Designing studies that provide adequate informed consent to clients

The Melbourne Clinic

Background

There are a broad range of intellectual and reading abilities in the general adult population. Unless you are specifically assessing clients on IQ or reading measures as part of your study, you will not necessarily be able to discern, at face value, which participants have low intellectual and/or reading abilities.

Designing your studies carefully is important first and foremost so that participants are adequately consented to the study, and secondly because failing to recognise participants with low reading and intellectual skills may impact on your results (especially if you are using self-report measures the clients are required to read and fill in, independently).

Intellectual functioning:

If you are recruiting a normal community sample it is likely that 25 percent of your clients will have below Average range intellectual functioning (i.e. IQ < 25th percentile), with a number also possibly having diagnosed or undiagnosed intellectual disabilities (i.e. IQ < 2nd percentile). If you are recruiting a mental health sample, the percentage of clients in your sample with lower than average IQ is likely to be even higher, as most mental health conditions are associated with cognitive dysfunction.

Reading abilities:

In a normal adult community sample reading grade proficiency for the two middle quartiles (e.g. the 25th to 75th percentile) falls between the schooling grades of Year 7 and Year 12. Thus, around 25 percent of your sample may have a reading proficiency level below Year 7. In a mental health sample an even higher percentage may have reading proficiency below Year 7, as higher rates of Learning Disorders (such as dyslexia) are seen in individuals with mental health conditions.

Designing your study

Intake/screening:

When going through basic intake questions for your study with participants, clients should be asked if they have any difficulty with reading, or if they have a known intellectual disability, prior to them being asked to read through the consent form and process/understand the information relevant to the study. Such questions could include:

1) Do you have any difficulty reading words accurately?
2) Do you have any difficulty understanding what you read?
3) Do you have an intellectual disability?

If potential participants answers “yes”, to any of these questions, it does not mean that they need to be excluded from the study. Rather, these questions will flag potential participants who may need extra assistance with the informed consent process.

Potential participants with reading problems may need extra time to go through the consent form and information sheet, and for a researcher to be on hand to answer questions and clarify terms. They may also need the consent form and information sheets read out loud to them (possibly several times), and they may need to be given the option to discuss the study and study information with a friend/relative, prior to signing up for the study. Potential participants with intellectual disabilities will also require these procedures, and in the case of participants with a known intellectual disability, consent for the participant to commence the study should always be sought from their next of kin or guardian, in addition to the participant.

Asking the questions listed above does not guarantee that you will identify all participants with reading/intellectual difficulties, as some may lack insight about their difficulties. Researchers responsible for the informed consent process should look out for participants who appear to be struggling with understanding the requirements of the study (asking repeated or unrelated questions, appearing confused about the study, exhibiting poor concentration and attention which impacts on their ability to take in information about the study). Where this is observed, or suspected, extra care (as above) should also be taken to ensure these participants are adequately consented for the study.

One way to check how much the potential participant understands about the study is to ask them to repeat the information back to you, in their own words. This can be done in a non-patronising way by asking a question such as the following:

“I am required to make sure that participants properly understand what is required for the study. Can you tell me what you understand about the study, based on what we have discussed/you have read?”

If there are any doubts about the potential participant’s capacity to understand the requirements of the study, they should not be included in the research.

Information sheets and consent forms

Given the wide range of intellectual and reading skill levels in the general adult population, it is very important that information sheets and participant consent forms are written in a manner that is easily understood. A specific set of guidelines has been written to assist researchers with this. Please see the accompanying sheet **“Guidelines for Consent Forms and Information Sheets”**.

Running the study

During your study, any participants that have indicated they have difficulties with reading or an intellectual disability, or participants identified by researchers as having difficulties in these areas during the consent process, may need extra assistance. This will be particularly important if there are self-report measures in the study.

If a client with reading or intellectual difficulties is given self-report questionnaires to fill out they may have difficulty understanding the information. In these instances they may not feel comfortable telling researchers that they do not understand the measures, or that it is too much for them/overwhelming. As a result they may make guesses about what they should tick/write/choose to the best of their abilities – which may be incorrect due to reduced comprehension/understanding, or they may randomly fill out forms (i.e. ticking boxes or circling items without reading/understanding the content). This can significantly affect the validity of your study results.

There are several ways to attempt to reduce the impact this may have on your study:

1) Choose self-report measures that have clear, well written questions that are easily to read. Questions should avoid jargon, technical terms and complicated vocabulary. Pilot test your measures with a sample group first, if possible, and ask them to flag what they do not understand. Run the self-report questionnaires through the reading ease/grade measures (outlined in the Guidelines for Consent Forms and Information Sheets) to determine if they are too complicated.
2) Have a researcher sit with any clients who have reading or intellectual difficulties, when they are filling in their forms. Provide clarification of any information they do not understand, and/or read out the questions in the forms, as well as the response choice options, to the participant.