Using a Brief Intervention to Improve Decisional Capacity in Schizophrenia Research

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Studies have shown that individuals with psychiatric or general medical illness can benefit from interventions designed to enhance decisional capacity for research informed consent. In some cases, interventions have been rather lengthy or complex. The current study was designed to determine whether a brief intervention could improve decisional capacity in people with schizophrenia. Thirty individuals with schizophrenia and 30 healthy comparison participants were presented with a hypothetical research scenario. Decisional capacity was assessed with the MacArthur Competence Assessment Tool–Clinical Research version. Those with schizophrenia received a brief intervention aimed at improving understanding of the research protocol, after which decisional capacity was reassessed. A neuropsychological battery and symptom rating scales were also administered. At baseline, the schizophrenia group earned significantly lower scores than the comparison group on 2 aspects of decisional capacity (understanding, appreciation). At follow-up, the schizophrenia group had improved significantly on understanding and was no longer significantly different from the comparison group on any of the 4 dimensions of decisional capacity. Follow-up analyses also showed a significant effect of the intervention on a subset of the schizophrenia group who had performed most poorly at baseline. Participants with schizophrenia earned significantly lower scores than those in the comparison group across multiple neuropsychological domains. These findings add to the existing literature indicating that brief interventions can improve decisional capacity in individuals with schizophrenia, despite the fact that the illness typically causes significant cognitive dysfunction. The use of such interventions will enable a larger number of people with schizophrenia to make informed decisions regarding research participation.

Key words: informed consent/decisional capacity/ethics/schizophrenia

Introduction

It has been established in the literature that individuals with schizophrenia, on average, have significantly greater difficulty than healthy controls with regard to processing consent form information and demonstrating adequate capacity for research informed consent.1–2 This fact, however, merely represents a relative difference in performance between mentally ill and non–mentally ill individuals and should not be taken as evidence that psychiatric patients typically lack the capacity to provide informed consent. Indeed, in our schizophrenia research program it has been our experience, based on both clinical observation and quantitative data, that 80% or more of individuals with schizophrenia are able to make independent and informed decisions regarding research participation, even within the context of relatively complex research protocols.3

Despite these encouraging findings, the fact remains 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. For these reasons, recent years have seen increasing interest in finding new ways to improve decisional capacity.

Some of the more effective and commonly used strategies to enhance capacity have included the use of simplified consent forms,4–5 repetition of consent form information and use of interactive computerized learning aides,6 use of video presentation during the consent process,7–8 and the provision of corrective feedback for individuals demonstrating confusion during the consent process.9–11 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. The reader is referred to the work of Dunn and Jeste for a more extensive review of this literature.12

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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. The current study was conducted to determine whether even a very brief (e.g., less than 30 minutes), semi-individualized intervention that would be practical for both inpatient and outpatient research could improve decisional capacity in potential schizophrenia research participants.

**Methods**

This study was approved by the University of Iowa Institutional Review Board, and prior to beginning study procedures, all participants provided written informed consent following a thorough discussion of the study. Participants were also required to provide acceptable responses to all questions on the Evaluation to Sign Consent (ESC). Each participant was compensated in the amount of $50.00.

**Participants**

Participants included 30 individuals with a DSM-IV diagnosis of schizophrenia (22 men, 8 women) and 30 healthy comparison participants (26 men, 4 women). Healthy individuals were chosen as a comparison group because, not having significant psychiatric or medical illness, they are presumed to have an adequate level of decisional capacity for research informed consent.

Exclusion criteria for the comparison group included the following: (1) current psychiatric diagnosis or treatment, (2) history of major mental illness (e.g., schizophrenia, bipolar affective disorder), (3) history of significant head injury or other neurological insult, and (4) history of substance abuse. Participants with schizophrenia were recruited through inpatient and outpatient research programs at the University of Iowa Hospitals and Clinics (6 outpatients, 24 inpatients), while those in the healthy comparison group were recruited from the community as part of another study.

**Assessment of Decisional Capacity**

After obtaining consent for the actual study, the examiner asked each participant to pretend that she or he was a potential candidate for another research study and, together with the participant, read through a detailed informed consent document for a hypothetical double-blind, placebo-controlled trial of a cognitive-enhancing agent called Synaptoclear. The examiner then administered the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), a structured interview that was customized for the hypothetical study for quantification of each participant’s decisional capacity on 4 dimensions: understanding, appreciation, reasoning, and ability to express a choice.

**Intervention**

Participants in the schizophrenia group were then administered a brief (20–30 minutes) educational intervention designed to improve their understanding of the hypothetical consent form information. The intervention consisted of a computerized presentation of the same hypothetical study information in a bulleted, much simplified format, with 1 key point per presentation slide. Participants were asked to view the presentation and read along as the examiner read aloud each presentation slide. Following the educational remediation, the examiner reviewed with the participant all MacCAT-CR “understanding” items for which the participant did not receive maximum credit. In this manner, participants received both a standardized intervention (the computer presentation) and individualized discussion and corrective feedback regarding the specific aspects of the research protocol that they found confusing. The MacCAT-CR interview was then repeated to assess participants’ decisional capacity following the educational remediation. Finally, the examiner administered the ESC, a briefer structured interview designed to assess the adequacy of participants’ understanding of the hypothetical study. Participants in the healthy comparison group were administered the MacCAT-CR and ESC on a single occasion only and did not undergo remediation.

**Neuropsychological and Psychiatric Assessment**

The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS, Form A) was administered to all participants to assess level of global neuropsychological functioning and performance across the 5 RBANS domains, including immediate memory, delayed memory, visuospatial/constructional, language, and attention. Selected subtests from the Wechsler Adult Intelligence Scale–III were also administered, including vocabulary, matrix reasoning, and letter–number sequencing, in order to assess word knowledge, reasoning and problem-solving skill, and working memory capacity. Schizophrenia participants were also administered the Scale for the Assessment of Negative Symptoms (SANS) and Scale for the Assessment of Positive Symptoms (SAPS).

**Statistical Analysis**

Between-group comparisons were conducted using 2-tailed independent groups t-tests. Degrees of freedom were adjusted when necessary due to unequal variance between groups. An alpha level of 0.05 was maintained for all between-group comparisons, so as not to obscure differences between the groups. Within-group comparisons were conducted using 2-tailed paired samples t-tests. Bonferroni correction was used for the 4 main within-group comparisons (i.e., when testing changes in the 4 decisional capacity scores for significance). Thus,
p values below .0125 were considered significant for these comparisons.

Results

The schizophrenia group and healthy comparison group did not differ significantly in age or education (schizophrenia—age: mean = 34.10 years [SD = 10.65]; education: mean = 12.72 years [SD = 2.31]; comparison group—age: mean = 30.00 years [SD = 11.46]; education: mean = 12.70 years [SD = 0.94]). Among participants with schizophrenia, scores on the SANS and the SAPS were as follows: negative symptoms: mean = 8.40, SD = 3.48; positive symptoms: mean = 5.07, SD = 2.67; and disorganized symptoms: mean = 3.27, SD = 2.73.

As shown in table 1, the schizophrenia group performed significantly more weakly than the comparison group across all neuropsychological measures. As shown in table 2, at baseline, the schizophrenia group earned significantly lower scores than the comparison group with regard to understanding (t [39.52] = −2.68, p = .011) and appreciation (t [58] = −2.45, p = .017) of the hypothetical research scenario. Following the intervention, the schizophrenia group showed statistically significant improvement on understanding (t [29] = −2.85, p = .008) and was no longer significantly different from the comparison group on any of the MacCAT-CR domains (p = .13—.33).

Even though subjects in the schizophrenia group showed significant improvement in understanding following the intervention, their relatively high baseline scores on this variable created a potential ceiling effect that likely obscures the true amount by which the intervention could raise understanding scores. For this reason, we conducted an exploratory analysis on a subset of the schizophrenia group (those with baseline understanding scores of less than 23), in order to examine postintervention scores among participants who had a reasonable amount of room for improvement.

For this subset of participants (N = 10), understanding scores increased significantly, from a baseline mean of 18.0 (SD = 4.7) to 20.6 (SD = 4.9; t [9] = −2.59, p = .029). The effect size for this change is moderate in size (Cohen’s d = 0.6). Appreciation and reasoning scores increased also but did not reach significance (p > .05). All participants across both groups were ultimately able to pass the ESC, indicating adequate understanding of the hypothetical research scenario.

Discussion

The above findings provide additional evidence that a large proportion of individuals with schizophrenia are able to provide research informed consent and that their ability to do so can be improved through the use of a brief and practical intervention. There are several additional and important points to make about the current study. First, consistent with previous research, individuals with schizophrenia demonstrated relatively strong decisional capacity even without remediation, although not at the level attained by participants in the healthy comparison group. Second, the schizophrenia group showed significant improvement and was not significantly different from the healthy comparison group in any aspect of decisional capacity following the intervention. This was the case even though the intervention was very brief and was conducted with a group of individuals who were, on average, in the borderline range (seventh percentile) with regard to global neuropsychological functioning. Last, the degree of improvement among

Table 1. Neuropsychological Scores for the Schizophrenia and Healthy Comparison Groups

<table>
<thead>
<tr>
<th>Test</th>
<th>Schizophrenia mean (SD)</th>
<th>Comparison Group mean (SD)</th>
<th>t (df = 58)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeable Battery for the Assessment of Neuropsychological Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Scale Score</td>
<td>78.83 (17.15)</td>
<td>95.50 (12.43)</td>
<td>−4.31</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Immediate Memory</td>
<td>83.27 (16.22)</td>
<td>98.00 (12.79)</td>
<td>−3.91</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Delayed Memory</td>
<td>83.60 (19.54)</td>
<td>95.80 (12.94)</td>
<td>−2.85</td>
<td>.006</td>
</tr>
<tr>
<td>Language</td>
<td>89.67 (13.83)</td>
<td>95.43 (13.34)</td>
<td>−1.64</td>
<td>.106</td>
</tr>
<tr>
<td>Visuospatial/Constructional</td>
<td>85.13 (16.55)</td>
<td>96.67 (15.49)</td>
<td>−2.79</td>
<td>.007</td>
</tr>
<tr>
<td>Attention</td>
<td>76.10 (20.44)</td>
<td>99.30 (15.05)</td>
<td>−5.01</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Wechsler Adult Intelligence Scale–III Subtest Scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vocabulary</td>
<td>9.63 (3.18)</td>
<td>11.33 (2.06)</td>
<td>−2.46</td>
<td>.017</td>
</tr>
<tr>
<td>Matrix Reasoning</td>
<td>10.10 (3.06)</td>
<td>12.47 (2.45)</td>
<td>−3.31</td>
<td>.002</td>
</tr>
<tr>
<td>Letter–Number Sequencing</td>
<td>7.83 (3.12)</td>
<td>11.60 (2.65)</td>
<td>−5.04</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Note: Repeable Battery for the Assessment of Neuropsychological Status (RBANS) scores are standard scores (normative mean = 100, SD = 15); Wechsler Adult Intelligence Scale–III subtest scores are scaled scores (normative mean = 10, SD = 3). P values are from 2-tailed t-tests.

*DF was adjusted due to unequal variance between the groups for RBANS Total Scale Score, Delayed Memory, and Vocabulary.
A Brief Intervention to Improve Decisional Capacity

Table 2. Decisional Capacity Scores on the MacArthur Competence Assessment Tool for Clinical Research for Schizophrenia and Healthy Comparison Groups (mean [SD])

<table>
<thead>
<tr>
<th>Variable</th>
<th>Schizophrenia Baseline</th>
<th>Schizophrenia Postintervention</th>
<th>Comparison Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding (0–26)</td>
<td>22.37 (4.18)a</td>
<td>23.57 (3.71)b</td>
<td>24.60 (1.81)b</td>
</tr>
<tr>
<td>Appreciation (0–6)</td>
<td>5.23 (0.77)a</td>
<td>5.40 (0.93)a–b</td>
<td>5.70 (0.70)b</td>
</tr>
<tr>
<td>Reasoning (0–8)</td>
<td>5.00 (1.62)</td>
<td>5.37 (1.69)</td>
<td>4.93 (1.23)</td>
</tr>
<tr>
<td>Choice (0–2)</td>
<td>1.97 (0.18)</td>
<td>2.00 (0.00)</td>
<td>1.97 (0.18)</td>
</tr>
</tbody>
</table>

Note: Possible ranges for variables are shown in parentheses. Across rows, values not sharing a common superscript letter are significantly different based on 2-tailed t-tests (see text for t-scores).

The subset of schizophrenia group participants we studied was moderately large in size (Cohen’s d = 0.6), and all of the schizophrenia group participants were ultimately able to demonstrate adequate understanding of the hypothetical research scenario, as measured by the ESC.

The above findings add to the existing data indicating that individuals with schizophrenia are able to benefit from attempts to improve decisional capacity. Specifically, the current study serves most closely as a replication of work by Dunn and coauthors, who also used a relatively brief intervention that included simplified, computerized presentation of consent form information and postintervention testing that involved corrective feedback. It is worth noting that those studies involved the assessment of decisional capacity within the context of an actual consent process as participants were being enrolled into an ongoing research protocol. Although such an approach increases the ecological validity of their findings, the protocol under consideration was relatively basic and did not involve a treatment trial or complex concepts such as randomization, double blinding, placebo control, and side effects. The current study, although reliant on a hypothetical research scenario, indicates that individuals with schizophrenia are able to benefit from an enhanced consent process, even when faced with a much more complex research protocol.

A common criticism of this type of study is that participants are certain to show improvement because, in the intervention process, the investigators are merely “teaching to the test.” Indeed, such a statement is true to some degree, but it should not be levied as criticism, because the goal of the intervention is to improve decisional capacity within the context of the specific research protocol in question, not improvement of more general cognitive ability. Therefore, such a situation is altogether different from having a research participant study the same word list repeatedly and then interpreting improved recall of the list as evidence of generally improved memory function. Furthermore, when using instruments such as the MacCAT-CR, examiners are careful to have participants respond in their own words as much as possible, as opposed to verbatim repetition of what they have been told. This increases the likelihood that improved scores do reflect actual improvement in understanding.

This study has several limitations. The fact that the groups did not differ significantly on any aspect of decisional capacity following the intervention must be interpreted cautiously, given our relatively modest sample size. We are also unable to comment specifically on what aspect of the intervention we used was most helpful, as all participants in the schizophrenia group received both the standardized computer presentation and the individualized corrective feedback components. It should also be reiterated that individuals in the comparison group did not receive the intervention, so it is not known how much they would have improved if they had. Nonetheless, we consider them to be a valid comparison group because healthy people do not typically experience any form of enhanced consent process in actual research, and the high baseline MacCAT-CR scores earned by these individuals in the current study indicate that they would not have required such intervention. It is also important to note that the schizophrenia group received a second administration of the MacCAT-CR. Given that this involves additional disclosure of consent form information, it is conceivable that this contributed to that group’s improved scores, in addition to the intervention described above. Finally, the type of intervention used in the current study did not address all aspects of decisional capacity but, rather, focused mainly on understanding and, to a lesser degree, appreciation.

The current study and others like it have provided convincing evidence that a large percentage of individuals with psychiatric illness are able to make informed decisions regarding participation in research and that those individuals who initially lack this capacity may benefit significantly from enhanced consent procedures. One of the next challenges in this area of research will involve developing new strategies to improve not only basic understanding of research protocols but also the ability to reason with this information in a more organized and efficient manner as possible. Such research will move the field closer to the ideal balance of providing adequate subject protection while also avoiding the unnecessary exclusion of those individuals who have difficulty with traditional consent procedures.

Acknowledgments

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