioning which will be web-hosted as well as existing in written form and will feed into CCG networks through a range of professional networks. They are:

    - A guide to the BSL versions of the standard assessment tools used in IAPT including evidence for their validation and reliability, practical details of where they can be obtained and guidance for their administration if used with a Deaf patient.
    - A statement of the clinical cut-off thresholds to be used with the BSL assessment tools within IAPT and evidence base for their specification.
    - A summary of the evidence concerning outcomes for a large cohort of Deaf people who have experienced service provision through the BSL Healthy Minds service, re-analysed according to the correct clinical cut-offs that have now been established.
    - A statement of what we do not know about the effectiveness and cost effectiveness of a specialist BSL IAPT provision in comparison with Standard IAPT with reasonable adjustments.
    - A description of the key components of a linguistically and culturally appropriate IAPT service for Deaf people (regardless of who is providing this and in what structure) with suitable caveats about where there is or is not evidence for the utility and effectiveness of the components separately or together.
    - A summary of the small amount of evidence gathered from Deaf service users and other members of the Deaf community concerning preferences for service provision set alongside key issues in the lack of choice between different models of delivery of provision where these exist.
    - A summary of related concerns and guidance documents where they exist concerning Deaf people's access to health services e.g. the new 'information standard', the forthcoming report from NHS England on interpreting and translation provision in primary health care.

These components will also form the basis of a short summary in BSL aimed at the general Deaf public so they too can be informed about significant steps forward that have been made concerning e.g. correct clinical cut-offs when the BSL instruments are used, information being provided to Standard IAPT services, what we know and what we do not know about effectiveness and cost-effectiveness of a specialist service in comparison with a standard service with adaptations. We have the expertise and skills in-house to produce such a video and will web-host it on our research team website for general access.

Plan of investigation and timetable

Area of project	Specific tasks	Mth 1	2	3	4	5	6	7	8	9	10	11	12
Investigate the acceptability of randomisation / participatory approach to the design of recruitment materials (PPI group)	Ethics application: UoM												
	6 x workshops with Deaf people (first meeting)												
	6 x FGs with Deaf people (second meeting)												
	Production of draft materials for pilot testing												
	Refinement of study 1 materials to provide resources on trial engagement with Deaf BSL users												
	Analysis from FGs												
	An academic paper on conceptual translation												
Secondary data analysis of pre-existing outcome data	Ethics application: NRes												
	Transfer and analysis of BSL Healthy Minds anonymised data												
	Map numbers of BSL IAPT users and Deaf users of standard IAPT												
	Comparative analysis (clinical cut-offs)												
	An academic paper on the validation of cut-offs												
	Comparative paper on secondary data analysis												
Modelling standard / BSL IAPT as accessed by BSL users	Ethics application												
	R&D approvals												
	Survey and interviews (modelling Standard IAPT)												
	Transfer of Standard IAPT anonymised data												
	Analysis of outcome data from sample of standard IAPT services												
	Interview data collection for modelling BSL-IAPT												
BSL version of EQ-5D	Ethics application: UoM												
	Translation of EQ-5D (5 stages)												
	Report to EuroQol (on fwd trans)												
	Report to EuroQol (on back trans)												
	Prepare EQ-5D web platform												
	Respondent testing of BSL EQ-5D including interview												
	3rd and then final version of EQ-5D												
	Pilot BSL EQ-5D for reliability testing												
	Reliability analysis of EQ-5D												
	EQ-5D 5L BSL uploaded to EuroQol												
	Academic paper on EQ-5D 5L BSL												
Exploratory economic Evaluation	Literature review and report												
	Synthesise data from studies 2, 3, 4 and published literature to build model												
	Preliminary analyses to test model structure, identify data needs												
	Final model analyses re net costs, QALYS, data needs for future trial												
	Paper reporting literature reviews and economic model												
Resources and information for commissioners	Guide to BSL assessment versions												
	Report on clinical cut-off thresholds												
	Report on outcomes for Deaf people seen through BSL Healthy Minds												
	Report on key components of linguistically/culturally-appropriate IAPT service												
NIHR reports													

Area of project	Specific tasks	Mth 13	14	15	16	17	18	19	20	21	22	23	24
Investigate the acceptability of randomisation / participatory approach to the design of recruitment materials (PPI group)	Ethics application: UoM												
	6 x workshops with Deaf people (first meeting)												
	6 x FGs with Deaf people (second meeting)												
	Production of draft materials for pilot testing												
	Refinement of study 1 materials to provide resources on trial engagement with Deaf BSL users												
	Analysis from FGs												
	An academic paper on conceptual translation												
Secondary data analysis of pre-existing outcome data	Ethics application: NRes												
	Transfer and analysis of BSL Healthy Minds anonymised data												
	Map numbers of BSL IAPT users and Deaf users of standard IAPT												
	Comparative analysis (clinical cut-offs)												
	An academic paper on the validation of cut-offs												
	Comparative paper on secondary data analysis												
Modelling Standard / BSL IAPT as accessed by BSL users	Ethics application												
	R&D approvals												
	Survey and interviews (modelling Standard IAPT)												
	Transfer of Standard IAPT anonymised data												
	Analysis of outcome data from sample of standard IAPT services												
	Interview data collection for modelling BSL-IAPT												
BSL version of EQ-5D	Ethics application: UoM												
	Translation of EQ-5D (5 stages)												
	Report to EuroQol (on fwd trans)												
	Report to EuroQol (on back trans)												
	Prepare EQ-5D web platform												
	Respondent testing of BSL EQ-5D including interview												
	3rd and then final version of EQ-5D												
	Pilot BSL EQ-5D for reliability testing												
	Reliability analysis of EQ-5D BSL												
	EQ-5D 5L BSL uploaded to EuroQol												
	Academic paper on EQ-5D 5L BSL												
Exploratory economic Evaluation	Literature review and report												
	Synthesise data from studies 2, 3, 4 and published literature to build model												
	Preliminary analyses to test model structure, identify data needs												
	Final model analyses re net costs, QALYS, data needs for future trial												
	Paper reporting literature reviews and economic model												
Resources and information for commissioners	Guide to BSL assessment versions												
	Report on clinical cut-off thresholds												
	Report on outcomes for Deaf people seen through BSL Healthy Minds												
	Report on key components of linguistically/culturally appropriate IAPT service												
NIHR reports													

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 any future 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 two three-hour sessions with the PPI group including travel expenses, refreshments and payment for time/expertise in accordance with INVOLVE guidelines. 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 will also engage our PPI group in evaluation of their experiences within the project and aim to produce some short video comments from them that can serve as indicators of good practice in PPI with Deaf people both for this project and for future work within the NIHR portfolio.

References

1. Smith A. *Written Ministerial Statement on British Sign Language*. http://www.publications.parliament.uk/pa/cm200203/cmhansrd/vo030318/wmstext/30318m02.htm (accessed 24 March 2013).

2. The Scotland Parliament (2015). *British Sign Language (Scotland) Bill*. http://www.scottish.parliament.uk/parliamentarybusiness/Bills/82853.aspx (accessed 21 October 2015).

3. British Society for Mental Health and Deafness. *Deaf people's mental wellbeing put at risk by lack of services. Press Release July 2010.* http://www.bsmhd.org.uk/news0710.htm#1 (accessed 24 March 2013).

4. Fellinger J, Holzinger D, Pollard, R. Mental health of deaf people. *The Lancet* 2012;379(9820):1037-1044.

5. Alexander A, Ladd P, Power S. Deafness might damage your health. *The Lancet* 2012;379(9833):979-981.

6. Hindley P, Hill PD, McGuigan S, Kitson N. Psychiatric Disorder in Deaf and Hearing Impaired Children and Young People: A Prevalence Study. *Journal of Child Psychology and Psychiatry* 1994;35(5):917-934.

7. Kvam MH, Loeb M, Tambs K. Mental Health in Deaf Adults: Symptoms of Anxiety and Depression Among Hearing and Deaf Individuals. *Journal of Deaf Studies and Deaf Education* 2007;12(1):1-7.

8. Department of Health. *A Sign of the Times: Modernising Mental Health Services for people who are Deaf.* London: HMSO; 2002.

9. SignHealth. *Why do you keep missing me? A report into Deaf people's access to primary health care.* SignHealth; 2008.

10. Kuenburg A, Fellinger P, Fellinger J. Health Care Access Among Deaf People. *Journal of Deaf Studies and Deaf Education* 2015; advance online publication doi: 10.1093/deafed/env042

11. Clark DM. Implementing NICE guidelines for the psychological treatment of depression and anxiety disorders: The IAPT experience. *International Review of Psychiatry* 2011, 23:375-384.

12. Parry G, Barkham M, Brazier J, Dent-Brown K, Hardy G, Kendrick T et al. *An evaluation of a new service model: Improving Access to Psychological Therapies demonstration sites 2006-2009. Final report.* NIHR Service Delivery and Organisation programme; 2011.

13. Flynn H. Healthy Minds for Deaf People: Outlines a new IAPT service which aims to increase access to psychological therapies for users of British Sign Language. *Best Practice Health Counselling and Psychotherapy Journal* 2012; July:34-39.

14. Rogers KD, Young A, Lovell K, Campbell M, Scott PR, Kendall S. The BSL versions of the Patient Health Questionnaire, the Generalised Anxiety Disorder 7-Item and the Work and Social Adjustment Scale. *Journal of Deaf Studies and Deaf Education* 2013;18(1):110-122.

15. IAPT. *IAPT Service Directory – NHS services for depression and anxiety.* http://www.iapt.nhs.uk/services/services/ (downloaded 19 February 2015 using Wayback Machine http://archive.org/web/ as longer available in this format at that URL).

16. Featherstone K, Donovan JL. 'Why don't they just tell me straight, why allocate it?' The struggle to make sense of participating in a randomised controlled trial. *Social Science & Medicine* 2002;55:709-719. doi:10.1016/S0277-9536(01)00197-6

17. Bowen A, Hesketh A, Patchick E, Young A, Davies L, Vail A et al. on behalf of the ACT NoW investigators. Clinical effectiveness, cost effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke, a randomised controlled trial (The ACT NoW Study). *Health Technology Assessment* 2012;16(26) http://www.hta.ac.uk/1390 (accessed 24 March 2013). doi:10.3310/hta16260

18. Pollard RQ. Ethical conduct in research involving deaf people. In: Gutman VA (ed.) *Ethics in mental health and deafness.* Washington DC: Gallaudet University Press; 2002;162–178.

19. Mayer C. What Really Matters in the Early Literacy Development of Deaf Children. *Journal of Deaf Studies and Deaf Education* 2007;12:411-431.

20. Belk RA, Trump D, Middleton A, Young AM. Genetic counselling in British Sign Language (BSL). Journal of Medical Genetics, 2011;48 (Suppl 1),SP20.

21. Gilbody S, Richards D, Barkham M. Diagnosing depression in primary care using self-completed instruments: UK validation of PHQ-9 and CORE-OM. *British Journal of General Practice*. 2007;57(541):650-652.

22. NICE. *Guide to the methods of technology appraisal 2013.* London: NICE, 2013.

23. Rawlins MD, Culyer AJ. National Institute for Clinical Excellence and its value judgments. *British Medical Journal*, 2004;329(7459):224-227.

24. Lancaster G, Dodd S, Williamson P. Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice.* 2002;10,307–312.

25. Rogers K, Evans C, Campbell M, Young A, Lovell K. The reliability of British Sign Language and English versions of the Clinical Outcomes in Routine Evaluation – Outcome Measure with d/Deaf populations in the UK: an initial study. *Health & Social Care in the Community*, 2014;22(3),278-289.