Frequently Asked Questions: Collaborative Team Grant on Improving Cognition in People with Progressive Multiple Sclerosis

August 2018

1. **What is the Collaborative Team Grant (Team Grant)?**

At the MS Society of Canada, the Team Grant is designed to fund multiple sclerosis research conducted by researchers and clinician scientists within Canadian institutions in collaboration with other national and international experts in the field or related fields. Studies funded by the Team Grant stimulate the exchange of knowledge, data, and research techniques, and provide opportunities for scientific training for young researchers. The Team Grant supports transformative research that can advance knowledge in the field, and have significant impacts on the management of MS and the quality of life for people affected by MS.

2. **What is the most recently funded Collaborative Team Grant project?**

The Multiple Sclerosis Society of Canada is supporting a $5 million, multicenter, international clinical trial to investigate whether cognitive rehabilitation and aerobic exercise can improve cognition in people living with progressive MS. The study has the potential to provide a treatment option for people living with progressive MS who are affected by cognitive (thinking, problem-solving) difficulties.

To identify a potential treatment for cognitive difficulties experienced by people living with progressive MS, the research team will test if 12 weeks of cognitive rehabilitation, 12 weeks of exercise or 12 weeks of a combined approach of cognitive rehabilitation and exercise will improve cognitive function. The research team hypothesizes that the combined approach of the two therapies will be more beneficial than either one alone.

3. **Who will be eligible to participate in the clinical trial?**

The study will recruit 360 individuals, aged 25-60, with a confirmed diagnosis of progressive MS (primary progressive or secondary progressive MS). Individuals will be **ineligible** if:

- their EDSS score is ≥7.0
- they have a history of central nervous system disease other than MS

- have used steroids in the past three (3) months
- participate in regular aerobic training
- have severe mental illness

Interested participants must also be able to travel to the sites where the interventions will be administered.

This is not the complete list of inclusion criteria. For more information please visit the research portal (to be updated once recruitment begins).

4. Which sites are recruiting participants?

The researchers and the sites recruiting participants are listed below:

- Dr. Anthony Feinstein (Principal Investigator), Dr. Jiwon Oh: Sunnybrook Research Institute, Toronto, Canada
- Dr. Peter Feys: University of Hasselt, Hasselt, Belgium
- Dr. Ulrik Dalgas: Aarhus University, Aarhus, Denmark
- Dr. Jennifer Freeman: Plymouth University, Plymouth, UK
- Dr. Giampaolo Brichetto: Italian Multiple Sclerosis Foundation, Genoa, Italy
- Dr. John DeLuca, Dr. Nancy Chiaravalloti: Kessler Foundation, East Hanover, USA
- Dr. Mara Rocca, Dr. Massimo Filippi: Ospedale San Raffaele, Milan, Italy
- Dr. Matilde Inglese: University of Genoa, Genoa, Italy
- Dr. Maria Pia Amato: Don Gnocchi Institute (University of Florence), Florence, Italy
- Dr. Jeremy Chataway: University College London, London, UK
- Dr. Rob Motl, Dr. Brian Sandroff: University of Alabama at Birmingham, Birmingham, USA

5. How many participants will be accepted at each site?

Each site will be recruiting between 30-40 participants.

6. Within Canada, can people from outside of the province of Ontario participate in the clinical trial?

No, participants must attend therapy sessions that will take place twice a week for 3-4 hours over a 12-week period. Participants must be able to travel regularly to the site, located in Sunnybrook Research Institute therefore recruitment will not occur outside of Ontario. There are additional sites internationally that people can apply to but again, participants must live close to the sites where testing will take place in order to travel regularly to these locations. The Sunnybrook site will organize your travel to and from the hospital and cover all the travels costs.

7. Can I participate in the clinical trial?

Once recruitment begins in Canada, information for interested participants will be available on the MS Society research portal website. For participation in Toronto, contact the study coordinator, Cecilia Meza at meza-c@hotmail.com. For international sites, contact the lead investigator in the country of residence. Email addresses can be provided on request from Cecilia Meza.

8. What are the interventions?

The interventions are cognitive rehabilitation and exercise.

Cognitive rehabilitation will be administered by the research team and will be computer-based.

The exercise intervention will be based on your level of fitness and be individually tailored to your abilities.

9. How frequent will the interventions be administered?

All interventions will be administered in a hospital or clinic setting under medical supervision. The intervention sessions will occur twice a week over a 12-week period. Assessments will be taken at baseline, and again at three and six months.

10. Are there any safety concerns related to the interventions?

Potential participants will be screened carefully beforehand for potential cardiac and other medical risks that may prevent them from taking part in the exercise component of the study. While falls are possible, particularly during exercise interventions, safety measures such as spotters and other mobility aids will be available.

11. What are the outcome measures of the clinical trial?

A neuropsychological evaluation will be performed to measure cognitive performance. This includes the Brief International Cognitive Assessment for MS (BICAMS), which measures information processing speed and verbal and non-verbal (visual) memory. The primary outcome measure is information processing speed. Secondary outcome measures include speed of walking, depression, fatigue, anxiety, and quality of life.

12. How long is the study expected to take?

The trial is expected to begin in early 2019, with an anticipated completion date of 2022. The MS Society will provide updates related to the progress of the study as this information becomes available.

For more information, please contact the MS Society at the msresearchgrants@mssociety.ca.