Schizophrenia Patient Value Mapping Study

This Participant Information Sheet and Consent Form tells you about the research project. It explains the purpose of the research, procedures and risks involved. It tells you about the sort of information you will be asked about, how that information will be used and with whom it will be shared. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Participation in this research is voluntary. If you don't wish to take part, you do not have to. If you choose not to participate, your treatment will not be affected. If you decide you want to take part in the research project, you will be asked for your consent to participate.

By consenting to participate you are telling us that you:

- Understand what you have read
- Agree to take part in the research project
- Consent to the use of your personal and health information as described

Purpose of the Study

Community and Patient Preference Research (CaPPRe) is working with a pharmaceutical company, Janssen, and mental health organisations, SANE and One Door, to conduct research with people who have been diagnosed with schizophrenia.

CaPPRe are specialists in conducting research to determine people's preferences. We are looking at ways to gather larger numbers of views from patients on what they think about benefits and disadvantages of treatments. This type of research is called 'Patient Value Mapping' and may be used to help those who assess new treatments understand how patients value certain benefits and disadvantages of treatments.

What's involved?

We would like to invite you to participate in an online survey. You will be asked questions about your experience of living with schizophrenia, your experience with different treatments and your quality of life. You will also be asked to consider scenarios for different treatments and to choose which treatment option you prefer. The answers to these questions will tell us which factors are most important to you when choosing between treatments. If you decide to take part and later change your mind, you are free to withdraw at any stage. Around 100 other persons with schizophrenia will be participating.

How long will it take?

Completing all the questions in the survey should take around 25-30 minutes. The survey has been designed in a way that allows you to take a break approximately halfway through the survey. Once you see the 'break screen' and would like to take a break, you can do so by copying the link shown and storing it somewhere to later paste in your browser to continue. Alternatively, you can continue the survey without taking a break.

Your participation is voluntary, and you can stop at any time. The first part of the survey asks questions to determine whether you are eligible to participate in the survey or not. You will receive $40 for completing the survey, which you can choose to receive via bank transfer or provide as a donation to SANE or One Door. The $40 is paid to reflect your time to complete the survey. You will not be reimbursed if you are not eligible to participate in the survey. Survey completion is anonymous, however if you wish you receive your reimbursement via bank transfer, you will be asked to provide your banking details. These details will be kept separate to the survey data and only used for the purpose of the bank transfer.

Questions of a sensitive nature

We have considered the views of patients when designing and wording the survey. It is possible that you may find some of the questions uncomfortable. Some questions in the surveys ask questions of a sensitive nature. If you feel uncomfortable you can stop at any time. Your participation is entirely voluntary.

If you find the survey stressful and would like to seek additional support and advice, or if you have any further medical questions, we encourage you to speak to your treating healthcare professional/s.

Participating in this survey may also raise questions for you about your schizophrenia treatment. If you have any questions, you may wish to discuss them with your doctor.

What will result from the survey?

Taking part could help improve understanding about patients' perspectives on the benefits and disadvantages of treatments and the results could be used by stakeholders in future discussions with e.g. healthcare providers about (new) schizophrenia treatments. We also intend to publish the results so that others can learn from them. A summary of study findings will be available to participants following completion of the entire project. If you would like to receive a summary of the findings, we will collect your email address (please note that your email will only be used for the purpose of forwarding study results to you and will be deleted after the study information has been provided).

Voluntary Participation/Right to Refuse or Withdraw

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. There is no formal process to withdraw consent, and you may withdraw consent at any point in time by closing the survey window. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, or your relationship with those treating you. If you do withdraw your consent during the research project we will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

Confidentiality

CaPPRe respects and understands your privacy is very important. By providing your consent you agree to us collecting and using personal and health information you have provided for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your personal details will not be forwarded to any other parties, nor will you be contacted by CaPPRe for anything other than this research project unless you choose to be. Your data will be stored in a secure encrypted (protected) environment in Australia and only CaPPRe will have access to the data. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Any information you provide will be collected by CaPPRe. Any information that is shared with Janssen will be done in report form. The personal information you provide, including sensitive personal information about you will not be shared.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in a combined form such that no individual person can be identified. Janssen will be provided with a report of the findings containing only combined de-identified data. The research data will be kept securely for a period of 5 years.

Adverse Event Reporting

Any safety reports we receive are taken seriously. In order to continuously monitor the safety of Janssen's products, if in the survey you describe a side effect that you have experienced while taking a Janssen medication, whether or not it was caused by the medication, we will report these details to Janssen's Drug Safety team. In such an event, Janssen's Drug Safety team may also try to collect more information about the event from your healthcare professional and we may then also ask you to provide your healthcare professional's contact details and consent for Janssen's Drug Safety team to contact them. If you consent to this, Janssen's Drug Safety team may contact your health care professional and obtain follow up details by either emailing or faxing them an Adverse Event form. All information collected is handled confidentially according to the Privacy Act.

Contact information

If you have any questions or concerns you can contact CaPPRe at karen.winkler@cappre.com.au

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee chair, Bellberry Human Research Ethics Committee 08 8361 3222.