UNIVERSITY OF CALGARY

Patient Consent Form

Project Title: A Randomized Controlled Trial of A Nutrient Supplement in The Treatment of Fibromyalgia.

Severed under Section 24(1) of the FOIP Act

Investigators: [redacted], B. Kaplan, PhD

Supported by: Health Research Fund (Alberta Heritage Foundation for Medical Research), and

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This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what this research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

Purpose

You are invited to participate in a study which will evaluate a nutrient supplement (primarily minerals) in the treatment of patients with Fibromyalgia (FM). The participants in this study will be people from the Calgary area who have been diagnosed with FM for at least one year, by the American College of Rheumatology criteria.

Significance

FM is a chronic musculoskeletal condition which is associated with significant pain and functional disability. The cause of this condition is not known, and the degree of disability due to FM is reported to be as severe as rheumatoid arthritis. No medication to date has proven successful in consistently relieving FM and this leads patients to seek help from complementary medicine. To date there is little or no good data on the efficacy of complementary medicines in the treatment of FM. Based on preliminary observations, there are indications that a randomized controlled study of a particular set of nutrient supplements is warranted.

The Supplements

The supplement that we are evaluating consists mainly of [illegible], with a few vitamins and other nutrients. If you participate, you will be asked to take 24 gelatin capsules per day, divided however you like into 3 or more doses.

Benefit/Harm

Although we cannot be certain that your participation in this study will benefit you, we can be fairly confident that it will not harm you. The supplement has been used by many people in the past without any known side effects. In a study of 12 children conducted by Dr. Kaplan in 1998, heart rate, blood pressure, and blood tests remained normal when the children took the supplement.

Study Procedures

If you choose to participate, you will be randomly assigned into one of 2 treatment groups, active or placebo supplements. You will not know which group you were in, until the study has been completed (expected completion date: September 2000). You will be assessed on three occasions through physical exams and completion of the following questionnaires and tasks: a Background Information questionnaire, the Fibromyalgia Impact Questionnaire, Illness Intrusiveness Questionnaire, Depression Scale, Self Efficacy questionnaire, the Quality of Life Questionnaire, and an auditory information processing task. In addition, you will be asked to make a brief phone call every night to report a symptom score to an answering machine.

There will be a total of three visits over a 6-month period. All assessment visits will occur at the McCaig Centre for Joint Injury and Arthritis Research. If you participate, you will be asked to make no changes in your medications during the course of the study unless the change is considered necessary by your primary physician. You will be

allowed to decrease your intake of currently prescribed medications for FM. You will also be requested to not try any alternative medicines or other forms of therapy until you have completed your involvement in this study: these would include physiotherapy, herbal products, or undertaking special exercise programs, etc.

Confidentiality

All information about you that is collected in this study, will be held in the strictest confidence. The only people who will have access to the information required for this research project are the study investigators and designated staff. Someone at the clinic will collect your questionnaires and answer any questions you have, but will not be looking at your information unless requested. The final results will be reported as part of a large group as numbers and percentages. Your name will never appear in any reports related to this study.

Liability and Compensation

As health care professionals, it is our responsibility to place patient well being above all else. It is with this in mind that we have undertaken this research project. We do not anticipate any harm will come to you as a result of our questions and treatment. However, in the event that you do have problems resulting from participating in this research project, no compensation will be provided for you by The University of Calgary, the CRIIA, Dr. Bonnie Kaplan or . You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact:

Dr. Bonnie Kaplan 229-7365

If you have any questions concerning your rights as a possible participant in this research, please contact the Office of Medical Bioethics, Faculty of Medicine, University of Calgary at 220-7990.

(Participant Name - Print)	(Participant Signature)	(Date)
(Investigator)		(Date)
(Witness Name - Print)	(Witness Signature)	(Date)