



# Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude pilote de phase II sur l'effet du méthylphénidate sur la fonction cognitive des patientes en rémission d'un cancer du sein
Protocole ID	CogMet
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT02970500">NCT02970500</a>
Type(s) de cancer	Sein
Phase	Phase II
Type étude	Support
Médicament	Méthylphénidate
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL
Ville	Québec
Investigateur principal	Dr Bruno Gagnon
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Statut	Actif en recrutement
But étude	Cancer-related cognitive Impairment, (CRCI) commonly referred to as "chemo brain" or "brain fog"—impact severely on the Quality of Life (QoL) of cancer survivors. It still remains underdiagnosed and challenging to treat. One of the treatment options is the use of psychostimulants such as Methylphenidate (MP), but well-designed clinical trials to test its efficacy are limited. We will conduct a phase II study with a mixed method design to explore the preliminary efficacy of MP to improve cognitive function and Quality of life in breast cancer patients after treatment with chemotherapy and/or radiotherapy and determine the parameters needed for designing a phase III study. This study will include two phases: Phase one: randomized placebo-controlled clinical trial, phase 2 open-label trial.
Critères d'éligibilité	<ul style="list-style-type: none"><li>• Breast cancer stade I, II or III</li><li>• had received chemotherapy and/or radiotherapy</li><li>• being in remission of her breast cancer</li><li>• complaining of cognitive impairment</li></ul>
Critères d'exclusion	<ul style="list-style-type: none"><li>• <b>Current or recent use of psychostimulant drugs</b></li><li>• <b>Women receiving drugs like:</b><ul style="list-style-type: none"><li>• Anticoagulants</li><li>• Antidepressants</li><li>• Drugs (cocaine)</li><li>• Erythropoietin</li><li>• Drugs acting on the cerebral dopaminergic system, including drugs that inhibit monoamine oxidase</li><li>• Currently taking John's wort, natural medicines for depression or supplements for fatigue.</li></ul></li><li>• <b>Conditions that may increase the risk of cognitive impairment or toxicity of methylphenidate such as :</b><ul style="list-style-type: none"><li>• Pregnancy and breastfeeding</li><li>• Migraine, headache</li><li>• Bipolar status</li><li>• Cerebral tumor or any brain injury</li><li>• Metastatic cancer</li><li>• Alcohol addiction</li><li>• Drug</li><li>• Active Major depression</li></ul></li></ul>

- Parkinson disease
- Dementia
- Epilepsia,
- Glaucoma
- Cardiovascular diseases
- Auto-immunes and chronic inflammatory disease
- Narcolepsia
- Pheochromocytome
- Thyrotoxicosis
- Motor tic, Gilles de la Tourette syndrome
- Anxiety