Respondent's Information Sheet for Study 3

JAWATANKUASA ETIKA UNIVERSITI UNTUK PENYELIDIKAN MELIBATKAN MANUSIA (JKEUPM)
UNIVERSITI PUTRA MALAYSIA, 43400 UPM SERDANG,
SELANGOR, MALAYSIA

RESPONDENT'S INFORMATION SHEET

STUDY TITLE :
The Effectiveness of Group Internet Cognitive Behavior Therapy for Insomnia for Medical Students

INTRODUCTION:
The purpose of the study is to investigate the effectiveness of two methods of intervention in improving sleep quality and executive functioning. The two methods of intervention are (1) Internet Group Cognitive Behavior Therapy for Insomnia, (2) Internet Group Sleep Hygiene Education where participants with do regular procedures in terms of medical treatments. Respondents will be divided randomly into these two interventions and need to committedly involve this study for six weeks, followed by follow-up sessions (after one-month, three-months, and after six-months from post intervention). Follow-up sessions just in terms of assessments and not in the form of therapy. Psychological measurements will be conducted before intervention, after intervention, and during the follow-up sessions

WHAT WILL YOU HAVE TO DO?
There are several tasks that you will have to do in this study:

(1) Socio-demographic profile- You are requested to complete the socio-demographic profile in the questionnare, including your contact details such as e-mail address and telephone numbers. This is very important in order for us to share with your the findings of the research after the study is completed.

(2) Psychological measures_ Six sets of questionnaires will be distributed for you to answer throughout the study. One set of the questionnare will be distributed before the intervention, another one set will distributed after you have completed session four in the therapy and another four sets will be distributed after the intervention (i.e., immediately after the intervention being completed, after 1-month, 3-months, and after 6-months). The measures included in the questionnares are (a) Pittsburgh Sleep Quality Index (PSQI); (b) online Trail Making Tests (dTMTs); (c) SLEEP-50; (d) Dysfunctional Beliefs and Attitudes about Sleep-16 (DBAS-16); (e) Presleep Arousal Scale (PSAS); and (f) Sleep Hygiene Index (SHI). All of the questionnaires are in English language. You will be remunerated with Ringgit Malaysia Fifty (RM 50) for your effort upon completion of the questionnaire at the end of 6-month follow-up session.

(3) Internet Group Cognitive Behavior Therapy for Insomnia (ICBT-I): Group ICBT-I will help you understand about sleep quality and how to use cognitive and behavioral strategies to cope with sleep quality and executive functioning. You will be committed to six weeks programme of Group ICBT-I with six online sessions, once weekly frequency for 45-50 minutes.

(4) Internet Group Sleep Hygiene Education (ISHE): Group ISHE will expose you to various techniques of sleep hygiene in order to improve sleep quality and executive functioning. You will be committed to six weeks programme of Group ICBT-I with six online sessions, once weekly frequency for 45-50 minutes.

WHY YOU ARE BEING CHOSEN?

You have met the inclusion criteria for this study:

1. Age at recruitment Individuals 18 years or older;
2. Currently a medical student in Klang Valley, Selangor and living in Malaysia;
3. Willing and able to provide written informed consent;
4. Being able to read and understand English;
5. Have reliable Internet access at home or at university;
6. Proficiency (self-reported) in basic computer/internet skills (as required to participate in the RCT and complete online assessments, etc.).

WHO SHOULD NOT ENTER THE STUDY?

The esclusion criteria for this study are:

1. Evidence of a sleep disorder (e.g., possible obstructive sleep apnoea, restless legs syndrome;
2. Currently consumes alcohol;
3. Medical history contraindicating use of CBT-I, for example, (a) epilepsy (self-report) within the preceding 12 months, or (b) recent cardiac surgery, or (c) currently in an attack phase of multiple sclerosis;
4. Individuals whose work schedule includes night shifts;
5. Pregnancy;
6. Inadequate opportunity to sleep or living circumstances that prevent modification of sleep pattern (e.g., having an infant residing at home);
7. Currently receiving psychological treatment for insomnia;
8. Registered at or under the care of any of the trial centres;
9. Serious physical health concerns necessitating surgery or with a prognosis of under 6 months;
10. Those taking prescribed sleeping pills more than 2 nights in the past 2 weeks prior to study entry; and
11. Those with suicidal ideation with intent. This study will not omit participants for any other physical or mental health problems.

WHAT WILL BE THE BENEFITS OF THE STUDY:

(a) TO YOU AS THE PARTICIPANTS?

If you choose to participate in this study, you may gain several benefits such as:

1. Improve in sleep quality by learning techniques to identify and modify the negative thoughts and learning how to reduce presleep arousal.
2. Improve sleep hygiene by learning specific skills to cope with difficulties initiating sleep or maintianing good sleep.
3. Increase number of social support as the intervention will be run in a group setting.
4. Free consultation of the intervention from experienced therapist.

(b) TO THE INVESTIGATOR?

1. Able to train the respondents with poor sleep quality on cognitive techniques, behavioral strategies, and sleep hygiene in order to improve sleep quality.
2. Able to improve the quality of sleep related rehabilitaion in medical univesity in the country.
3. Able to promote the support system among respondents in order to reduce dependency on profecctional experts.
4. Obtain data and information on te efcctiveness of the intervention from Malaysia to be compared with other countries in the form of publications and intrenational conferences.

ARE THERE ANY RISKS?

Similiar studies have been conducted in overseas previously. As far as it is concerned, the is almost no or minimal risk should be anticipated by the respondent. Instead you may feel more confident in dealing with your sleep and you life. However, if you feel you will be exposed to psychological related risk (e.g., feeling embrassed, worried, or upset) and /or socially related risk (e.g., loss of privacy and reputations), please share it with the researchers before, during and /or after the study. It is important howerver to note that the therapy will be conducted professionally by an expert therapist who have experienced handling group therapy. Rules and regulations of cinducting group therapy will also be imposed in order to minimise the risks, if any.

ARE THE POSSIBLE DRAWBACKS?

Intervention (a) and (b) are psychotherapies whereby it involves discussion between the therapist and the respondents. If there are any side effects from medications taken, respondents may seek advices from their respected physician.Whatbis importants in this study, professional supervisions by professional experts will help both the therapist and respondents from violating any ethical problems.

WILL THE INFORMATION AND MY IDENTITY REMAIN CONFIDENTIAL?

Definitely. All data in this study will remain confidential.The analyst will use the ID number and only the raw scores will be mentioned without revealing the identity of each participant.

WHO SHOULD I CONTACT IF I HAVE ADDITIONAL QUESTIONS DURING THE COURSE OF THE RESEARCH?

Should you have any quiries regarding the study, please do not hesitate to contact the following person that are responsible in this study.

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Respondent's Consent Form for Study 3

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CONSENT FORM (RESPONDENT)

RESEARCH TITLE :
The Effectiveness of Group Internet Cognitive Behavior Therapy for Insomnia for Medical Students

RESEARCHERS: Prof Dr. Firdaus Binti Mukhtar & Vijandran A Mariappan

I…… Identity Card No.....
address……
.....hereby voluntarily agree to take part in the clinical research *(clinical study using questionnaire) as specified above.

I have been informed about the nature of the clinical research in terms of methodology, possible adverse effects and complications (refer to Respondent's Information Sheet). I understand that I have the right to withdraw from this clinical research at any time without giving any reason whatsoever. I also understand that this study is confidential and all information provided with regard to my identity will remain private and confidential.

I wish to *know / don't wish to know the results of the tests performed on my sample.

*** delete where necessary**

Signature ……
(Respondent)

Date :……..

Signature ……
(Witness)

Name :……..

I/C No. :……..

I confirm that I have explained to the respondent the nature and purpose of the above-mentioned clinical research.

Date ……

Signature ……
(Researcher)