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Enhancing the informed consent process in psychiatric outpatients with a brief computer -based method

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ABSTRACT

Informed consent is a key element of ethical clinical research. Those with mental disorders may be at risk for impaired consent capacity. Problems with procedures may also contribute to patient's ´difficulties in understanding consent forms. The present investigation explores if a brief technologically based information presentation of the informed consent process may enhance psychiatric patients understanding and satisfaction. In this longitudinal, within-participants comparison study, patients who initially were judged to lack capacity to make research decisions ($n=41$) and a control group ($n=47$) were followed up. Decisional capacity, willingness to participate and cognitive and clinical scores were assessed at baseline and after receiving the computer-assisted enhanced consent. With sufficient cueing, patients with impaired research-related decision-making capacity at baseline were able to display enough understanding of the consent form. Patient satisfaction and willingness to participate also increased at follow up. Implications of these results for clinical practice and medical research involving people with mental disorders are discussed.

1. Introduction

Obtaining Informed Consent (IC) is a key component of biomedical research that seeks to uphold the ethical value of patient and participant autonomy (Rowbotham et al., 2013). However, the increasing emphasis on regulatory procedures, combined with more complex and highly technical research procedures, has resulted in lengthier IC documents that are often highly technical and difficult to understand. Although not conclusive, available data suggest that a certain percentage of potential research participants do lack adequate decisional capacity, and furthermore, even among those who do have such capacity, there are those whose grasp of the relevant consent form information is less than optimal (Flory and Emanuel, 2004; Jeste et al., 2006; Purcaru et al., 2014; Seo et al., 2011; Ghormley et al., 2011). This lack of understanding during the IC process is a particular concern for potentially vulnerable populations such as mentally ill patients that may require safeguards tailored to protect their rights (Anderson and Mukherjee, 2007; Fraguas et al., 2007; Westra and de Beaufort, 2015; Neilson et al., 2015). Researchers should consider these caveats as they decide which populations or individual subjects may require more intensive evaluation or further educational efforts to enhance decisional capacity.

For all these reasons, recent years have seen increasing interest in finding new ways to improve research participants' understanding. Given these concerns and the ubiquity of alternative communication modalities, it is logical to consider innovative methods of communicating information in the IC process (Synnot et al., 2014). As the familiarity of computer-based approaches to communication may increase, it is likely that such methods will become part of a new standard of practice in the research consent process (Karunaratne et al., 2010).

Some of the more effective and commonly used strategies to enhance capacity have included the use of simplified consent forms, repetition of consent form information and use of interactive computerized learning aides, use of video presentation during the consent process, and the provision of corrective feedback for individuals demonstrating confusion during the consent process. Across such studies, the preponderance of evidence has shown that even individuals with severe psychiatric conditions such as schizophrenia are able to benefit significantly from attempts to improve decisional capacity (Moser et al., 2006).

Abbreviations: DSM-IV TR, Diagnostic and Statistical Manual of Mental Disorders Text Revision; EC, enhanced consent; GAF, Global Assessment Functional Scale; IC, informed consent; MacCAT–CR, MacArthur Competence Assessment Tool for Clinical Research; MMSE, Mini-Mental State Examination; SC, standard consent; SD, standard deviation

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Although typically successful, a potential drawback to using the types of interventions mentioned above, is that they can be time consuming, sometimes taking place in multiple sessions across the course of several days (Carpenter et al., 2000). The time necessary to ensure that participants are able to provide meaningful consent prior to entry into clinical trials can be a serious barrier in the research arena. Investigators must balance the need to protect human subjects with the time and resources necessary to test the decisional capacity of potential participants (Kon and Klug, 2006). In minimal-risk studies conducted in general population, it may be not reasonable to forego lengthy assessments. When, however, research participation entails greater risk or the study population is vulnerable, it would be prudent for researchers to develop tools to assess potential subjects' comprehension of study protocols and their decisional capacity. Such tools must balance the need for comprehensive assessment with the real-world limitations of time and resources. How to best balance the need to ensure adequately IC with the burdens of assessment on both investigators and research subjects themselves, constitutes a real challenge.

The current study was conducted to determine whether even a brief intervention could improve decisional capacity. Hence we carried out a follow-up study in which we determined the presence or absence of capacity to make consent research decisions at baseline and then we sought the participants' capacity after receiving an education intervention. Our secondary aim was to explore if the brief technologically based information presentation of the IC process may improve patient understanding and satisfaction.

2. Methods

2.1. Participants

Between December 2013 to March 2014 consecutively referred or identified patients seeking treatment for a DSM-IV TR diagnoses of psychotic, mood and anxiety disorders at an urban-located Mental Health Centre in south-eastern Spain were invited to participate in this cohort study. The research ethics committee of Sta María del Rosell Hospital in Cartagena, Health Service of Murcia, approved the study. Full details are given elsewhere (Morán-Sánchez et al., 2015).

We recruited community-dwelling outpatients aged >18 years with diagnosis matching 1 of the 3 targeted conditions. Other inclusion criteria were fluency in Spanish, current score on the Spanish version of the Mini-Mental State Examination (MMSE) (Lobo et al., 1999) 20 or higher and voluntary IC to participate in this study.

2.2. Procedures

We used an interactive consent process to ensure adequate understanding of the protocol basics. A research assistant met with the potential participants and gave them both verbal and written information about the study. Cognitive state was evaluated by using the MMSE excluding those patients with advanced cognitive impairment. The research assistant reviewed the information in the consent form with the potential participants, and then, written IC was obtained from all patients or from their legal guardians.

Within one month following the initial assessment, all patients attended a second appointment at which they completed capacity evaluations. Patient information was collected through the use of a questionnaire designed to obtain data on variables regarding patient demographics and clinical characteristics. Level of functioning was evaluated using the Global Assessment Functional Scale (GAF) (Endicott et al., 1976).

2.2.1. Assessment of capacity

Judgments on mental capacity were based on a clinical assessment (review of available records and aclinical interview) and the administration of the Spanish version of the MacCAT-CR (Baon, 2013). This instrument is a semi-structured interview that was customized for the hypothetical study for quantification of each participant's decisional capacity on the four commonly recognized dimensions of decisional capacity: (a) *understanding* the relevant information; (b) *appreciation* of the effects of research participation on the patient´s own situation; (c) *reasoning* with the information in a decisional process and (d) *expressing a choice* about participation (Jeste et al., 2009). This instrument has been widely used in research and is described in detail elsewhere (Carpenter et al., 2000; Appelbaum and Grisso, 2001).

MacCAT-CR administration involves disclosure of information about the study that subjects are being asked to consider, in this case a hypothetical medication trial designed by us, followed by questions that assess the four dimensions of decisional capacity. The hypothetical trial, designed for outpatients, involved random, blinded exposure to a new headache tablet named "Semoca" versus placebo; risks included those of blood draw and non-life-threatening side effects of the drug. The inability to guarantee direct benefit was explained as well. The hypothetical consent form was modeled after phase II studies of similar agents. It was 5 doubled-spaced pages and had a Flesch-Kincaid reading level of 13 years, the reading level generally suggested in the literature (Streiner et al., 2015).

Each ability is assessed by specific questions with answers rated on a 0–2 scale with higher scores reflecting better performance. The MacCAT-CR does not yield a limit score or a total score on the four abilities, but for practical purposes in some studies, cut-points have been determined to identify those who lack capacity (Carpenter et al., 2000; Stroup et al., 2011; Hein et al., 2014; Kim et al., 2001). Previous studies in populations with dementia or psychiatric disorders have demonstrated a high degree of reliability (Cairns et al., 2005) and indications of validity (Baon, 2013; Grisso et al., 1997). An Understanding score of 20 or higher on the 26-point scale was required as a minimum for being capable, according to the study of Carpenter although clinical judgment was the final determinant of competence to consent even if a subject achieved this threshold (Carpenter et al., 2000). This threshold reflected an a priori judgment by the investigators of what constituted minimally adequate understanding of this specific research protocol.

After each interview we scored the four subscales according to MacCAT–CR criteria and made a global judgment about the patient's capacity to consent to research, based on information from both the MacCAT–CR and a clinical interview with the patient. A consensus judgment was reached between the interviewer and the research team, when the judgment was felt to be difficult. In practice this amounted to ten interviews.

All patients who were initially found to lack capacity were followed up. We also followed up a comparison group randomly drawn from the people who were initially regarded as being capable. Fig. 1 shows the flow of patients through the study.

The follow-up assessment took place during a period of two months. At follow-up, the capacity assessment was repeated using a computed-based Enhanced Consent (EC) instead of the Standard Consent (SC). The MacCAT-CR interview was then readministered. We repeated the same process to score the MacCAT-CR subscales and we followed the same approach to reach a binary (yes/no) decision about decisional capacity we used at baseline assessment. Participants were asked if they felt more comfortable in making decision about being involved in the hypothetical study after receiving EC. We also asked whether if they prefer or not the EC after having been shown the original SC as a comparison. GAF and