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Developing a self-help Intervention: Recognise, self-help and help-seeking (ReSHaPe) for depressive and anxiety symptoms to improve well-being among low-socioeconomic households in Malaysia

Submission date
14/02/2021

Recruitment status
No longer recruiting

Registration date
23/02/2021

Overall study status
Completed

Last Edited
18/08/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depression and anxiety are common mental disorders in the general population. The National Health and Morbidity Survey has shown there is a high level of mental health issues among the low-income population as compared to the high-income group in Malaysia and intervention is important to overcome this issues and ensure better wellbeing. This research is necessary because good mental health improve self-care thus better wellbeing. As the percentage of physical illness like hypertension and diabetes are high in the low-income group and its close relationship with the development of mental illness, good self-care confers a better control of the disease. To date, the research in Malaysia pertaining to mental health is still very limited.

Who can participate?
Individuals who are part of the low-income population that staying in the Petaling District, Malaysia

What does the study involve?
Participants are required to follow through with an online psychoeducation material (ReSHaPe) with a duration of 15 to 20 minutes on alternate weeks according to their own pace. At the end of each session, they are required to answer a quiz and to complete a simple assignment. The material takes 12 weeks to complete.

What are the possible benefits and risks of participating?
Benefits: Health Promotion will be given to the participants. Referral for counselling and treatment
Risks: You may experience some emotional discomfort when answering certain questions in the mental health assessment questionnaires. You can choose to stop answering the questions and contact the researchers as stated at the end of this information sheet.

Where is the study run from?
University Malaya (Malaysia)

When is the study starting and how long is it expected to run for?
August 2019 to February 2022

Who is funding the study?
Malaysia Research University Network (MRUN)

Who is the main contact?
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Additional identifiers

Protocol serial number
UM.TNC2/UMREC - 811

Study information

Scientific Title
Developing a psychosocial intervention: Recognise, Self-help and HelP-seeking (ReSHaPe) for depressive and anxiety symptoms to improve the well-being among the low-socioeconomic households at low-cost flats in Malaysia

Acronym
ReSHaPe

Study objectives
1. There is significant difference between the mean scores of depression, anxiety, resilience , quality of life, weight and BMI status among B40 residents at the community housing project in the intervention in comparison to the control.
2. There is significant difference between the mean different of the depression, anxiety , quality of life status, resilience , weight and BMI among B40 residents at the community housing project within the intervention arm upon repeated measure at T1 (Pre-test), T2 (Post-Test) and T3 (Follow-up).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2020 Universiti Malaya Research Ethics Committee (Non-Medical) (Research Service Centre, Level 2, Research Complex, Education and Innovation, University of Malaya 50603 Kuala Lumpur, Malaysia; +60 (0)3-79676289; umrec@um.edu.my), ref: UM.TNC2/UMREC – 811

Primary study design
Interventional

Study design
Interventional non-randomized study with quantitative and qualitative follow up

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Common mental disorders (depression and anxiety) at the community level among the low socioeconomic population

Interventions
Study Design:
An internet-based controlled quasi-experimental study will be conducted with a post-intervention qualitative study to evaluate the effectiveness of the psychosocial intervention following a logic model approach.
Two main evaluation processes will be conducted during the quasi-experimental study, namely, process evaluation and outcome evaluation. Data collection will be conducted at three-time points; baseline (pre-test T1), endline (post-test T2 at 3 months) and follow-up (T3 at 6 months). After the intervention period, a post-test analysis will be conducted on both groups.

Settings:
Eligible participants from the low socioeconomic households are recruited from the 3 sub-division of Petaling Districts namely Sungai Buloh, Petaling Jaya and Damansara through social media campaign (video of recruitment and electronic poster have been emailed to all the head of the community)
Preliminary Recruitment
Baseline assessment form link was sent to the community leaders at the 3 subdivision areas and filled by the low socioeconomic households.
Two medical officers trained in mental healthcare were on standby and screened through the baseline assessment using PHQ-9 and GAD-7 and history of current mental illness. Eligible and consented participants will be recruited and baseline data will be filled.
Participants from the area of Sungai Buloh, the Damansara and Petaling Jaya will be recruited either in the intervention arm or in the control arm according to the residential area.

Intervention Arm:
- ReSHape: Recognise, self-help and Help-seeking: a module developed based on the quantitative data and the qualitative data.
- All the Baseline, Endline and follow-up questionnaires, healthy mind modules, ReSHaPe Modules will be delivered to the participants through RedCap database platform.
- ReSHepS: 3 main modules which split into 6 submodules.
- The 6 modules will be sent to the participants in video forms will be alternate with reinforcement online training: to update their record of their weekly activities for 12 weeks.
- An honorarium will be given to the participants upon completing their assignment.

Control Arm:
- Participants who fulfilled the inclusion and exclusion criteria will be included in the control arm and will be given a healthy mind module under the ministry of health. They will be given the intervention arm module or material at the end of the study.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline (pre-test T1), endline (post-test T2 at 3 months) and follow-up (T3 at 6 months):

1. Quality of Life (EQ-5D-5L)
2. Depression (PHQ 9)
3. Anxiety (GAD-7)

Key secondary outcome(s)
Measured at baseline (pre-test T1), endline (post-test T2 at 3 months) and follow-up (T3 at 6 months):
1. Resiliency (Resilience Scale 14 items)
2. Health literacy measured using the Short-Form Health Literacy Questionnaire (HLS-SF12)
3. Weight (kg), height (cm), BMI (kg/m²)
4. Help-seeking behaviour measured using the Mental Help Seeking Attitudes Scale (MHSAS) and The Self-Stigma Of Seeking Psychology Help (SSOSH)
5. Poverty Attribution measured using PA 21

Completion date
01/02/2022

Eligibility

Key inclusion criteria
1. Adult >18 years old from the community
2. Can communicate with English or BM language
20 Mild to moderate score on and PHQ-9 (<=10) or GAD-7 (<=8)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
112

Key exclusion criteria
1. Residents who has difficulty in speaking, hearing or any means of communication
2. Residents who have self-reported unstable severe psychotic mental illness such as schizophrenia, bipolar disorder and any form psychotic illness
3. Any PHQ-9 score ≥10 or GAD-7 score ≥ 8 will be referred for clinical diagnosis and will be excluded from the study (this is based on clinical assessment by a trained medical officer in mental health)
4. Refuse to give consent

Date of first enrolment
06/02/2021

Date of final enrolment
14/02/2021

Locations

Countries of recruitment
Malaysia

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Sponsor information

Organisation
Malaysia Research University Network (MRUN)

Funder(s)

Funder type
Research organisation

Funder Name
Malaysia Research University Network (MRUN)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Universiti Malaya Research Ethics Committee (UMREC Non-Medical) (umrec@um.edu.my) and the research team Principal Investigator Prof. Mas Ayu Said (mas@ummc.edu.my).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/02/2022	22/02/2022	No	No
Participant information sheet	Participant information sheet version 2.0	11/11/2025	11/11/2025	No	Yes
Protocol file			18/08/2022	No	No