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Assessing Understanding and Obtaining Consent from Adults with Intellectual Disabilities for a Health Promotion Study

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Abstract

People with intellectual disabilities are often excluded from research, in part because they may be perceived as lacking capacity to provide informed consent. A requirement of informed decision making about research participation is ability to understand the study description and disclosures presented during the consent process. The authors' aims were to determine the extent to which study participants with intellectual disabilities were able to answer questions about key aspects of study disclosures, identify ways in which people who provided appropriate answers for all of the questions differed from those who had difficulty with one or more of the questions, and examine patterns of responses to see if certain issues were more difficult to understand than others. The authors piloted a short set of questions to assess the extent to which adults with intellectual disabilities were able to answer questions about key aspects of a health promotion study. More than half of study participants correctly answered all of the questions. For those not able to answer all questions, identifying potential risks of being in the study proved the most challenging. The findings indicate that many people with intellectual disabilities likely can provide their own consent to participate in low risk studies.

Keywords

intellectual disabilities; informed consent; research participation

Introduction

There is considerable need for research to address health issues facing people with intellectual disabilities (ID), such as the high prevalence of obesity, oral health problems, abuse, and health care disparities in this population (Havercamp, Scandlin, & Roth, 2004; Horner-Johnson & Drum, 2006; Owens, Kerker, Zigler, & Horwitz, 2006; Rimmer & Wang, 2005; Yamaki, 2005). Unfortunately, people with ID are often excluded from research studies (Lennox et al., 2005). In the U.S., policies of federal funding agencies have sought to ensure greater representativeness and relevance of research by mandating inclusion of women and racial minorities in research (U.S. Department of Health and Human Services Public Health Service, 2011), but as yet there are no corresponding mandates regarding inclusion of people with disabilities.

There are a number of explanations for limited representation of people with ID in research studies, including the fact that people with ID constitute a relatively small segment of the population (Zeldin & Bazzano, 2010). Furthermore, people with ID have historically held little power or influence (Iacono, 2006a; McDonald & Keys, 2008). The combination of

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cognitive limitations and social powerlessness places people with ID at risk for exploitation within the research process (Dalton & McVilly, 2004). In response, ethics committees sometimes go to such lengths to avoid harm that their requirements discourage researchers from attempting to conduct research with people with ID (Aman & Handen, 2006; Iacono, 2006a). While the potential vulnerability of people with ID warrants caution, exclusion of people with ID from research denies this segment of the population the opportunity to contribute to scientific knowledge and means that the benefits gained from research studies may not be applicable to people with ID (Aman & Handen, 2006; McDonald & Keys, 2008; McVilly & Dalton, 2006).

One reason for excluding people with ID from studies is that they may lack, or be perceived as lacking, ability to provide informed consent. In fact, it is not unusual for studies to list ability to provide informed consent as an inclusion criterion (Foxcroft et al., 2011; Staehr et al., 2011). What is less common in study descriptions is any explanation of how ability to consent was assessed. It is possible that people with ID may simply be assumed to be incapable and thus ineligible. However, many researchers in the ID field agree that a diagnosis of intellectual disability should not automatically lead to the presumption that an individual is incapable of decision making and providing informed consent to participate in research (McDonald & Kidney, 2012). Capacity to consent is typically conceptualized as encompassing four components, which include the ability to: 1) understand relevant information; 2) appreciate the consequences of the information for one's own situations; 3) reason about the available options; and 4) communicate a choice (Appelbaum, 2007). Thus, a key aspect of capacity for consent is the ability to understand the study disclosures that are presented (del Carmen & Joffe, 2005). In fact, the National Institutes of Health have focused on this as the primary issue, defining consent capacity as "ability to understand information relevant to making an informed, voluntary decision to participate in research" (NIH, 2009). Both Institutional Review Board members and ID researchers have expressed concerns about how well people with ID understand research procedures and risks presented during the consent process (McDonald et al., 2009). Although limitations in understanding are by no means exclusive to those with ID, assessing ability to understand important components of study disclosures can be a critical step in determining whether and how to include people with ID in a study.

Earlier attempts to address the above concerns involved testing of general cognitive abilities, including those related to decision-making. These were generally in-depth assessments, often requiring specialized training to administer. However, some researchers criticized the potentially burdensome nature, both for the researcher and for the individual with ID, of psychological assessments to determine general capacity for decision-making (Iacono, 2006b). More recently, the focus has shifted to streamlined approaches to aid investigators' judgments about consent capacity for specific studies (NIH, 2009). For example, a brief set of questions can ascertain the extent to which people with ID understand aspects of the study that are relevant to making an informed decision about participation (Aman & Handen, 2006). Such approaches are applicable for individuals with any condition that may impact cognitive functioning, such as ID, psychiatric disability, traumatic brain injury, stroke, dementia, substance abuse, or psychoactive medications (NIH, 2009).

Assessment of consent capacity can be a relatively informal screening process during the initial phases of a consent discussion to identify individuals who may have problems understanding consent-related issues. The screening may include questions about issues such as the purpose of the research, the voluntary nature of participation, and possible risks and benefits (NIH, 2009). Those who have difficulty answering questions may be excluded from the study, provided with additional information and screening, or enrolled with consent of an authorized representative (NIH, 2009). The most appropriate strategy may vary depending

upon the risks and requirements of the particular study. Brief screening measures have been tested in other populations that may have impaired consent capacity, (e.g. adults with schizophrenia or Alzheimer disease) as well as those not expected to have impaired capacity, such as adults with diabetes (Jeste et al., 2007; Palmer et al., 2005). Similar methods have also been applied to ensure understanding among individuals with ID (e.g. Arscott, Dagnan, & Kroese, 1998; Hughes, 2010; McDonald, Kidney, & Patka, 2012). However, there has been less discussion of what steps to take when respondents with ID have difficulty answering screening questions.

Aims

This article describes a pilot implementation of a short set of questions to assess understanding of consent-related study disclosures among adults with ID. Our aims were to: 1) Determine the extent to which study participants were able to answer questions about key aspects of the disclosures; 2) Identify ways in which people who provided appropriate answers for all of the questions differed from those who had difficulty with one or more of the questions; 3) Examine patterns of responses to see if certain issues were more difficult to understand than others. Further, we describe one approach to including people with ID who may not have adequate consent capacity.

Methods

Participants

Participants were adults with intellectual disabilities who were interested in participating in a health promotion study. The study was a randomized controlled trial of a health promotion program designed for people with disabilities. The program was primarily educational in nature, with some moderate exercise included. Study measurements were non-invasive. Thus, this was considered a low-risk study.

Individuals were identified through community based disability organizations, educational transition programs, service agencies, and disability related events (e.g. Special Olympics games). To be eligible for the study, individuals were required to be: 1) 18-65 years of age; 2) receiving state services for people with ID, such as case management; 3) living in non-institutional settings (e.g. group home, family home, independent apartment); 4) confirmed by service provider or family member to have ID in the mild to moderate range and demonstrate sufficient understanding of study information that staff judged them to be able to participate in and learn from the health promotion intervention; and 5) willing to participate in the study for a full year and be assigned to either the experimental condition or the control group..

Measure

Six questions were developed, based in part on examples from Ciemnecki et al. (2006). The questions ascertained the extent to which participants understood the study information that had been presented to them. Level of understanding was used to assess appropriateness for participation in the health promotion intervention, as well as how consent should be obtained for those included in the study (see Procedures). Terms within the questions were explained as needed. The questions were:

1. Please tell me, in your own words, what is this study about?
2. What will you be doing if you take part in this study?
3. What are the risks of being in this study?
4. When I say your taking part is completely voluntary, what does that mean to you?

5. When I say that your answers will be kept confidential, what does that mean to you?
6. What can you do if you start the study but don't want to finish it?

Procedures

Assessing understanding—Study staff met one-on-one with potential participants who had expressed interest in the study during the recruitment phase. Meetings were conducted either in person or by telephone. In some cases, scheduling the meeting required first explaining the study to a support provider such as a parent, other family member, legal guardian, case manager, or paid support staff. In these cases, the process was only allowed to continue with the agreement of the support provider, who served in the role of gatekeeper. Support providers also offered insight as to how the potential participant best understood or processed information, and suggested techniques to help ensure the participant's comprehension. The suggestions included strategies such as: speak slowly, repeat questions, rephrase questions if the individual appears confused, and provide the individual enough time to process the information.

Project staff began each meeting with a potential participant by establishing rapport with the individual to help him or her feel comfortable. This was typically accomplished by referring back to how they had met during the recruitment phase and then engaging in casual conversation about the potential participant's hobbies, interests, work, or other daily activities. Next, staff explained the study purpose and procedures and the responsibilities and rights of study participants using common everyday words, short sentences, and active voice. A basic script for the study explanation was developed using the Fleish-Kincaid statistic in Microsoft Word to achieve a grade school reading level. Staff then asked potential participants the six questions listed above to determine whether they had understood the study information that was presented. If the potential participant had difficulty answering a question, the staff member explained that portion of the information again, rephrasing if needed, and then gave the respondent a second chance to answer the question. Capacity to answer appropriately was determined by the staff member conducting the interview. Correct answers were determined by the individual's ability to paraphrase the study information using their own words and frame responses as the information applied to their own situation. Where any doubt existed as to the appropriateness of a response, we erred on the side of caution and marked the item as insufficiently understood. Depending on the potential participant's attention span and ability to remember and process information, the screening procedure described above was sometimes broken into two meetings. The first meeting consisted of explaining the study to the participant (and to a support provider if applicable). During the second meeting, staff reiterated a brief description of the study and then asked the comprehension questions. Time was given between calls to allow for the participant to think about the information, often with the assistance of a support provider. Support providers were asked not to attempt to persuade the participant but to explain the study in a manner and environment most conducive to the understanding of the participant.

Respondents who were unable to answer any of the questions after two attempts were excluded from the study. The rationale for this decision was that these individuals likely also would have difficulty understanding and benefiting from the information presented as part of the health promotion intervention. Those who could answer some but not all of the questions were asked to bring an authorized research representative (ARR) to the initial study meeting. An ARR is someone designated to provide consent on behalf of an individual determined to have limitations in decision making capacity. Additionally, ARRs are charged with monitoring and supporting the individual's best interests throughout the study and assisting in withdrawing from the research if the individual desires. In accordance with local

IRB policy, ARRs may be chosen by the individual with ID and may include (as applicable) the individual's legal guardian, spouse, parent, adult child, adult sibling, or other adult relative or friend (OHSU Research Integrity Office, n.d.). In the case of potential participants who were not their own guardians, we asked that their legal guardian attend the initial study meeting or designate a proxy to attend and serve as ARR. This was required regardless of how individuals answered the questions assessing understanding of study information.

Obtaining signed consent and assent—Signed consent was obtained during an initial study meeting prior to the start of the health promotion intervention. These were group meetings with 10-20 potential study participants and their ARRs, as applicable. All attendees were provided with a copy of the study consent form, which consisted of written information prepared using the local IRB's template. With the exception of university-required liability language, the consent form was written at a grade school reading level using common words and short, direct sentences. The form was structured using a question and answer format, with content provided to address the following questions: 1) What is the purpose of this study? 2) What is required to participate in this study? 3) What can I expect as a study participant? 3) What effect will this study have on my care? 4) How will my privacy be protected? 4) What are the possible risks of participating in this study? 5) What are the possible benefits of participating in this study? 6) Will it cost anything to participate? 7) What if I am harmed or injured in this study? 8) What are my rights as a participant?

Project staff provided an oral overview of the study and the consent form. After presenting the key points in each section of the consent form, staff invited and responded to questions from attendees. A further question and answer period occurred at the end of the review of the consent form. The voluntary nature of the study was emphasized. Individuals who were their own guardians and had correctly answered all questions assessing understanding then signed the consent form if they wished to continue with the study. Individuals with ARRs discussed the study with their ARRs while staff circulated through the room to answer any additional questions. Staff spoke with each individual with an ARR to ask for a verbal indication of whether or not the individual wished to participate in the study. Staff read aloud a brief assent form which stated that project staff had: 1) explained the study and described good and bad things that might happen to the individual; 2) asked questions to make sure the individual understood what would happen in the study; 3) answered any questions the individual had about the study. The form also stated that the individual had thought about the study and decided to participate. If individuals confirmed all of the above points and wished to enroll in the study, they signed the assent form. The guardian or ARR then signed the consent form.

All study procedures were reviewed and approved by the Institutional Review Board of Oregon Health & Science University.

Results

Two individuals were unable to answer any of the questions and were thus excluded from the health promotion study. The remaining 131 all wished to participate in the study and were enrolled as research participants. Of these, 75 (57%) were able to answer all six questions assessing understanding of the study protocol. Those who had difficulty answering one or more questions and thus needed an ARR for this study were significantly more likely to be living with family or in a group or foster home rather than an independent home or apartment (X^2 (df=1) = 4.40, p = .043). There were no significant differences between those who did and did not need an ARR with regard to age, sex, marital status, or education. There

were no disagreements between individuals with ID and ARRs regarding the decision to participate in the study.

The prevalence of correct responses to most of the individual questions was high. Specifically, 96% of respondents were able to appropriately describe what the study was about, 96% correctly described what they would be doing if they took part in the study, 93% were able to explain what voluntary participation meant, 88% could specify what it meant that the data they provided would be kept confidential, and 93% were able to state what they could do if they started the study but did not want to finish it. However, nearly half (48%) of the participants had difficulty identifying potential risks of being in the study.

Discussion

More than half of the sample was able to demonstrate adequate understanding of the study. These results indicate it is certainly possible for people with ID to understand study disclosures, provided those disclosures are given in simple language as part of a dialogue with potential research participants. However, 43% of the sample had difficulty answering at least one of the questions about the study disclosures. This gives credence to concerns that have been raised about whether consent obtained from adults with ID is truly informed (McDonald et al., 2009). Based on our findings, it is critically important to explain research studies carefully to potential participants with ID and ascertain the extent to which the information is actually understood before proceeding.

There are a number of more detailed measures available for assessing capacity to consent to research or medical treatment. Many of these measures measure general capacity and must be administered by trained or licensed professionals. The length of time required for administering these measures ranges from 10 minutes to 1.5 hours (Dunn, Nowrangi, Palmer, Jeste, & Saks, 2006). With a few exceptions (Fisher, Cea, Davidson, & Fried, 2006), most of these measures were not developed specifically for people with ID, and may be difficult to implement with this population. Our experience indicates that a brief set of questions to assess understanding can be successfully used as part of the consent conversation in a sample of adults with mild to moderate ID. Other studies (e.g. Arscott, Dagnan, & Kroese, 1998; Hughes, 2010; McDonald, Kidney, & Patka, 2012) have also used short, straightforward measures similar to the one we employed to assess understanding.

In the U.S., the need for such tools may soon be expanded in light of proposed changes to the Common Rule. The U.S. Department of Health and Human Services is considering requiring researchers to ask questions to ascertain how well individuals understand the information provided to them, at least for certain types of studies (U.S. Department of Health and Human Services, 2011). This requirement may be applicable to a range of population groups, including those not typically considered vulnerable. One recent study found evidence that college students did not carefully read a sample consent form and had difficulty answering recall questions about key information (Pedersen, Neighbors, Tidwell, & Lostutter, 2011). Thus, quizzing any potential research participants about study disclosures may be an important step in ensuring that individuals -- regardless of disability status or other factors that may influence consent capacity -- are actually aware of the procedures, risks, and requirements associated with a study such that they can provide truly informed consent. Applying screening questions as a matter of standard practice has the added benefit of treating all research participants equally. In other words, people with ID and those in other potentially vulnerable groups would not be singled out for assessments of consent capacity, which could itself be considered a form of discrimination. Instead, study procedures would be focused on ensuring informed consent for all.

Employing ARRs provides one alternative to study exclusion, in which people can be included even if they do not demonstrate full understanding of study disclosures. Using ARRs is an attempt to balance the need to protect people with ID or vulnerable groups from exploitation while preserving their right to take part in research. Because use of an ARR is separate from the issue of legal guardianship (OHSU Research Integrity Office, n.d.), people with ID who are their own legal guardians can obtain decision-making assistance in one arena of life while maintaining independence in other areas. Even when an ARR is used, it is important that people with ID be involved in the decision making process to the extent possible, including providing assent (OHSU Research Integrity Office, n.d.). Ideally, the ARR should engage in a process of supported decision-making to help the individual with ID weigh the pros and cons of participating (Bach & Rock, 1996; McVilly & Dalton, 2006); the ARR then provides consent based on the preferences expressed by the person with ID.

There are other approaches that may be less restrictive than using ARRs. For example, if initial screening suggests difficulty with understanding, researchers could provide additional education about consent issues and more detailed assessment prior to determining that an individual has insufficient consent capacity (NIH, 2009). Researchers and IRBs may also set different cut points for the level of consent capacity required depending on the complexity and risk of a given study. For lower risks studies, some evidence of understanding even if not complete might be deemed sufficient for an individual to provide informed consent. In these cases, responses to certain questions might be weighted more heavily than others. Researchers may also use strategies shown to improve comprehension, such as multi-media consent presentations (Eyler & Jeste, 2006).

People in our sample had the most difficulty describing the risks involved in the health promotion study. This may have been because the particular study was low risk. The risks that were described in study disclosures were rather abstract (e.g. loss of confidentiality although the information being shared was not particularly sensitive). Such a threat may not have been deemed relevant by study participants. It is important to examine this issue further with a higher risk study to determine whether people with ID can identify study risks when clear risks do exist. If the concept of risk is one that people with ID have difficulty understanding even when study risks are more concrete, such a finding would suggest that strategies to improve understanding of risk and/or use of ARRs might be particularly advisable for higher risk studies. The overarching need is for flexible approaches that respond to the needs of participants and facilitate research inclusion to the extent possible while maintaining high ethical standards for protecting research participants from harm.

The concept of research benefits was not directly addressed by our questions, but is another important issue for potential research participants to weigh in making their decisions about whether or not to take part in a study. Participants have the right to expect that research provide some concrete benefit either to them or to others like them. Like risk, the anticipated benefits of research can be challenging to explain. Examination of understanding of study benefits among individuals with and without ID would be a useful addition to the literature on research ethics. Further, researchers and IRBs should consider how an understanding of benefits (or lack thereof) should be weighed in the context of understanding of other issues when making determinations about consent capacity.

Limitations and Future Directions

There is wide variability in potential limitations in decision-making within the population of people with ID. Our study utilized a convenience sample of people with mild to moderate ID; therefore, our findings may not be generalizable to other samples or the broader ID population. For this study, some of the consent comprehension screening interviews were conducted in person and some by phone. In the process of conducting the screenings, we

discovered that in person meetings were more successful than phone meetings. In person meetings made it easier to establish rapport, hold the participant's attention while explaining the study, and observe whether the participant appeared confused. It is possible that more participants would have been able to understand the information better and provide appropriate answers to more of the questions if all screenings had been conducted in person. We recommend in-person interviews for future applications of similar assessments. We assessed understanding specific to our health promotion study. The extent to which people with ID are able to answer similar questions about other studies may vary widely depending on the topic and study design. Furthermore, determining whether or not responses to the open-ended understanding questions demonstrated sufficient understanding was somewhat subjective. This is a common issue with such measures. Future research could examine inter-rater reliability of scoring responses to the six questions.

The study disclosures were based on a standard written consent form accompanied by a project staff member's explanation of the material covered in the form. Understanding might have been increased with other support methods such as use of pictures to illustrate consent information, and/or use of an advocate to help describe and explain the study. Similar strategies have been used or suggested by others (Aman & Handen, 2006; Cameron & Murphy, 2006; Fisher, 2003; Swain, et al., 2011). Additional research is needed to determine the extent to which such methods help people with ID understand the issues involved in research participation. Continued development and testing of these and other accommodations could ultimately aid people with ID in making their own, self-determined decisions about participating in research and may increase the extent to which people with ID are included in research studies (McDonald et al., 2009; McDonald & Kidney, 2012).

Conclusion

It is important for research samples to reflect the diversity of the population, including people with ID. Rather than assuming that people with ID lack capacity to consent to research, researchers can take steps to assess and facilitate informed consent. Measuring understanding of study disclosures is an important first step. Our findings indicate that many people with ID demonstrate sufficient understanding to provide their own consent. When understanding is limited, various accommodations may be employed, including use of surrogate consent, advocates to assist with the consent process, and adaptations to consent forms to make them easier to understand.

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