

FIRST-EPISODE SCHIZOPHRENIA

ALTERNATIVE MENTAL HEALTH TREATMENT ONTARIO OUTREACH PROJECT

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Our outreach project, localized to the geographic catchment of Southern Ontario and US vicinity, aims to provide an advanced drug-free treatment regimen that offers hope for first-episode schizophrenia (FES). First-episode schizophrenia is identifiable in people with consistent psychotic symptoms lasting 6 to 24 months. It is in this FES group that researchers believe early treatment offers the most benefit. Indeed it is in this group that there exists the greatest potential to bring brain chemistry back to a state of normalcy.

We are **currently accepting patients** for a one year open-label clinical trial (where everyone knows what the treatment is) and we encourage all interested to **call our Toronto clinic** toll free at 1-877-ORTH-871 or locally at 416-944-8824. Although medical referral is not mandatory, we work with an array of medical professionals and encourage inter-professional collaboration.

In this international outreach effort, the Naturopathic Medical Research Clinic (NMRC), located in Toronto, Ontario, will use an advanced drug-free nutrient-based protocol with a central nutrient foundation that has been used successfully over the past half century.

We intend to report on the effectiveness of this unique first-episode treatment method in the sample of patients. Reporting will not only help future research efforts, but will also help society appreciate the value of a drug-free approach considered to offer profound hope.

It is important to note that FES patients taking drug medication can safely and simultaneously use this nutrient-based protocol. In society, we see a high drug drop-out rate in FES. Indeed many patients (upwards of 40%) opt not to take drug medication at all. With this existing demographic sample we aim to determine the comparative effectiveness of an advanced nutrient-based protocol in drug-naïve versus drug-medicated FES. Although the fact that the benefit of using neuroleptic drugs in FES is not established, the majority of modern day psychiatric researchers will assert: 1) that medication benefits outweigh apparent risks, 2) that maintaining medication while implementing an alternate treatment method does not negatively alter results or study validity and, 3) that drug sedative effects play a paramount role in maintaining socially acceptable society decorum.

We all look forward to the day when FES patients will be given the opportunity to live life free of major sedation. The NMRC treatment protocol archive on first-episode and chronic schizophrenia encompasses a comprehensive array of nutrient targeted patient data. Our archive supports the use of an exceptional model of wellness in FES. In considering the protocol of choice in first-episode cases, we have taken into account sixty years of evidence-based archives and a decade of in-house data on alternative clinical treatment outcomes in schizophrenia. The chosen FES protocol is a clinical nutrition vitamin and mineral regimen that combines adjunct thyroid treatment when indicated. **The clinical nutrition component is an advanced and novel clinical nutrition (orthomolecular) regimen that addresses core nutrient deficiencies and dependencies.** We consider this approach to provide the best treatment outcome scenario in FES.

There will be a comprehensive lab testing component integrated in this trial as we aim to determine the metabolic and biochemical factors that define good responders. There will also be a comprehensive component that assesses symptoms and quality of life functional recovery aspects. **An international outreach effort of this quality will facilitate an understanding of the most effective alternative treatment model for FES, and thereby offer hope to a segment of society that so drastically needs it.**

This outreach project is considered an 'in-house' open-label research endeavor and as such does not require grant funding or natural health product regulatory body approval. In this case, under this research design, eligible participants will be required to pay for a portion of assessment and treatment services and supplement costs. A four-part service package fee covers one year of assessment and treatment services. Monthly supplement cost estimates are available and vary depending on body weight and protocol allocation at the 6 month mark. At the 6 month mark, participants are allocated to either the thyroid or the multi-EPA treatment stream, and iron deficient cases are supplemented as indicated.

Eligible Candidates are those who:

- i) have a diagnosis of FES or who through a collaborative effort in assessing symptoms are provided with a solid FES diagnosis; participants must be moderate to severely symptomatic and functionally semi-independent in society; diagnostic uncertainty excludes participation but candidates with prodromal symptoms of 1-2 years will be considered for a separate open-label trial with a streamlined treatment intervention;
- ii) are on, off, or have never taken neuroleptic medication; if on medication, participants are not to discontinue or withdraw unless directed under psychiatric supervision; if progress is substantial and withdrawal from medication is indicated, this is to be done only as recommended under psychiatric supervision with the aim of maintaining the lowest effective dose to avoid receptor related confounds to treatment outcome (dose reductions should thereby not exceed 15% of the 'stabilized' dose of neuroleptic every 3-6 months during the one year study protocol);
- iii) are less than 2 years post-onset at the time of starting the protocol;
- iv) are age 18 to 40; those aged 14-17 or 41-55 will be considered for a separate open-label trial with similar treatment intervention;
- v) are willing to allow their progress to be documented by providing disclosure to report data on their case up to 5 years post-treatment (anonymity is respected in all cases);
- vi) are committed to adhering to the protocol to ensure compliance; participants are excluded if they use other alternative treatments during the one year study protocol; participants must be able to form an alliance with the research team to comply with protocol structure; where possible, patients should be accompanied by caregivers to provide a support network that ensures compliance; a compliance contract is mandatory;
- vii) are willing to pay for treatment and participate without subsidization; a heavily discounted rate applies to encourage access to all socio-economic populations; participants must be able to afford transportation to and from the Toronto clinic and other miscellaneous out-of-pocket expenses;
- viii) do not have a history of a chronic condition that is a confound to treatment response; for example, active liver disease such as active hepatitis, illicit drug use, alcohol abuse, peptic ulcer, assaultive or flagrant uncooperative behaviour, or moderate to severe destructive behaviour.