Introduction

This glossary in BSL concerns common terminology used in information and recruitment materials for randomised controlled trials. It accompanies the work reported in *Chapter 3* on trial-related terminology and also acts as a standalone resource for other research teams in the future who may be carrying out trials in BSL or wishing to recruit Deaf BSL users as participants. As a resource, this will be made publicly available. As an accompaniment to the report, this helps to illustrate further some of the issues discussed in *Chapter 3*.

Why was this glossary created?

The SORD (Social Research with Deaf People) team at the University of Manchester have been working on a large NIHR-funded project looking at the effectiveness and cost effectiveness of two types of mental health care service for Deaf people (for a BSL summary of the project, see http://research.bmh.manchester.ac.uk/bsliaptevaluation). In the future, we may run an expanded study to establish a solid evidence base about this area of practice. One option for that study would be to run a Randomised Controlled Trial (RCT). If we do that we need to be able to explain information about the trial so people can decide whether or not they are willing to take part. Deaf BSL users are not usually included in mainstream research trials, so there were no 'signs in everyday use' for a lot of the concepts we need to explain. It is important that the information about our research is clear, so people can make the right decision for them, so we asked Deaf people to help us think about these concepts and explore signs and expressions that would help future participants to fully understand what a trial was about. This research is published in English and reported in BSL too (see *Appendix 1a.* and *Appendix 1b.*). Also, the user group we worked with suggested we put these signs they had been discussing in a glossary so that other researchers could use them too.

How the glossary was created?

Our researchers met with 19 Deaf BSL users, in four separate groups, in three different areas of England. The researchers who facilitated the groups are Deaf native signers. The people in the groups were introduced to the purpose of the study and clinical trials in general. We then asked the groups to talk about on how to provide good information in BSL to support recruitment and informed consent.

PowerPoint was initially used as a prompt to different sections of the discussion. In some instances the prompts were visual diagrams; in others the prompts were specific words written in English that could be referred back to during the discussion. The facilitators introduced temporary "placeholder" signs for each term or concept the groups discussed. Participants then developed and expanded upon these.

Each focus group was filmed and the video files were analysed. Suggested signs and common alternatives were noted, and are presented here, along with advice on elements which may need to be carefully considered when creating participant materials for individual projects.

Aims of this glossary

We hope this glossary will:

- encourage discussion within a community that has historically been excluded from participation in clinical trials thus providing an opportunity for BSL users to develop vocabulary and understanding around what is, to most, a new area.
- give researchers wanting to include Deaf BSL users in trials or similar research activity a starting point for developing appropriate participant materials and having discussions in BSL which support recruitment and informed consent.
- be a starting point for our team to further investigate how best to present such materials to people who might want to take part in a trial. We do not know yet whether it is better give the information in a direct-to-camera video, have a face-to-face discussion, show a video discussion, etc., so we need to do more work to find out.

A word of caution

This glossary is not intended to be a definitive guide to how these terms should be presented in BSL to potential trial participants. Terminology may change and develop as these concepts become more familiar to community members. Trial teams should also give careful consideration to the specifics of their individual trial structure and consider the accompanying commentary before deciding how best to present their material. With this in mind, we have chosen to frame this glossary and the presentation of signed terms within a structured discussion of what we have learned

through our work, following a logical progression which aims to build understanding, rather than a traditional alphabetical structure.

Culturally appropriate delivery

There is still more work that needs to be undertaken to determine the most preferred and effective means of presenting trial and consent materials over and above what we have been able to do in the current project. Potential options for culturally appropriate, preferred and effective delivery include: face-to-face explanation directly in BSL; BSL video to be watched autonomously; BSL video with supporting documentation; BSL and written English presented simultaneously for the potential participant to be able to consult both language versions; dialogic presentation vs to-camera presentation. From our experience on this study, making materials available in both languages in advance, followed by an opportunity to ask questions directly of researchers before giving consent proved preferable.

Terms

Each entry included in this glossary consists of the following components:

- a definition of the term (in BSL and English)
- a suggested BSL sign for the term
- commentary on factors researchers should bear in mind when using this term, both during the creation of BSL materials and in direct discussion with Deaf participants

Where appropriate, entries may also include:

- possible alternative BSL signs for the term

There may be a logical order to introducing these concepts to participants, since they interconnect with each other, and understanding of one can support understanding of others. When producing participant materials, consider giving participants access to this glossary in full, alongside your own materials. Please see *Chapter 3* of the main report and the published paper Young et al. 2016[34] for a more in depth discussion.

The following text in English is an accompaniment to the materials in BSL (see *Appendix 1b*.) and does not fully stand alone because the preferred and alternative signs used are not fully described in the English below.

What is this glossary?

A glossary is a list of words and definitions linked to a particular subject, and this one contains BSL signs and definitions for some trial-related terminology. It is similar to a dictionary.

Each entry contain notes (in BSL and English) that explain the meaning of the term, a suggested sign for the term and, where appropriate, suggested variations/alternative signs as well as some advice about any possible linguistic, contextual or cultural issues researchers should bear in mind if they decide to use these signs when creating participant materials for their own projects.

FEASIBILITY - the possibility that something can be done or achieved.

FEASIBILITY STUDY - usually a small scale study carried out in order to work out whether a much larger scale study is justified. So, for example, if you wanted to test a new drug or intervention, this would need to be a big study. Before you started that, you would need to do some ground work to make sure it was possible to run such a big study. You would have to work out how many participants you would need for your study, then find out if there really were enough people out there for you to recruit; you would also need to know whether people are likely to want to get involved, whether you could get people involved quickly enough, whether the staff delivering your new drug or intervention need training, and how long that would take, and so on. In essence, a feasibility study is a study which focuses on answering the question "should we proceed with the proposed large scale project idea?" All activities of the study are directed toward helping answer this question.

- In print, this word (Feasibility) can be misleading to those who use English as a second language, since the suffix (end of the word) is likely to be more familiar than the root of the word, and may lead people to consider unrelated concepts such as DISABILITY, RESPONSIBILITY, FLEXIBILITY. To avoid this issue, it may be wise to provide a more detailed explanation, such as the one in this glossary.

TRIAL - a carefully controlled study which aims to check whether a drug or a therapeutic intervention is safe to use and effective. There are different ways to run a trial – they do not all follow the same structure.

- For many people, this word has strong associations to other, more familiar contexts, in particular, legal trials or trial periods. To avoid confusion, a definition should be provided. Additionally, we found that Deaf people preferred that any potential confusing contexts should be explicitly pointed out and so suggest it should be stated that, in this case, 'trial' is not being used in relation to court/legal domain, or 'to try/a trial period'.

RANDOMISED CONTROLLED TRIAL (RCT) - A study in which people are allocated at random (by chance alone) to different treatment or intervention groups. There are usually two groups, but sometimes there are more. One of these groups is the standard of comparison group or control group. The control group may receive a placebo ("sugar pill"), or no intervention at all, or whatever the usual standard of care is. The other groups will receive the new drug, intervention or treatment that the researchers are trying to find out about. Participants are not usually told which group they are in, so they do not know whether they are getting the new treatment or not. Sometime the researchers do not know which group people are in either, and sometimes they do know. If people do not know who is allocated to which group, this reduces unconscious bias.

- The word RANDOMISED is unlikely to be familiar to any lay audience, but they are likely to recognise the first part of the word, RANDOM, and draw associations from that. Similarly, the preferred BSL sign draws on the concept of chance – a helpful association in this instance. (See also following entry).

RANDOMISATION - a process based on chance alone by which study participants are assigned to a treatment group.

- BSL carries a higher degree of specificity than you would find in an equivalent English phrase. Deaf BSL users are accustomed to this and expect

it. Therefore, researchers will need consider the following elements of their own specific trial when producing participant materials or talking to participants.

  - Does the trial have two arms or groups, or more? These will need to be clearly established in signing space.
  - Are people allocated to groups individually, or by group? Individuals are represented by a single raised finger; groups by a different, rounded handshape.
  - Where are participants drawn from? From a regional or national sample, or from a particular locality. This help to establish context.
  - Is the trial a single-blind or double-blind trial?

  Deaf BSL users are likely to want details such as these established early on.

- Additionally, be conscious of the implication of agency within the sign. This is unavoidable, as the sign cannot be separated from the person producing it (BSL has no written form), so it is advisable to explicitly contradict this within the explanation.

INFORMED CHOICE - The voluntary choice a person makes about whether or not to become a trial participant. The person first needs to understand the trial and the possible consequences of taking part, and be able to think about it and make a decision for themselves. See also 'consent'.

- In English, 'informed' can mean having or showing knowledge of a subject or situation, and 'informed' is also past tense of 'inform'; to have given (someone) facts or information. Thus, to be informed in this case may be two-stage process; to have been told by someone else and to be/become knowledgeable. In BSL, some verbs do not just tell you what is being done, but can carry additional information about who is doing it, and to whom. It is important to make sure it is clear that it is the participant who is 'being informed' (gaining knowledge and understanding), and can then make their (informed) choice, not simply that they are informing the researcher of their choice.

CONSENT - a person must agree to take part in a trial and give their permission before they receive any type of medical treatment or intervention. They must also have the capacity to do this which usually implies sufficient knowledge and understanding to be aware of what they are consenting to.

- In BSL, the signer can combine two or more individual signs to produce a compound sign, which can represent a single English word. This allows for a more nuanced understanding than either of the individual signs alone would. In relation to consent, the suggested compound sign incorporates ideas of agreement and permission – both important in the context of giving consent.

EXPERIMENTAL STUDY - a study in which a treatment, procedure, or program is intentionally introduced and a result or outcome is observed.

- Because the form of a sign can influence conceptual understanding, it is recommended that the commonly used sign for experiment, which is an iconic representation of test tubes being poured is avoided, as this may limit participant's thinking solely to laboratory science, when the study may actually concern a complex intervention such as psychological or physical therapies.

ASSESSMENT TOOLS – tests which establish a baseline prior to treatment or intervention and/or which monitor progress, outcomes and effects. Participants are assessed before they start in the trial, then again during and at the end.

- The assessment tool used will be specific to individual trials. Given the expectation of specificity, it might be wise to state clearly which assessment tools will be used, what they are for and also how they will be administered - on paper, on a computer, by a researcher or clinician or self-administered, etc.
- Again, beware of associations to other contexts, particularly in relation to the word 'tool'.

OUTCOME MEASURES – the measures by which the research team decide in advance of a trial how they will establish the effectiveness of any treatment or intervention. So, when researchers are planning a trial, they decide how they will

measure if something they have introduced is successful. An outcome measure is both the means of establishing this e.g. through assessment or tests AND the margin of change or improvement that is acceptable e.g. must be twice as good as before. What is defined as the outcome measure is fixed before the trial starts.