PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects and interventional studies)

1 . Title of study:
Effectiveness of Group Cognitive Behavioral Therapy on Pain, Functional Disability and Psychological Outcomes among Knee Osteoarthritis Patients Seen at Malaysian Government Hospital

2. Name of investigator and institution:

Principal investigator:	PROF. MADYA DR. MANOHAR
Co-investigator:	PROF. LEKHRAJ RAMPAL
	PROF. DATO'DR. MUNN-SANN LYE
	PROF. SHERINA MOHD SIDIK
	DR. ZUBAIDAH
	FOO CHAI NIEN

This study will be conducted at Orthopaedic Clinic in government hospital, namely Hospital Putrajaya and Hospital Serdang.

3. Name of sponsor: Research University Grant Scheme (RUGS), University of Putra Malaysia

4. Introduction:

You are invited to participate in this research study because you have diagnosed with knee osteoarthritis that relates to knee pain and loss of joint mobility and functions that requires Cognitive Behavioral Therapy (CBT) intervention. This research study uses a CBT approach that has been proven effective for the management of knee osteoarthritis pain. This study can help you to change how you think and what you do that helps you to feel better on your knee pain problem. It is a self- management program where you can learn for yourself in taking control of your knee condition, rather than letting it control you. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide you doctor with information on your health history; you may harm yourself if you are not truthful with the information provided.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. What is the purpose of the study?

The purpose of this study is to develop and implement a cognitive behavioral therapy module, and to evaluate its effectiveness in reducing level of knee pain, functional disability, psychological distress (depression, anxiety and stress), pain catastrophising, fear- avoidance beliefs, and improving in self- efficacy in pain management in patients with pain and dysfunction due to osteoarthritis of the knee.

This research is necessary because it may provide and teach you skills so that you can manage knee pain effectively on your own and minimize the effect of knee osteoarthritis on your everyday life.

In Malaysia, there will be about 262 subjects will participate in this research study. The whole study will last about eight (8) months and your participation will be about six (6) months.

6. What kind of study products *[or procedures]* will I receive?

If you agree to participate in the study, the doctor may need to review your clinical and radiological examinations to determine if you are suitable for the study. If you are deemed suitable, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below. You have equal chance of being assigned to each of the groups (Group 1 or 2). Neither you nor the doctor will know which group you are assigned to but in case of emergencies, this information is available to your doctor.

Group 1: Cognitive behavioral therapy (three sessions; two and a half hour for each session) provided with The Knee Book added to standard routine care

Group 2: Standard routine care provided with The Knee Book

7. What will happen if I decide to take part?

a) You do not have to stop taking your medication to participate in this study.
b) If you would like to change your medication during this study, you should discuss this first with your doctor.
c) You are willing to devote energy to out-of-session work (e.g., homework). Homework exercises will help you apply the skills learned in session
d) You will also be setting personal goals that you would like to achieve during the study.
e) You are willing to devote the time needed for weekly sessions and need to make a commitment and effort to learn new skills and work toward your goals.
f) Before you start with CBT, you will be enquired to complete some assessment measures. These questionnaires will ask you about the history of your knee pain and the impact of knee pain has on your life You will also be enquired to complete some

assessment measures after attended all five sessions of CBT, one month and six months after the CBT program.

8. When will I receive the trial product and how should it be kept?

You will be contacted personally by the study staff about the date and time given the study program at each study visit throughout the treatment period of the study. You must not inform the study program to anyone else.

9. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the study doctor. You must inform your study doctor immediately if you make any changes to any of your current treatments, even those which you have been taking for a long time.

It is very important that your study doctor be informed very rapidly of any eventual changes to your health during your participation in the study. Besides, attend your clinic and physiotherapy session as usual on your appointment date.

10. What kind of treatment will I receive after my participation in the trial?

No study product or treatment will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

11. What are the potential risks and side effects of being in this study?

There are no risks for subjects on placebo. However, there is little risk in getting cognitive behavioral therapy. You may explore painful feelings, emotions and experiences. Besides, you may feel emotionally uncomfortable at times. You may cry, get upset or feel angry during a challenging session, or you may also feel physically drained. However, the therapists will minimize any risks. The coping skills you learn can help you manage and conquer negative feelings and fears.

Notify your study doctor immediately if you think that you has become pregnant during the study. If you are pregnant, the study therapy will be discontinued immediately and you will be removed from the study.

Please ask your study doctor if you need more information on risks and side effects. The trial staff will inform you in a timely manner about any new findings or changes about the study product which may affect your health or willingness to continue in this study. Where necessary, you may be asked to reconsent to participate.

12. What are the benefits of being in this study?

This research will provide you with psychological and emotional support to enable you to reduce the symptoms and progression of knee osteoarthritis. Additionally,the result of this research will enable the investigator and the health care team members to determine better ways of helping you and other people with recent onset chronic knee pain for better pain management.

13. What if I am injured during this study?

If you are injured as a result of being in this study, you should contact your study doctor. In the event of a bodily injury or illness directly resulting from the study product or a medical procedure required for this study, the sponsor will not pay the compensation. The sponsor is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your study doctor or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

14. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get treatment for your disease or condition. The study doctor will discuss in more details the benefits and risks of those existing treatments with you if you do not participate in this study.

15. Who is funding the research?

This study is sponsored by Research University Grant Scheme (RUGS), University of Putra Malaysia who will pay for all study procedures. All other drugs and procedures that are not required by the study but are part of your routine medical care will have to be paid by you or your insurance. The sponsor will financially compensate the time spent by the study staff, use of facilities, etc., for including you in the study.

16. Can the research or my participation be terminated early?

The study doctor or the sponsor may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed and arrangements made for your future care. You may be asked to attend a final follow-up visit.

17. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

With your permission your family doctor will be informed of your participation in the study.

You will not be informed of the study findings unless if you require it.

18. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor, Prof. Manohar Arumugam at telephone number +603- 8947 2637. If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287 4032.

INFORMED CONSENT FORM

Title of Study: **Effectiveness of Group Cognitive Behavioral Therapy on Pain, Functional Disability and Psychological Outcomes among Knee Osteoarthritis Patients Seen at Malaysian Government Hospital**

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study.

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date: