Title

Addressing Challenges in Gaining Informed Consent for a Research Study Investigating Falls in People with Intellectual Disability

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Figure Legend:

Figure 1: The Three-Item Decisional Questionnaire

Figure 2: Flow of events through the consent process

Figure 3: Flow of study participants through the study process

Accessible Summary

- People with intellectual disability do not often take part in research
- When people with intellectual disability are thinking about taking part in research it is important that they are given support to participate in the decision making

- This paper describes how an informed consent process was developed for people with intellectual disability and how it is working in a current study

Abstract

Background People with intellectual disability encounter substantial health care discrepancies, yet are under-represented in research. Whilst people with intellectual disability can make valuable contributions to research and consequently improve their quality of life, researchers encounter multiple challenges including them in research. One challenge is to support them in making an informed decision to participate in research. Therefore the aim of this paper is to describe and reflect on a consent procedure used while gaining informed consent, when recruiting potential participants into an ongoing study.

Methods A systematic and holistic consent procedure, underpinned by ethical guidelines, was developed and used alongside recommended strategies to engage people with intellectual disability in a research study.

Results Only 3 participants (7.5%) were deemed capable of consenting independently, while 37 participants (92.5%) required the support of a proxy. Of these 37 participants, 22 participated in the consent process, while 15 depended mainly on their caregiver to make decisions for them. Adapted communication strategies were found to facilitate a person who has an intellectual disability's participation in the consent procedure. The adapted written information sheets were of secondary importance.

Conclusion The consent procedure was a respectful means of determining a person's capacity to consent and indicating where there was a need for proxy consent. Appropriate communication strategies and the inclusion of familiar caregiver(s) were critical components

for facilitating the person with an intellectual disability to participate in the consent procedure.

Key words

Intellectual disability, Informed consent, Mental competency, Research participation, Accidental falls

INTRODUCTION

Developmental intellectual disability has been estimated to affect approximately 153 million people worldwide (Vos et al., 2016). In Australia for example, intellectual disability occurs in 1.9 per 100 children born, equating to approximately 5000 children with an intellectual disability born each year (Leonard, Petterson, Bower, & Sanders, 2003). People living with intellectual disability experience more mental and physical health problems than the general population (Cooper et al., 2015).

Reports over the last decade suggest that significant healthcare discrepancies amongst people with intellectual disability are persisting (Ward, Nichols, & Freedman, 2010), including poor detection of treatable life-threatening conditions, resulting in potentially preventable and premature deaths (Trollor, Srasuebkul, Xu, & Howlett, 2017). There is a critical need for research and improved services aimed at improving the lives of people with intellectual disability (Brolan et al., 2012; Trollor et al., 2017).

However, people with intellectual disability are underrepresented in medical research (Feldman, Bosett, Collet, & Burnham-Riosa, 2014) and there are barriers to their participation (Iacono, 2006; Iacono & Murray, 2003). The reason poorer health outcomes in

people with intellectual disability persist is partly due to multiple barriers to receiving health services and therefore require evidence based interventions that are tailored specifically for them (Bartlo & Klein, 2011). Therefore, including people with intellectual disability in research is one pathway to the provision of evidence-based and targeted services. It is important to recognise that people with intellectual disability not only have the equal right to, but can also make valuable contributions to the betterment of their lives through meaningful participation in research (McDonald, Kidney, & Patka, 2013).

There is still no clear consensus about how to meaningfully include people with intellectual disability in the informed decision-making processes for participation in research, (McDonald & Kidney, 2012; McDonald & Patka, 2012) but researchers in this area have identified several challenges in this regard. It is highlighted that the comparatively lengthy consent processes (Taua, Neville, & Hepworth, 2014), recruitment legalities (Lennox et al., 2005) and limitations in the participant's ability to provide consent independently (Dye, Hare, & Hendy, 2007) are barriers to including people with intellectual disability in research studies. Researchers in the field have systematically shared strategies to address these challenges (Archibald & Munce, 2015; Kidney & McDonald, 2014; Becker et al., 2004) and this present study adopted several of them to develop the informed consent process.

Upholding the ethical principle of respect (National Health and Medical Research Council, 2007) when involving people with intellectual disability in research can be challenging and further investigation of optimal mechanisms to include people with intellectual disability in research is much needed. Therefore, the aim of this paper is to describe an informed consent process used when recruiting persons with intellectual

disability for a study which is currently investigating falls among people with intellectual disability, and to reflect on the methods of informed consent used.

METHODS

Research Aims and Study Design

The aims of the study are to investigate the rate of falls in older adults with intellectual disability living in the community, with daily recordings of falls, and to explore the participants' experiences when seeking healthcare services after having a fall using semi-structured interviews.

This research is currently in the recruitment phase. This paper describes the consent process undertaken with the first 40 participants of the study and describes the researcher's experiences in using this consent process.

Participants

There is evidence that people with intellectual disability show signs of 'premature aging' (Carmeli, Iman, Bachar & Merrick, 2012) and develop aging-related health conditions, such as dementia and diabetes, from the third decade in life (van Schrojenstein Lantman-de Valk et al., 1997). Falls often relate to aging and therefore, participants that are eligible for inclusion in the present study are adults aged 35 years and older, who have a diagnosis of intellectual disability or a diagnosis in which intellectual disability coexists (e.g. Down syndrome).

The study focuses on older adults with intellectual disability living within the community; therefore, participants are either living at home with their family, in

independent units with or without paid support, or in small group homes with up to two to four co-inhabitants with paid support.

Participants are recruited from a supporting organisation who provide services to people with intellectual disability. Potential candidates who fulfil the inclusion criteria are identified by the employees of the organisation who work closely with them. The employees who are familiar with the person who has an intellectual disability are responsible for making contact and gaining permission for the researcher to approach them and/or their legal guardian to discuss the research project.

Procedure and Materials

Ethics

The study is aligned with human research ethics guidelines from the National Health and Medical Research Council (NHMRC) (National Health and Medical Research Council, 2007)) and the specific ethical guidelines for researchers in Western Australia (WA) in relation to adults who may lack the capacity to give consent (WA Health Ethics Application Form, 2013). This states that where there is any uncertainty regarding the ability of the potential participant to provide informed consent, their guardian or next-of-kin is asked to sign a separate consent form which records that they agree to the person under their legal care participating in the study and that they believe the person is not likely to object. The study has received ethics approval from *BLINDED FOR REVIEW*, Human Research Ethics Committee and the affiliated local organisation for people with intellectual disability (*BLINDED FOR REVIEW*).

Informed consent procedure

Informed consent to participate in the study investigating falls in people with intellectual disability is gained directly from the potential participant where possible. The informed consent process for the current study is designed to provide a collective perspective of the capacity of the person with intellectual disability to consent. It involves the researcher undertaking repeated observations of the participant and gives the caregiver the opportunity to provide their opinion as to whether the individual with an intellectual disability can understand what the study involves and has capacity to provide consent. It also includes a Three-item Decisional Questionnaire (3-IDQ) adopted from Palmer et al, 2005, (Figure 1). The researcher adapts the wording of questions, when required, to ensure that the person who has an intellectual disability understands the questions in their own context as far as possible. A score of more than three out of a total score of six suggests that the potential participant adequately understands the research and the extent of their participation, thereby signifying their ability to provide informed consent independently. Figure 2 presents the processes of the informed consent procedure.

Adapted plain language statements are prepared and used with the person with intellectual disability when the study is first discussed. The study is also explained using information sheets prepared according to recommendations for engaging people with intellectual disability in research (Kidney & McDonald, 2014), (Appendix 1). The next of kin, family member or caregiver is asked to be present during this process to provide a supportive, comfortable environment and to provide oversight to the discussion.

Each meeting is an opportunity for the researcher to engage with the person who has an intellectual disability and their caregiver, as relationship-building with the person who has an intellectual disability and their caregiver is crucial for the researcher to gain an

understanding of their capacity and their interest to participate in the study (Archibald & Munce, 2015).

Consent forms

Three consent forms have been prepared for the present study: i) a consent form adapted to facilitate the participant's understanding of the study and the procedures (Appendix 2); ii) a version for a legal guardian to record their agreement for the person who has an intellectual disability to participate in the study; iii) a form for the caregiver(s) to provide informed consent to support the participant with data collection and facilitate communications with the researcher.

Results

From October 2015 to January 2017, 68 individuals were approached after they or their caregiver agreed to an initial discussion. Of these 28 (42%) did not proceed, either because they were not interested, or their legal guardian declined on their behalf. As part of the consent process, the researcher explained the level of commitment required and asked if the person with intellectual disability and their caregiver had capacity to participate. In doing so, the legal guardians made the informed decision with the person with intellectual disability to proceed or not with participating in the research. Guardians declined either because they felt that the person with intellectual disability did not have the capacity to participate in the study or because they could not take the caregiver role of helping with data collection, or both reasons. The informed consent process was subsequently conducted with 40 individuals who all subsequently enrolled in the study.

Participants' median age was 42.5 years (range 35-86 years) and further demographic information is presented in Table 1. Responses from the participants and their caregivers during the consent process are recorded in Figure 3. Two participants were able to organise an initial meeting with the researcher independently and four required support from caregivers. For the other 34 participants, the initial meeting was organised between the researcher and the caregiver.

Table 1. Participant demographics

Variable	**Categories**	**n (%)**
Age (year)	35– 40	4 (10)
	41– 50	17 (42.5)
	51 – 60	8 (20)
	61 - 70	4 (10)
	71 – 80	4 (10)
	> 80	3 (7.5)
Gender	Male	25 (62.5)
	Female	15 (37.5)
Living arrangements	Independent living with paid support	4 (10)
	Living at home with family with paid support	17 (42.5)
	Group home[a] with paid support	19 (47.5)
Mobility status when	Independent without aid[c]	21 (52.5)
indoors	Independent with aid	9 (22.5)
	Dependent[b] without aid	2 (5.0)
	Dependent with aid	8 (20.0)

Mobility status when outdoors	Independent without aid	19 (47.5)
	Independent with aid	7 (17.5)
	Dependent with aid	14 (35.0)

a: A group home is where 3-6 people with a disability are provided with paid support staff to live in the community

b: To be dependent for mobility is to have another person support

c: An aid is either a walking aid, a shopping scooter, a manual wheelchair or a powered wheelchair

Fifteen participants did not participate in the discussion about the study. Their legal guardians were asked to sign the consent form which recorded that, in their opinion, the person with intellectual disability for whom they were responsible would not object to participating.

A total of 25 participants showed interest and engaged in the discussion with researcher. Three of these participants took part in the discussion of the study without any support and subsequently were deemed capable of providing consent independently by successfully scoring four to six on the 3-IDQ (Figure 1), and showing their ability to understand risks, benefits and purpose of the study.

The remaining22 participants required support to understand the research and the researcher used the adapted information sheets (Appendix 1). It was found that all these participants still preferred additional interpretation from their caregiver such as the use of words, examples and objects of reference that were familiar to them. Only five out of these 22 participants took part in the 3-IDQ as they indicated adequate understanding and

maintained their level of engagement with the researcher up to this point of the consent process. They scored less than three which indicated limited understanding of the study. Therefore these 22 participants signed the consent form in the presence of their caregiver (Appendix 2) and their caregivers also signed the Legal Guardian consent form.

All paid and unpaid caregivers who were required to support the person with intellectual disability to complete the daily falls recordings and facilitate communication with the researcher were asked to complete the caregiver consent form. Two examples of the consent process undertaken are presented as case studies below in case studies 1 and 2.

Case study 1: Illustrates the consent process undertaken with a participant who was unable to independently provide informed consent.

Case Study 1

The researcher was alerted to Participant X being potentially eligible for inclusion in the study by staff members from the supporting organisation. It was advised that the most suitable person to contact to discuss the study was his mother, 'A'. A phone call was made to the family home, where A received the call. The researcher explained and discussed the research to A over the phone. In her opinion, X was not likely to object being part of the research. The researcher requested that A discuss the research with Participant X prior to a visit and if she felt if there was any indication that X was not interested, she should contact the researcher to cancel the visit. Prior to the appointment, the researcher spoke to and confirmed with A that X was not opposed to the researcher visiting.

X, was seen standing in the middle of the driveway in front of the house and swinging his arms in a playful manner. After noticing that the researcher parked the car on the road in front of the house, X walked back into the house.

The researcher was greeted at the front door by A and was shown into the house. The researcher observed that X responded to the researcher's presence with a nod and a smile. X only took a seat next to A when A beckoned him to sit on the couch next to her. It was noticed that X's response was very compliant in nature. He responded with a definite nod to questions he understood such as "it's a wonderful day, isn't it?", and a smile to open ended questions he did not quite understand for example, "do you know why I am here?"

As the study was being explained to X and A, A used references and examples to X's life. For example, when a 'fall' was mentioned, A provided the reference to the fall X had about a year ago at a community Show.

To convey in simple terms the risk and benefits of participation, the researcher explained to X that he would not get hurt by participating in the study and that he was not going to get any sweets if he participated.

When asked if he would still like to participate, X smiled and nodded. His mother A, supported his decision and stated that he would not object to participating. A stated that in her opinion X's behaviour indicated that he was willing to participate. A stated that if he was not interested, he would not have sat with the researcher for that length of time and he would have walked outside to where he was previously, or chosen to be in his room.

Prompts were provided to X while he was carrying out the 3-IDQ:

1. What is the purpose of the study?

   Prompt: *"What is (the researcher) here for? You remember we talked about you falling at the Royal show. She is here to study your falls. Yes?"*

   Response: Smiled and nodded. (Score 0)

2. What are the risks?

   Prompt: *"Will you get hurt if you are in the study? Yes or no? "*

   Response: No – shook head (Score 1)

3. What are the benefits?

   Prompt: *"Can (the researcher) give you any candy? Yes or no?"*

   Response: No (Score 1)

A advised that she was confident that Participant X was agreeable to participate because his behaviour during the visit and his body language was positive, but she was also certain that he did not understand the broader purpose of the research. His understanding was limited to task specific instructions such as 'have your dinner' or 'go change'. X signed the consent form in the presence of A. A also gave consent to Participant X participating. Although X participated in the 3-IDQ, he did not demonstrate adequate understanding of the study and therefore, his next-of-kin, A was asked to provide consent.

Case study 2: Illustrates the consent process undertaken with a participant who was able to independently provide informed consent.

Case Study 2

Participant Y was a 58 year old gentleman who lived alone in an independent unit. He had support for personal care, cleaning and meal preparation. The researcher was alerted that Y could be potentially eligible for inclusion in the study from a fellow colleague, 'B', who provided him with in-home therapy services. B advised Y of the research and discussed his potential involvement in the study. B reported that Y showed interest in being involved and consented for the researcher to contact him. According to B, Y lived on his own and made his own decisions. B reported he was able to organise his own appointments, services and transport on a daily basis.

Y was contacted by the researcher by phone and he mentioned that his therapist had told him that she was going to make contact. Over the phone, the researcher explained the research, particularly the level of involvement that would be required of Y if he chose to participate. Y responded that he could manage that and would like to help where he could. The appointment was organised over the phone, and with Y's permission his therapist was also informed, as she would be able to remind him about the appointment. B had reported that her experience with Y was that he could get confused with dates and events that were not routine. He retained events in his memory by associating them with the day of the week.

Y was alone when the researcher arrived. The researcher was pleasantly invited in and Y mentioned that he was expecting the visit. Y parked his wheelchair in front of the television and continued to watch the program that was on television. Respecting that he did not want to turn off his television, the researcher explained the research to him again, interrupting him only at commercial breaks. The researcher used short sentences and frequently asked Y what he understood from the researcher. Y expressed that he felt he

understood the research and was initially reluctant to interrupt his television time. However, he was happy to discuss the research in detail, once the researcher explained that it was necessary to ensure that he understood all that was involved and he then responded in the affirmative. After the explanation of the study, the researcher administered the 3-IDQ to Y:

1. What is the purpose of the study?

   Response: About falls. (Score 2)

2. What are the risks?

   Modification: *"Will any harm come to you if you take part in my study? "*

   Response: No (Score 2)

3. What are the benefits?

   Modification: *"Can I give you any money or rewards if you participate in the research"*

   Response: No (Score 2)

Y required some modifications to the questions to correspond to the language and words the researcher used during the explanation of the study. He did not elaborate when asked about what the study was, other than it was about falls, despite the researcher's previous efforts to describe and discuss the research. The responses, which he provided independently with no prompting or caregiver support, his interaction with the researcher and reports from "B" his therapist demonstrated reasonable understanding of the research and his involvement, therefore, Y provided consent independently.

Monthly follow-ups (either by phone or face-to-face contact) provided the opportunity for participants to ask any questions they may have had regarding the research,

including any issues related to their participation. To date 27 of these 40 participants have completed the 6-month observational period, and there have been no withdrawals.

Discussion

Informed consent and use of proxy

When considering all eligible potential participants, slightly more than 40% of caregivers declined on behalf of the person with intellectual disability. Reasons given by family were illness (family member or the individual), they had “too much going on”, or they believed that the person with intellectual disability had nothing valuable to contribute to this study.

Out of 40 participants enrolled, only three could successfully and independently answer the questions about the study and were considered to have understood the potential risk involved. There were 22 participants who engaged with the researcher and were able to have a discussion about their involvement in the study, with help from their caregiver. Fifteen out of the 40 participants did not engage with the researcher and the consent process was completed without their involvement. These fifteen participants were severely affected and did not have the cognitive ability to engage decision making in all parts of their lives. Daily decisions about their care are made on their behalf. The ability for people with intellectual disability to be involved in research is often influenced by the people with whom they are directly dependent.

Overall learnings

A patient (often time-consuming), sincere and flexible approach was taken in order to overcome barriers and to build trust and respect between the researcher, the person

with intellectual disability, and their support network. Many of the successful approaches taken in this study echo the efforts taken in other studies reporting success in reaching out to people with intellectual disability (Horner-Johnson & Bailey, 2013; Kidney & McDonald, 2014; Lennox et al., 2005). Successful strategies included a multilevel strategy for the provision of information and gaining of consent, and making the effort to be mindful of their abilities, lifestyle, family, formal and informal care supports. Our procedure, of necessity is time consuming and requires multiple interactions with potential participants and their caregivers and like others we recognise that this has budgetary implications in conducting this research (Pal, Hale & Mirfin-Veitch 2013).

Current experience in using the jurisdictional ethics guidelines (National Health and Medical Research Council, 2007) () and recommendations published in the literature (Kidney & McDonald, 2014; Palmer et al., 2005) formed a useful checklist during the study preparation, especially for the development of the recruitment procedure. The toolkit for accessible and respectful engagement (Kidney & McDonald, 2014) of people with intellectual disability in research was helpful to explain the current study in some instances, particularly when individuals with intellectual disability were interested and could understand the pictures used to represent their involvement. However, caregivers were still required to provide further explanations using familiar references from their daily lives (Case Study 1). For other participants who did not engage in conversation with the researcher (n=15), the toolkit was not useful. These participants were more severely affected and more dependent on care support. The research team in this study had extensive experience in working with people with intellectual disability, with the lead researcher employed full time in an organisation that provides services to people with disability including a large proportion of people with intellectual disability. Appropriate

training and experience are required to successfully interact and achieve good research outcomes in this group (Archibald & Munce, 2015).

Other than the three participants who provided consent independently, the remaining participants who completed the 3-IDQ required support to interpret the questions asked. This is consistent with Palmer et al (2005) where the questions were re-explained or clarified when the response was vague or indicated a misunderstanding. The questions were useful as guiding questions to determine whether they understood the researcher adequately and their involvement in the study. The three participants who scored four or more out of a total of six, indicating adequate understanding of the study, reflected high levels of engagement and independence during the informed consent process. Thus the use of the 3-IDQ gave an accurate representation of their decision-making capacity. Palmer et al 2005, also concluded that the 3-IDQ was sensitive to individuals with cognitive limitations.

Limitations

This paper describes the informed consent process used with the first 40 participants of the study and a further 38 participants are expected to be recruited to the study. Therefore, there is potential for new experiences to come to light. Communication with the person with intellectual disability proved challenging, particularly when the potential participant did not live with their family and the caregivers supported the individual for only a portion of their life. Five of the participants had consent provided on their behalf by their legal guardians from the office of the public advocate, who did not have day to day care responsibilities. Family members, who are more familiar with the person, often provided useful communication strategies but it was not always possible to meet with families.

Furthermore, the researcher had limited time to interact with the person with intellectual disability and was necessarily, and in part, dependent on the opinions of the caregiver as to whether the person with intellectual disability was able to provide consent. These study procedures have been facilitated by the extensive experience of the researchers in our local health care settings regarding intellectual disability, meaning our procedures may not directly translate to other settings. However, these procedures may provide a useful guide for researchers who would like to conduct research with people with intellectual disability in their own local setting.

Conclusion

This study found that the systematic and holistic approach described in our study procedure allowed the person with intellectual disability to participate in the consent process to the best of their ability. The procedure provided the opportunity for the caregiver to provide their opinion, the researcher to provide a clinical judgement and the participant themselves, within the limits of their cognitive abilities, to provide informed consent to participate in the study. We found that adapted communication strategies were the most important means of building rapport and subsequent engagement with participants.

Researchers should continue to investigate and report on the methods for conducting research, including gaining informed consent, in this hard to reach population, in order to provide more opportunities for people with intellectual disability to benefit from research.

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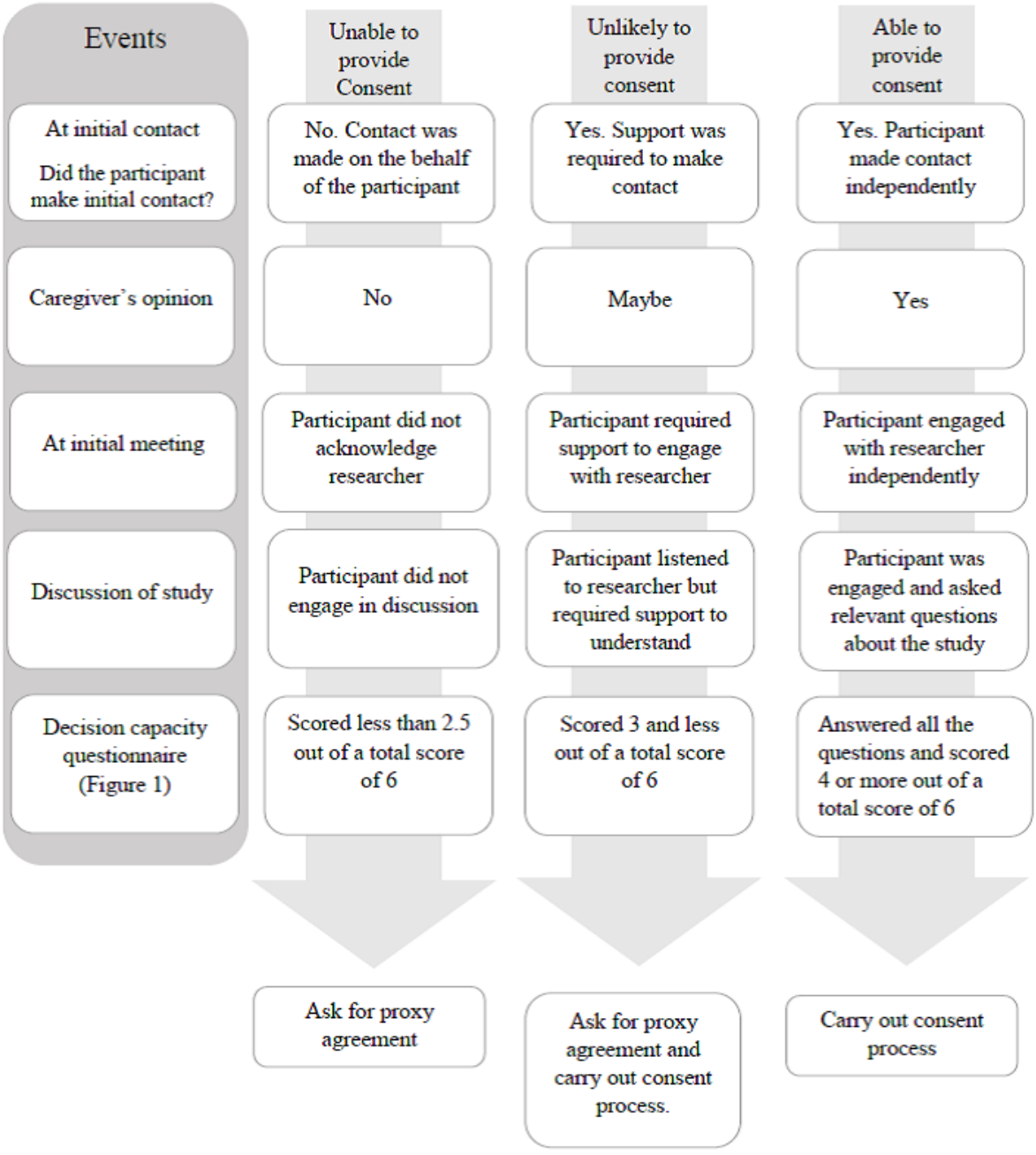
Figure 1: The Three-Item Decisional Questionnaire

1)	What is the purpose of the study?	0	1	2
2)	What are the risk?	0	1	2
3)	What are the benefits?	0	1	2
	Total:			

Score of 0 = incapable, 1= questionable, 2 = capable of each question
A higher total score reflects a better understanding of the study
(Adapted from Palmer et al, 2005)

Figure 2: Flow of events through the consent process



Note: Regardless of the participant's ability to provide consent, efforts will be made to engage the participant using individualised communication strategies and having caregiver present throughout the consent, recruitment and data collection process.

Figure 3: Flow of study participants through the consent process