



**Canadian Institute of Natural and Integrative Medicine (CINIM)**  
Suite 170, 1402 8th Avenue N.W., Calgary, Alberta T2N 1B9, Canada  
Telephone: 403-220 0022, Fax: 403-210 2080  
www.cinim.org

**PARTICIPANT CONSENT FORM**  
**FOR SPIRITUALITY AND DEPRESSION STUDY**  
(updated on June 20, 2005)

**Title of project:**     **A Spirituality Teaching Programme for Depression:  
A Randomized Controlled Trial**

**Sponsor:**             Alberta Heritage Foundation for Medical Research  
Norlien Foundation  
Max Bell Foundation

**Investigators:**     Dr. Badri Rickhi, Associate Professor, Dept of Psychiatry, U of Calgary  
Ms. Sabine Moritz, Director of Research, CINIM  
Dr. Hude Quan, Assistant Professor, U of Calgary  
Dr. Robin Reesal, Medical Director of Centre for Depression and Anxiety  
Ms. Helen Ewing, Executive Director of Centre for Depression and Anxiety  
Dr. John Toews, Associate Dean, Faculty of Medicine, U of Calgary

**PATIENT CONSENT FORM**

This consent form is only part of the process of informed consent. It should give you a basic idea of what the research is about and what your participation will involve. If you would like more detailed information, please ask. Take the time to read this carefully.

**WHY IS THIS STUDY BEING DONE?**

This study aims to test the effectiveness of a Spirituality Teaching Programme on individuals suffering from depression. Specifically, this study will assess the impact the Spirituality Teaching Programme has on depressive symptoms and quality of life.

There are three major reasons we have chosen to undertake this study:

1. Depression is a major health problem.
2. Although antidepressant drugs are available, they are frequently not fully effective and can have side effects.
3. There is increasing evidence that spirituality plays a role in mental health.

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

Approximately 120 people from Calgary will take part in this study. Sixty will be randomized into the Spirituality Programme Group and 60 will be randomized into the Waitlist Control Group.

## WHAT IS INVOLVED IN THE STUDY?

### Intervention: The CINIM Spirituality Teaching Programme

The CINIM Spirituality Teaching Programme was developed by a psychiatrist, Dr. Badri Rickhi. Key issues of the programme include the quest for meaning and purpose, connectedness (with others, nature or the divine) and values (e.g. compassion, love, justice and forgiveness). The program avoids focusing on any particular religion and is applicable to people with various cultural backgrounds.

The Spirituality Teaching Programme is home-study based and is delivered through CDs. It consists of eight 60-90 minute teaching sessions delivered over a period of 8 weeks and daily visualization exercises. The eight teaching sessions present concepts that assist the user to understand the influence of spirituality in their daily lives. Using the format of story telling, the CDs explain how these concepts can be applied to everyday situations in simple and easy ways. The purpose of the daily visualization practice is to create daily periods of tranquility and connectedness.

### Randomization (assignment to a group):

If you decide to participate you will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Thus, you will be randomly allocated to one of two groups – the Spirituality Programme Group or the Waitlist Control Group. The study coordinator will inform you of which group you are in.

However, the study nurses and physicians should be blinded regarding which group you are in. Please help us do this by NOT telling them which group you are in when talking to them. If you reveal your group assignment accidentally during a Study Visit to the study nurse, your current visit will be stopped and you may be required to come back at another time to meet with the alternative study nurse and to do the Study Visit again.

### Treatment:

If you agree to take part in the study, you will be assigned to the Spirituality Programme Group or the Waitlist Control Group. Depending on which study group you are allocated to, your participation will involve:

#### *Group 1: Spirituality Programme Group*

Participants in this group take part in the Spirituality Teaching Programme in the first 8 weeks of their trial participation (Group 1 Intervention Phase). During the following 16 weeks of the trial (Group 1 Follow-up Phase) they are free to continue the spirituality intervention and to use other depression treatments. Participation in the spirituality group includes:

1. Attendance of a pre-study Screening Visit and an Enrolment Visit. The study physician will perform a psychiatric assessment during the screening visit to determine if a diagnosis of major depression is present and to rule out exclusion criteria. A psychiatric assessment tool, the Hamilton Depression Rating Scale, will be administered by a trained professional at the Enrolment Visit and each following study visit;
2. Participation in the Spirituality Teaching Programme for the first 8 weeks of study involvement (Group 1 Intervention Phase);

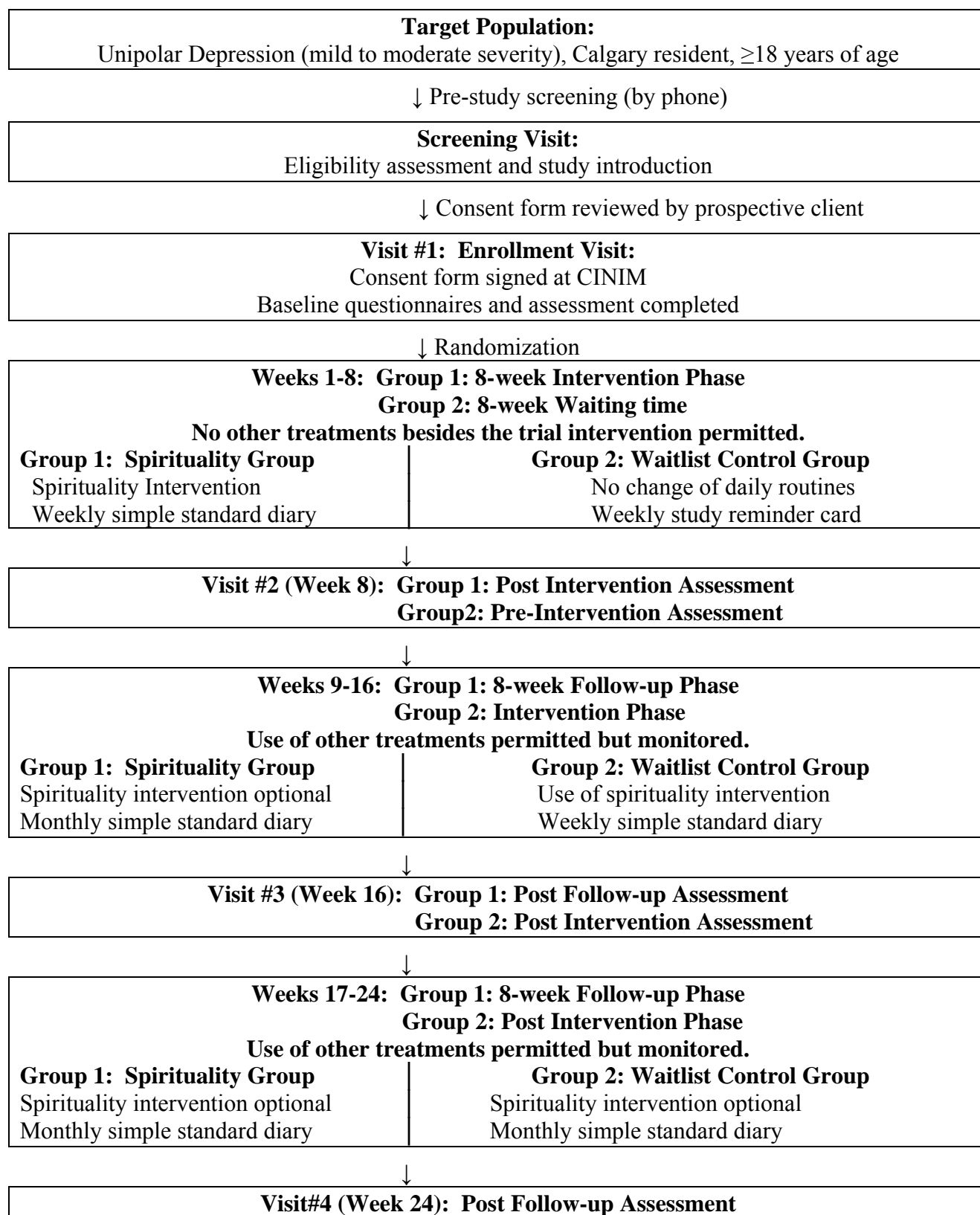
3. Continuing daily routines and keep current schedule and dosage if in use of antidepressant, as well as herbal remedies and psychological counselling, for the 8 weeks duration of the Intervention Phase;
4. Keeping a simple standard weekly diary regarding the use of the teaching session tapes for the Intervention Phase (8 weeks), and a simple standard monthly diary for the Follow-up Phase (16 weeks);
5. Attendance of a Post-Intervention (at Week 8) and two Post-Follow-up (at Week 16 and Week 24) assessment visits;
6. Completion of study questionnaires (completed at CINIM, taking approximately 15 minutes each time) at each assessment visit.

### Group 2: *Waitlist Control Group*

The waitlist control group participants are asked to continue their daily routines for the first 8 weeks of their trial participation (Group 1 Intervention Phase). During the second 8 weeks (weeks 9 to 16) this group will take part in the use of the Spirituality Programme. Participation in the waitlist control group includes:

1. Attendance of a pre-study Screening Visit and an Enrolment Visit. The study physician will perform a psychiatric assessment during the screening visit to determine if a diagnosis of major depression is present and to rule out exclusion criteria. A psychiatric assessment tool, the Hamilton Depression Rating Scale, will be administered by a trained professional at the Enrolment Visit and each following study visit;
2. Continuing daily routines and keep current schedule and dosage if in use of antidepressant, as well as herbal remedies and psychological counselling, during the waitlist period ( that is the first 8 weeks of study involvement);
3. Participation in the Spirituality Teaching Programme during weeks 9 to 16 (Group 2 Intervention Phase);
4. Keeping a simple standard weekly diary regarding the use of the teaching session tapes during the 8 week Intervention Phase (weeks 9 to 16), and a simple standard monthly diary in the 8 weeks Follow-up Phase (weeks 17 to 24);
5. Attendance of Pre-Intervention (week 8) , Post-Intervention (week 16), and Post-Follow-up assessment (week 24) visits;
6. Completion of study questionnaires (completed at CINIM, taking approximately 15 minutes each time) at the each assessment visit.

## Study Schematic



### Procedures and Medical Tests:

The study involves psychiatric assessments. There are no other procedures or medical tests involved in this study.

### Questionnaires:

You will be asked to fill out questionnaires at the Enrolment Visit and at each subsequent visit (at Week 8, Week 16 and Week 24). The 2 main questionnaires, the Short Form 36 Health Survey (SF-36) and Profile of Mood States (POMS), should take approximately 10 minutes to complete. There is also a Spiritual Involvement and Beliefs Scale (SIBS), a short baseline questionnaire as well as a short questionnaire on use of other therapies for depression.

### HOW LONG WILL I BE IN THE STUDY?

Regardless of which group you are randomized to, you will be part of the study for 24 weeks. If you are randomized to the Spirituality Programme Group then you will immediately start the 8-week Spirituality Programme, followed by a 16 weeks Follow-up Phase. If you are randomized into the Waitlist Control Group you will continue normal activities during the first 8 weeks of your study involvement, then take part in the Spirituality Programme during weeks 9 to 16. The final 8 weeks of study participation will be a Follow-up Phase, lasting from weeks 17 to 24, for both groups.

### WHAT ARE THE RISKS OF THE STUDY?

There are no anticipated risks of the study. You are required to keep current schedule and dosage if in use of antidepressant medication, as well as herbal remedies and psychological counselling, during the first 8-weeks of your study involvement. You may withdraw from the study at any time, or use the help of our on-call medical professional or other resources in emergency situations.

### ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We cannot promise that participation in this study will provide any benefits to you. You will be offered free participation in the Spirituality Teaching Programme that has been shown to be helpful to some patients. Participants in both groups will receive a free copy of the CINIM Spirituality Teaching Programme. Your participation in this study may help depressed individuals in the future to have access to this programme. If you agree to take part in the study, there may or may not be a direct medical benefit for you. We hope that information learned from this study will help you and other patients with similar conditions in the future.

### WHAT OTHER OPTIONS ARE THERE?

The intervention that is evaluated in this study can potentially help individuals deal with their depression. However, you may feel that the interventions used in this study are not suitable for you. You may choose to seek help from a qualified physician. Please notify us if you choose to do this.

### WHAT ABOUT CONFIDENTIALITY?

We do not require you to provide your name on the questionnaires you will be asked to complete during the course of this study. However, these questionnaires carry an identification code. This identification code will only be known by the researchers involved in this study. The identification code list will be kept separately from your completed questionnaires. Please be assured that the information you provide will be kept strictly confidential. Your records will be kept securely stored at the Canadian Institute of Natural and Integrative Medicine (CINIM), Calgary, where this research is carried out. In the event that this research is published you will not be identified.

### IS MY FAMILY PHYSICIAN AND/OR PSYCHIATRIST INVOLVED?

Yes. We need your permission to notify your family physician and your psychiatrist (if you have one) that you are enrolled in this study. We need to have his/her/their agreement with your enrolment.

### WHAT ARE THE COSTS?

You will not be paid for taking part in this study. However, the Spirituality Teaching Programme is offered to you free of charge. Public transportation and parking associated with your participation in this study will be reimbursed.

### WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Deciding not to take part or deciding to leave the study later will not result in any penalty or any loss of benefits to which you are entitled.

### COMPENSATION

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by The Canadian Institute of Natural and Integrative Medicine (CINIM), C1FILM Productions Corp. (the producer of the Spirituality Teaching Programme), the Calgary Health Region, the University of Calgary, or the researchers of this study. You still have all your legal rights. Nothing said in this consent form alters your right to recover damages.

### SIGNATURES

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 the health care you are entitled to receive. 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:

Ms. Tracy Xu, Study Coordinator (220-0022 ext.102), or  
Ms. Sabine Moritz, Director of Research, (220-0022 ext 103)  
at the Canadian Institute of Natural and Integrative Medicine (CINIM)

### DO I NEED TO SIGN ANYTHING ELSE?

Before you are eligible for this study and given this consent form, you should have signed "Permission for Assessment to be completed for Participation Eligibility in a Clinical Trial" so that the psychiatric assessment can be done to determine your eligibility. Also, we need your written permission to contact your family doctor and/or your psychiatrist to inform him/her of your participation in this study and to confirm your medical and psychiatric history.

If you have any questions concerning your rights as a possible participant in this research (A Spirituality Teaching Programme for Depression: A Randomized Controlled Trial), please contact Pat Evans, Associate Director, Internal Awards, Research Services, University of Calgary, at 220-3782.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

Participant's name (please print) \_\_\_\_\_

Participant's signature: \_\_\_\_\_

Date \_\_\_\_\_

Investigator/Delegate's name (please print) \_\_\_\_\_

Investigator/Delegate's signature \_\_\_\_\_

Date \_\_\_\_\_

Witness' name (please print) \_\_\_\_\_

Witness' signature \_\_\_\_\_

Date \_\_\_\_\_

A signed copy of this consent form has been given to you to keep for your records and reference.