

Client Participation in Clinical Research Trials By: Pat Finkle, Client Support Coordinator

“It might be the answer”, Rosemarie stated. This is the hope that she clung to for her late husband Bert and others who are affected by Alzheimer’s disease or related dementias, when they decided to participate in clinical trials. Clinical trials are the final step of research before the approval of a new drug that has the potential of becoming a viable treatment option. Bert decided that although his participation in the trial would not likely help him, it could help someone else. So, began the 18 month journey for Bert and Rosemarie into drug trials. Rosemarie recalled the many visits to Dr. Jennifer Ingram’s office, Bert sitting in a chair with an array of monitors and lines. “The staff tried their best to make it a comfortable experience, they served us lunch and made every effort to make us comfortable while Bert watched television and I knitted in the comfy leather chair beside him”. “Bert dreaded the trips to Whitby the most where he would undergo CT scans, but we always made a day of it”.

Scientists are involved in research around the world, investigating causes, treatments, cures, social implications and psychological effects of Alzheimer’s disease and related dementia’s. The future hope for a cure and quality of life for those affected lies in continued research. There are many benefits of participating in clinical trials; however anyone considering it should understand the consequences of their involvement. Potential participants should be informed and capable of grasping the implications. Should a person participate in clinical trials? This is a question that should be discussed early on in the disease process to ensure that the desires of the person are clear.

One must weigh the risks and benefits of participating in clinical trials. Clinical trials can present unknown side effects that may be unpleasant, serious or even life-threatening. Participation requires a considerable time commitment and may not result in the kind of benefits anticipated. Participating in trials can mean going off certain medications with no guarantee that participants are receiving the trial drug rather than a placebo. This information is kept private for the integrity of the research. While considering the risks is important, there are many benefits that should also be considered. A person participating in a trial may feel that they are fighting back and making a difference for others and their family members who they may be concerned about. They may also feel that they are playing an active role in their own health care by gaining access to new research treatments that otherwise would not be available.

A potential participant’s confidence is supported by the fact that clinical trials are governed by bodies that consider ethics and the professional integrity of the way research is conducted. The Tri-Council Policy Statement of Ethical Conduct for Research Involving Humans through the Natural Sciences and Engineering Research Council of Canada governs research conducted by universities and their affiliated hospitals in Canada, while Health Canada governs research by other bodies such as pharmaceutical companies. If a person is considering participation in a trial they should ask some important questions. What is the purpose of the study? Why do researchers believe that the treatment may be effective? What test and or treatments are involved? How might this treatment affect their daily life? What kind

of commitment is required in terms of time? Are there negative impacts such as discontinuation of current medications?

Sharon a caregiver for her husband Jim said that clinical trials were just the sort of hope that her husband needed. Her husband Jim gladly participated in a trial with his daughter and future generations in mind. Jim said “I will do whatever I can to make sure someone else doesn’t get it”. Sharon and Jim discussed some of the difficult questions that were posed at an Alzheimer Society First Link learning series. Sharon said Jim didn’t want to go to the coffee shop after the sessions like many of the others. He wanted to go home to discuss future planning. Jim made known his choices on many issues discussed. Jim told Sharon that he would like to donate his brain for research when he passes. A difficult thing for Sharon to hear, but she knew that Jim wanted to do everything that he could to advance research. Sharon’s advice to those considering participation in clinical trials is “Have the discussion”.

Everyone’s situation and journey with dementia is unique. Communicating with family and health care professionals, asking questions and understanding the impact on your life can help you to make an informed decision. There is opportunity locally to participate in clinical trials. In addition to her busy geriatric practice and community work, Dr. Ingram and staff at the Kawartha Regional Memory Clinic have conducted close to 30 clinical research trials for Alzheimer’s drugs. Deana Huntsbarger Clinical Trials Administrative Coordinator of Kawartha Regional Memory Clinic shared “We are profoundly grateful for the commitment and sacrifices our patients make to help further this research. We are honoured to share the journey together in the hopes for better treatments and perhaps someday a cure”.

Resources:

Alzheimer Society Tough Issues, Participation in Research; The University of Texas Health Science Centre, www.uth.edu;

Natural Sciences and Engineering Research Council of Canada www.nserc-crsng.gc.ca