

A web-based psycho-education intervention program for an adult community in Selangor, Malaysia

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| Submission date 02/09/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 04/03/2015 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 23/06/2016 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

We are conducting a study to determine the effectiveness and applicability of a web-based psycho-education intervention program for an adult community in Selangor, Malaysia. The aim of our study is to determine whether the web-based psycho-education program (self-management) is effective in reducing depression and anxiety symptoms, as well as to increase the participants' knowledge on mental health.

Who can participate?

Participants who have participated in the first phase of this study and who are still living in Selangor.

What does the study involve?

Participants will be invited to participate in the study by trained research assistants and will be briefed about the study. Upon consenting to participate in the study, the participants will complete an online assessment and then will be randomly allocated to either the intervention or the control group. Participants in the intervention group will be requested to complete four sessions of a web-based intervention program within 4 weeks. After the participants in the intervention group complete all the sessions, the participants in the control group are offered the same program. Participants in both groups will be followed-up at weeks 5 and 12.

What are the possible benefits and risk of participating?

The benefits of participating in the study are the participants will be able to know their current mental health status and increase their knowledge on mental health, and this possibly may help to reduce the symptoms of depression and anxiety. There could be a minimal risk in this study, such as eye strain while reading the information in the website.

Where is the study run from?

The web-based psycho-education program 'Program Komuniti Sihat' (Wellness Community Programme) will be conducted in Selangor, Malaysia in collaboration with Universiti Putra Malaysia.

When is the study starting and how long is it expected to run for?

The study is expected to start in early August 2014 and the follow-up assessments are expected to be completed at the end of October 2014.

Who is funding the study?

The study is funded by the Ministry of Science, Technology and Innovation under the E-Science fund by the government of Malaysia.

Who is the main contact?

Professor Dr Sherina Mohd Sidik

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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43400

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NMRR-14-698-21864

Study information

Scientific Title

A web-based psycho-education intervention program for an adult community in Selangor, Malaysia: study protocol of a randomized controlled trial

Acronym

N/A

Study objectives

It is hypothesized that the symptoms of depression and anxiety will reduce in the intervention group as compared to the control group. Knowledge of the participants is also expected to increase after the intervention. The null hypothesis is there is no significant difference between the intervention and control groups, in terms of reduction of depression and anxiety symptoms and increase in the knowledge on mental health.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University Putra Malaysia, 14/08/2013, ref. UPM/TNCPI/RMC/1.4.18.1

Study design

Parallel two-arm randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Depression and anxiety

Interventions

The study will involve an estimated of 288 participants, who have previously participated in the first phase of this study (A cross-sectional study on contributing factors of depression and anxiety among adults in Selangor, Malaysia). Participants in the intervention group will be invited to participate in the 4 weeks of web-based psycho-education program. The intervention program consists of 4 sessions, with each session accessed on each week. Participants in both groups will be followed-up at week 5 and week 12.

The control group in the study is a wait-list control group. After the participants in the intervention group complete all the sessions of the psycho-education program, the participants in the control group are offered the same program thereafter.

Intervention Type

Behavioural

Primary outcome measure

Change in depressive and anxiety symptoms. This is defined by a change in the sum score on the Patient Health Questionnaire 9 (PHQ-9) and Generalized Anxiety Disorder 7 (GAD-7) between the baseline and follow-up assessments at week 5 and 12.

Secondary outcome measures

Change in the mental health literacy score. This is defined by a change in the total score on the mental health literacy questionnaire between the baseline and follow-up assessments at week 5 and 12.

Overall study start date

01/03/2013

Completion date

30/11/2014

Eligibility

Key inclusion criteria

1. Participants who have participated in the first phase of this study and who are still living in Selangor
2. Having access to computer and internet connection
3. Are internet-literate

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

288 participants (144 participants each for the intervention and control group)

Key exclusion criteria

1. Currently receiving any psychotherapy for diagnosed psychiatric disorders
2. Report suicidal ideation

Date of first enrolment

28/04/2014

Date of final enrolment

14/08/2014

Locations

Countries of recruitment

Malaysia

Study participating centre
Universiti Putra Malaysia
Selangor
Malaysia
43400

Sponsor information

Organisation
Universiti Putra Malaysia (Malaysia)

Sponsor details
c/o Sherina Mohd Sidik
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Sponsor type
University/education

ROR
<https://ror.org/02e91jd64>

Funder(s)

Funder type
Government

Funder Name
E-Science MOSTI (Malaysia)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 21/06/2016 | | Yes | No |