Research Protocol (Version 2.0)

Title: Development And Evaluation Of A Digital Psychosocial Intervention Among Low-Income Urban Dwellers In Petaling District, Malaysia

Principal Investigator: Dr Wong Min Fui[1,2] Professor Hazreen Abdul Majid[2,3] Associate Professor Mas Ayu Said[7], Professor Rozmi Ismail[4]

Other Investigators: Professor Su Tin Tin[5], Professor Tan Maw Pin[6]

Institutional affiliations:

[1]Training Management Division, Ministry of Health, 62675 Putrajaya, Malaysia

[2] Centre for Population Health (CePH), Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia.

[3] Department of Nutrition, Faculty of Public Health, Universitas Airlangga, 60115 Jawa Timur, Indonesia.

[4] Psychology and Human Well-being Research Centre, Faculty of Social Sciences and Humanities, University Kebangsaan, 43600 Bangi, Malaysia.

[5] South East Asia Community Observatory (SEACO) and Global Public Health, Jeffrey Cheah School of Medicine & Health Sciences, Monash University, Bandar Sunway, 47500 Subang Jaya, Malaysia.

[6] Department of Medicine, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia.

[7] Centre for Epidemiology and Evidence-Based Practice, Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia.

1.0 Background

Over the past 50 years, Malaysia has made a stride in extreme poverty eradication and economic growth by shared prosperity. This resulted in rapid urbanization that rose from a baseline figure of 25% in 1960 to 72 % in 2010 (Thinagaran et al., 2017). This phenomenon has changed the population and social structures in the cities, leading to pockets of urban poor. Even though poverty is harsh in a rural area, a similar financial strain is experienced by low-income urban indwellers due to a mismatch between the income and the high cost of living (Siwar et al., 2016).

Socioeconomic status and living environment are the social determinant of Health (Wilkinson & Marmot, 2003), and it's the adverse effect on Quality of life among low-income urban indwellers were well proven in the longitudinal study. Worldwide statistics have shown, 36 million people have died of NCD and these people are from low and middle-income countries

(WHO, 2011). This is through the course of impoverished conditions which has led to social gradient for chronic illness. Studies have found that city in dwellers in the United Kingdom, who were exposed to poor housing conditions, have lower Quality of life. A United Kingdom mental health survey revealed an apparent social gradient for mental disorders among the city indwellers (NHS, 2014). As in Malaysia, it was found that higher social gradient for mortality rate among the poorer states (Mariapun et al., 2016). A recent study conducted among sub-urban communities revealed the severity of the mental health condition following income inequality (Thangiah et al., 2020).

1.2 Problem Statements

In Malaysia, household income has been taken as a benchmark to gauge the well-being of its people. By solely based on household income status as an indicator, Malaysia has been successful in reducing incidences of absolute poverty but not relative poverty. Therefore, the government has started to adopt a multidimensional approach to tackle relative poverty issues to protect well-being among the B40 community, individuals at risk of financial catastrophe due to marginal financial protection.

Household income distribution in Malaysia is based on the division of the total number of households by quantiles, and the National income threshold is defined as **B**ottom 40 per cent (<RM 3852) , **M**iddle 40 per cent (RM 3852-8319) and **T**op 20 per cent (≥RM 8320) (Hamid et al., 2019). The threshold is higher in the greater Klang Valley, like Selangor, whereby the B40 household income is more than RM 6,960.0 (translated to 2.5 million of Selangor population)(DOSM, 2019). Further analysis of the statistic showed 14.4 per cent of the household in Selangor are below RM 4,000, which is below the national B40 household income cut-off. Based on the latest household survey, absolute poverty in the urban area in Selangor has jumped from 0.4 per cent (2016) to 1.1 per cent (2019), while a reduction was observed in the rural areas. At the same time, the relative poverty rate was lifted from 10.7% to 15.3%(DOSM, 2019). This has proven, poverty can be harsh as well at urban settings due to income inequality.

Based on research by Khazanah, the B40 group are vulnerable to financial hardships as their income is merely sufficient for basic needs but does not protect them from risky scenarios such as catastrophic out of pocket expenditure due to critical medical illness (Hamid et al., 2019). Based on the housing development data, about 27.0% of B40 household live in the community housing projects (KPKT, 2016) and their wellbeing and poor living condition is a concern to policymakers as they are not protected against the financial risk.

Realizing the impact of disease trends on socioeconomic, a group of researchers from the University of Malaya (UM) have collaborated and initiated a community based participatory action research project (PARTNER) to improve the general wellbeing and health status of the low socioeconomic urban population. The research project conducted at Kerinchi community housing project revealed multiple NCD related risks among the B40 household, and the proportion was higher than the figure reported by NHMS 2015 (Amiri et al., 2014; Su et al., 2015). As a follow-up, a series of health promotion interventions, health screening and consultation, were conducted to serve the health needs that were detected among the Kerinchi's low-income community.

Rashid et al. (2019) further measured the rate of substance usage and mental status in the same community and found a high prevalence of smokers (16%) with high common neurotic symptoms, namely depression and anxiety (20%) among the poor urban in dwellers. Poor mental health with the high non-communicable disease is detrimental to the wellbeing of the urban low-income community that warrant a further exploration to look for the attributable risk so that public health measures can be implemented to optimize their quality of life.

1.3 Impact and Public Health significant

Malaysia is facing a double burden of diseases (Shahar et al., 2019). Apart from the rising cases of infectious diseases, the recent report of the National Health Morbidity Survey has revealed the increasing trend of chronic diseases in the country. Overall, the 2015 National Health and Morbidity Survey (NHMS) revealed an upward trend of cardiovascular risk which accounted for

a high prevalence of diabetes mellitus 17.5%, obesity 30.6%, hypertension 30.3% and hypercholesterolemia 47.7%. The survey noted higher diabetic cases among the urban population compared to the rural population (IKU, 2015).

Previous studies have shown poor mental Health predict the outcomes of non-communicable diseases (Correll et al., 2017; Lin et al., 2010). This may pose a challenge to the progress of the NCD strategic plan to reduce premature death by 2030 (MOH, 2016).

In 2016, more than 1 billion individuals worldwide were impacted by mental and addiction disorders. They are disabling conditions that cause 7 per cent of all global disease burden assessed in DALYs and 19 per cent of all years lived in disability (Rehm & Shield, 2019). The data from NHMS 2015 also showed a high prevalence of mental health issues (29.9%) among Malaysian adults, and this figure has tripled the 1996 figure (IKU, 2015). Depression among B40 was 2.7%, translated to more than half a million, reported by the latest NHMS 2019(IPH, 2019). In addition, Depression and anxiety were among the two mental illnesses which are commonly diagnosed in Malaysia and worldwide. (Ng, 2014; Patel & Kleinman, 2003).

It has been noted that people who are poor tend to age earlier, especially those with multiple pre-morbid chronic illnesses. Ageing is a global phenomenon, and Malaysia will be an ageing population by 2030(Salleh, 2018). By then, more older persons will be affected with poor mental issues with multiple NCDs (WHO, 2008). Malaysia healthcare system will be overburdened by older people with poor mental health and multiple co-morbidity that require long term medical care. As a consequence, an enormous medical cost is needed to manage these conditions (Sporinova et al., 2019; Vasiliadis et al., 2013; Welch et al., 2009).

Therefore an early intervention before the age of 50 is pivotal for a “healthier older person” to overcome the risks of unemployment, financial security, better mental health and wellbeing (Elliott, 2016).

1.4 Rationale of this study

Poverty has a long term effect on an individual's life, and it could even extend to the subsequent generation. PARTNER's study does not merely highlight poor health among B40 dwellers, but it also reflects a poor adaption to the poor socio-environmental condition among B40 groups. Poverty is a vicious cycle, and it begins with material deprivation, lack of access to education and healthcare, which leads to poorer health and less productivity (Sharma, 1985). Previous studies have shown, low socioeconomic status is associated with low health literacy(Rikard et al., 2016). Lack of knowledge makes them vulnerable to be stigmatized, apathetic and poor coping towards strain. These are precursors of poor mental wellbeing. Therefore, an intervention that acts to reduce the barriers while promoting positive mental health is required to break the vicious cycle of poverty experienced by the B40 urban dwellers.

To date, there are only 30 studies that have been done locally pertaining to health outcomes among the low socioeconomic status population in Malaysia. Evidence pertaining to mental health issues targeted at the B40 population are scarce and fragmented (refer to **Table 2.1** for the relevant studies**)**

An earlier study on knowledge, attitude and practice (KAP) of mental health help-seeking among rural and urban adults showed a lack of mental health knowledge in the general population with poor help-seeking among the urban indwellers (Yeap & Low, 2009). Another recent study among the students from the B40 groups recognized that self-stigma is a barrier to mental help-seeking attitudes (Ibrahim et al., 2019). Patients that belong to low socioeconomic status have relatively lower utilization of mental health services even when these services are free (Packness et al., 2019). These are barriers that could deter an individual from engaging in health promotion activities, as elucidated by Health Belief Model (Rosenstock, 1974).

Social and Welfare Department has provided four main types of financial aids or support for the B40 household (JKM, 2017) as an intervention to offer fast relief of their financial constraint. Ministry of Health has launched Protect Health Peka B40 in recent years to provide health aids

for the B40, while Housing Development Department has offered low-cost housing for the poor. In terms of interventions for Non-communicable diseases (NCD) at the community level, KOSPEN seems to be the only health related program that provides early detection of cardiovascular risk among the community.

Table 1.1 Overview of Agencies that Provide Community based Psychosocial Intervention for the Low socioeconomic population

Programmes	Types Of Intervention/Asistant	Targeted Population	Limitation
Government Based			
Ministry of Health			
Primary Care **Mental Health program commence in 2003**	Screening Curative	Persons who utilize the government healthcare	Unable to cater for effective mental health promotion attributed to inconsistency of implementation at different levels of stakeholders (refers to Investigator's internship report: IDI was conducted for 5 stakeholders on mental health programmes under Ministry of Health (MOH))
KOSPEN/KOSPEN PLUS	Screening of NCD - concept: behaviour modification via influence from the environment - Mental health screening was not included initially.	- Community Only selected location - Selected government body.	Evaluation study was done and showed less than half of the local community involved. Reason: no time(Lim et al., 2015)
Methadone Replacement Therapy	-Replacement therapy for Heroin Addiction - Psychosocial intervention	Low socioeconomic status client with addiction	- Focus on addiction (Baharom et al., 2012)
PEKA B40	Providing monetary assistant to the B40 for NCD Health screening	B40 Eligible age > 40 y.o	- Younger age group has higher mental health issues (Protecthealth, 2020)
Non -Ministry of Health			
Social and Welfare Department	Monetary and shelter homes for the disabled and the poor - Lacking in screening	Low Socio-economic/vulnerable population	Man power No collaboration with other agencies
Non-Governmental Agencies			
NGO **Malaysia Mental Health Association MIASA**	Advocacy to the policy Awareness program	Public	One off program Paid courses being offered. Cannot afford by the B40

Psychosocial interventions for mental health are offered by the government and non-governmental agencies Table 1.1. However, the effectiveness of these interventions is still unclear as the lack of evidence-based evaluation studies. A study from the social and Welfare Department has shown that financial incentive is an effective intervention for the poor. However, since this is a cross-sectional study involving a subset of the B40 (only those receiving the fund), generalisability is an issue (JKM, 2017). However, an evaluation study for KOSPEN done by Lim et al. has revealed that 54.0% of the communities never participated in the programmes due to their busy routine. Apart from that, inadequate funding, training and quantity of screening equipment were among the issues highlighted by the implementers(Lim et al., 2015). The investigator's recent internship in-depth interview (IDI) exploration of mental health policy implementation revealed common themes that emerged for community level: stigma and health promotion materials, whereas among implementors were related to fundings and human resources. Based on the SWOT analysis, the current mental health interventions are mainly clinically based and lack a community-based intervention to enhance mental health among B40. Programmes under the Ministry of Health (MOH) are well structured but lacking in community representation in formulating community-based intervention, especially for relapse prevention. In addition, as addressed in the National Strategic Plan for NCD (NSP-NCD), most of the programmes in the ministry lack evaluation indicators (NCD-MOH, 2016). Therefore, it is difficult to recommend a proper intervention for the B40 when there is limited baseline data to support the implementation.

Table 1.2 : SWOT Analysis of the Current Mental Health Intervention Programme

Strength	Weakness
- Adequate Social and Health policies that support the provision of Quality of healthcare in improving the Quality of life in the community	- Weak in implementation. There is a very minimal collaboration among the government agencies in implementing the programme. Poor coordination also leads to redundancy of the programmes(JKM, 2017). - Unmet needs, programmes are usually in a "Top Down" manner by the Ministry of Health without the feedback from the community - Inadequate evaluation indicators
Opportunities	**Threats**
- Lacking of psychosocial intervention to deal with the mentally strained for low income community.	- Political and Economic instability that could always halt the progression of the programme.

Therefore, this study will be focused on developing a tailor-made intervention that targets the psychosocial needs of the B40 population. This study will be framed according to the Medical Research Counsel (MRC) framework Figure 1.1 : a tool specially designed to develop, pilot, evaluate and implement a new intervention (Craig et al., 2008). In addition, the intervention will be conceptualized using the Health Belief Model **Figure 2.3** (Rosenstock, 1974). The type of intervention will be a health-promoting programme that is aimed at improving awareness and building psychological resilience through positive psychology. Resiliency helps the low socioeconomic population to overcome challenges and barriers to attain better mental wellbeing and quality of life. For the study to be feasible and accustomed to the local community, a mixed method followed by a feasibility study to test the effectiveness of the modules was employed.

1.5 Objectives

1.5.1 Research Question

How to improve the mental health issues and Quality of life among the B40 group at the community housing project?

1.5.2 General Objective

1. To identify the factors associated with mental health issues and Quality of life, explore barriers to help-seeking and develop a psychosocial intervention to improve mental health issues and Quality of life of B40 group at the community housing project, Subang Jaya local authority.

1.5.3 Specific Objective

Phase 1: Development: Situational Analysis

1. To identify the prevalence of symptoms of depression, symptoms of anxiety and Quality of life among the B40 residents of a community Housing project.
2. To identify the associated factors for the dependent variables.
3. To explore the influence of mental health barriers and facilitators on help-seeking in promoting mental health and good Quality of life.
4. To develop psychosocial intervention modules through a positive psychology approach to improve the mental health barriers and harness facilitators of mental help-seeking.

Phase 2: Feasibility study and Evaluation study

5. To evaluate the effectiveness of the psychosocial intervention through a) outcomes evaluation and b)process evaluation
    a) Outcomes evaluation through controlled-quasi-experimental study with pre-test and post-test to assess the change in primary outcomes (depression, anxiety and quality of life). Secondary outcomes basal mass index (BMI), poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), the strength of religiosity (SCSRF-5), health literacy(HL-6) and psychology resilience(RS-14).
    b) Process evaluation: evaluation form to assess the agreement, acceptance and feedback from the low-income respondents.

1.6 Hypotheses

1.6.1 Phase 1: Development: Situational Analysis

1a : Quantitative : Cross-sectional study

Specific Objective 2:

To identify depressive and anxiety symptoms in relation to sociodemographic risk factors, poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), strength of religiosity (SCSRF-5), health literacy(HL-6) and psychology resilience(RS-14) **.**

Null hypothesis (H_0):

There is no difference between the proportion of the **depressive symptoms** among B40 residents at the community housing project (based on scoring using the screening tools) in relation to sociodemographic risk factors, poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), strength of religiosity (SCSRF-5) health literacy(HL-6) and psychology resilience(RS-14) **.**

Alternative hypothesis:

There is a difference between the proportion of the **depressive symptoms** among B40 residents at the community housing project (based on scoring using the screening tools) in relation to sociodemographic risk factors, poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), strength of religiosity (SCSRF-5) health literacy(HL-6) and psychology resilience(RS-14)

Null hypothesis (H_0):

There is no difference between the proportion of the **anxiety symptoms** among B40 residents at the community housing project (based on scoring using the screening tools) in relation to sociodemographic risk factors, poverty attribution (PA-21), self-stigma (SSOSH), mental help-

seeking attitude (MHSAS), strength of religiosity (SCSRF-5) health literacy(HL-6) and psychology resilience(RS-14) .

Alternative hypothesis:

There is a difference between the proportion of the **anxiety symptoms** among B40 residents at the community housing project (based on scoring using the screening tools) in relation to sociodemographic risk factors, poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), strength of religiosity (SCSRF-5) health literacy(HL-6) and psychology resilience(RS-14).

Null hypothesis (H_0):

There is no difference between the proportion of the **Quality of life** among B40 residents at the community housing project (based on scoring using the screening tools) in relation to sociodemographic risk factors, poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), strength of religiosity (SCSRF-5) health literacy(HL-6) and psychology resilience(RS-14) .

Alternative hypothesis:

There is a difference between the proportion of the **Quality of life** among B40 residents at the community housing project (based on scoring using the screening tools) in relation to sociodemographic risk factors, poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), strength of religiosity (SCSRF-5) health literacy(HL-6) and psychology resilience(RS-14) .

Qualitative Study (In-depth Interview)

Specific Objectives 3

To explore the influence of mental health barriers and facilitators on help-seeking in promoting mental health and good Quality of life.

a) To explore the mental health literacy among B40 respondents regarding their perceptions on mental health issues, risk factors, signs and symptoms and treatment.
b) To explore the B40 perceptions on how psychological barriers such as causes of poverty attribution, self-stigma, the strength of religiosity, psychology resilience influence the uptake of health promotion activities and help-seeking.

1.6.2 Phase 2: Feasibility Study and Evaluation

Controlled-Quasi Experimental study

Specific Objectives 5

To evaluate the effectiveness of the psychosocial intervention through a) outcomes evaluation and b)process evaluation

a) Outcomes evaluation is done through controlled-quasi-experimental study with pre-test and post-test to assess the change in primary outcomes (depression anxiety and quality of life) and secondary outcomes (BMI, poverty attribution (PA-21), self-stigma (SSOSH), mental help-seeking attitude (MHSAS), strength of religiosity (SCSRF-5) health literacy(HL-6) and psychology resilience(RS-14).
b) Process evaluation: evaluation form to assess the agreement, acceptance and feedback from the low-income respondents.

Null hypothesis (H_0):

There is no significant difference in the mean differences for the **primary outcomes variables and secondary outcomes variables** among B40 respondents at the community housing project in the intervention compared to the control.

Alternative hypothesis: There is significant difference between the mean differences of the **primary outcomes variables and secondary outcomes variables** among B40 respondents at the community housing project in the intervention in comparison to the control arm.

Null hypothesis (H_0):

There is no difference between the mean scores of the **primary outcomes variables and secondary outcomes variables** among B40 residents at the community housing project within the intervention arm upon repeated measure at T1 (Pre-test) and T2 (Post-Test) compared to the control arm.

Alternative hypothesis:

There is a significant difference between the mean different of the **primary outcomes variables and secondary outcomes variables** 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) compared to the control arm.

1.7 The Research Development

This study was conducted based on the MRC framework (Craig et al., 2008). This framework is intended for developing interventions which are usually described as interventions that contain several interacting components. The preliminary phase of the study involved the cross-sectional to identify the factors associated with mental health issues and Quality of life. The outcomes from the cross-sectional study were explored further with a qualitative in-depth interview. With the findings of the mixed method, ReSHape module was developed and tested in the final feasibility study. In this study, the investigator will look into a few outcomes as depressive symptoms, anxiety symptoms and Quality of life as a result of the intended intervention for behavioural change.

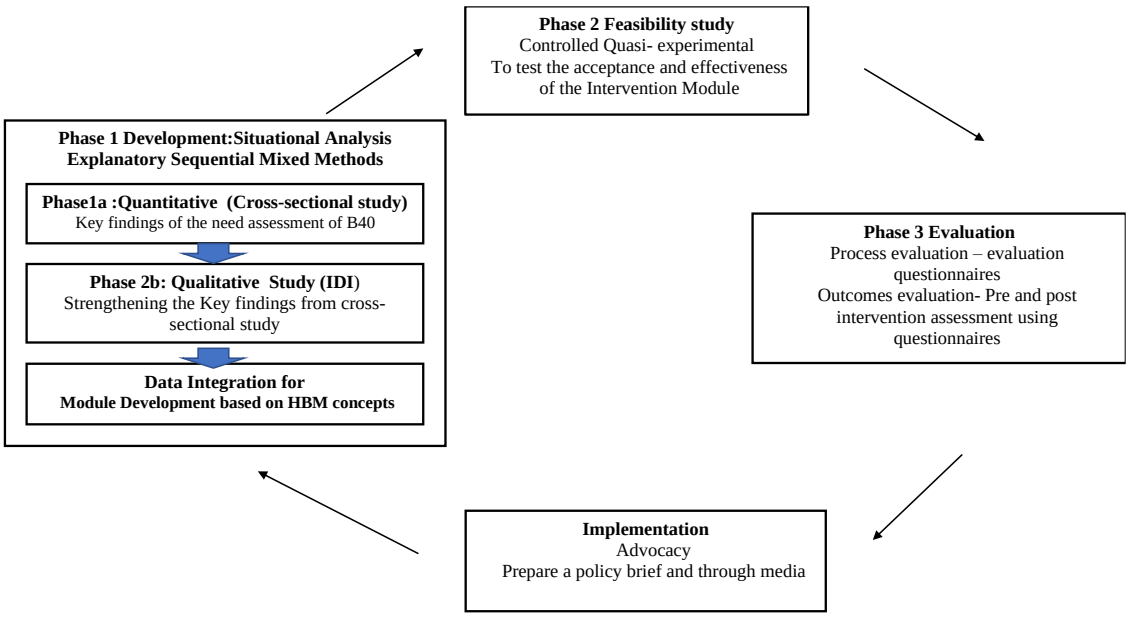

Figure 1.1 Adapted Medical Research Council (MRC) Framework for Present Study(Craig et al., 2008)

2.0 Review of Effective Intervention study among the low socio-economic

The literature findings **Figure 2.1** were summarized based on the framework-specific for low income and mental health issues proposed by Patel et al. (2018). The proposed ecological framework for intervention policy recommendation is comprised of three levels, namely the national level (the neo-material hypothesis), neighbourhood level (the social capital and the social comparison hypotheses) and individual level (psychological stress and social defeat hypotheses).

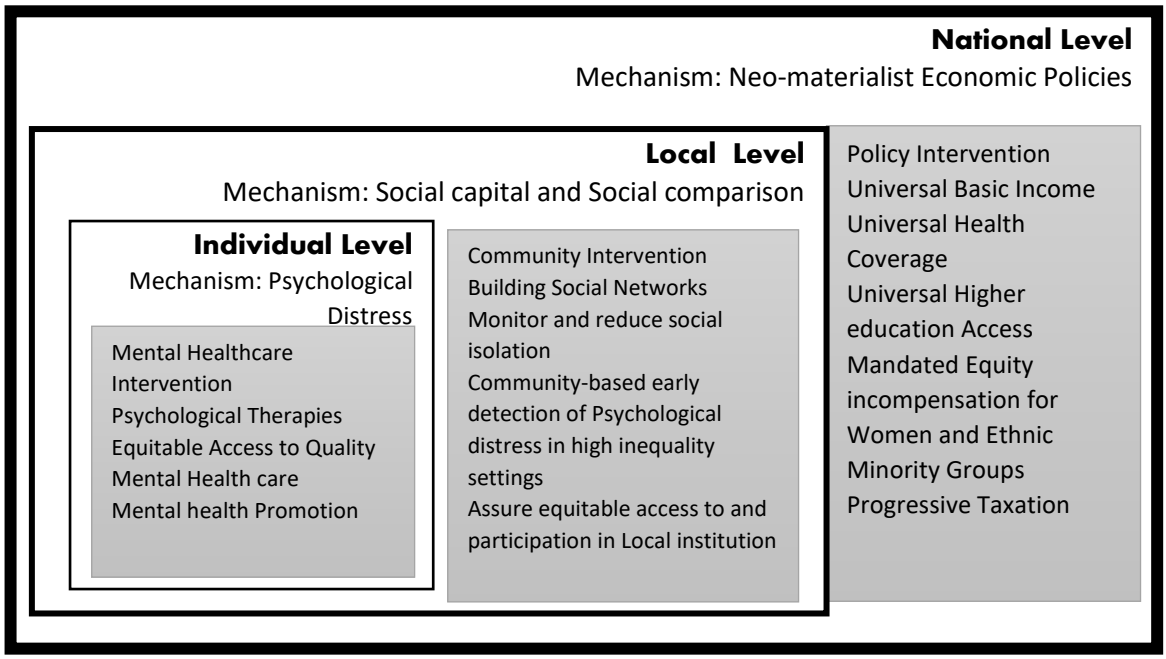

Figure 2.1: Social-Ecological Model by Patel et al. (2018) to address Mechanisms of income inequality on mental health issues and recommendations for interventions

2.0.1 Individual-level (psychological stress)

According to Patel et al., income inequality impacts general health mainly mediated through psychological stress. This is regarded as the distal mechanism mediating the effects of income inequality on depression. Apart from structural intervention, the proximal intervention includes parenting and life skill intervention, promotion of early detection, and self-help for mood and anxiety disorders, which should be part of the strategies to mitigate the adverse psychological effect personally (Patel et al., 2018) **Figure 2.1.**

Empirical evidence revealed psychological treatment was among the most promising intervention, cost-effective and feasible to be delivered by non-mental healthcare providers in low resource settings (Patel et al., 2017; Patel et al., 2016; Singla et al., 2017). Past evidence has shown promising treatment and relapse prevention for depression and anxiety through the administration of Cognitive Behavioral Therapy (CBT) for the non-clinical and clinical population. CBT is effective for depression, apart from an antidepressant, by promoting well-being and prevention of relapses (Hofmann et al., 2012). Even though findings from a systematic review

by Cristea et al. (2015) have nullified the supremacy of CBT compared to other psychotherapy, it is undeniable for its primacy in terms of correction of dysfunctional thoughts of mental health issues subjects. As for anxiety, CBT was superior as compared to control or pill placebo conditions and equally efficacious as relaxation therapy, supportive therapy, or psychopharmacology, but less efficacious in comparison to subjects with more severe anxiety symptoms (Hofmann et al., 2012).

CBT is structured therapy designed to help individuals to correct false self-beliefs that can lead to negative moods and behaviours. However, the highly structured and costly therapy requiring trained personnel is not feasible for scarce countries. Verhey et al. (2020) had conducted the latest systematic review on cognitive behavior therapy delivered by non-specialists at LMIC; results showed these interventions are acceptable, appropriate, and feasible for LMIC settings. It was observed, most of the studies have selected just one of the components of the CBT. For example, Bolton et al. have proceeded to test a flexible version of CBT, Transdiagnostic modules specifically designed for flexible treatments of varying and comorbid disorders among trauma survivors in a low-resource setting. The results showed overall improvement for the intervention as compared to the control, whereby 77% (−0.49 (95% CI: −0.59, −0.40)) reduction in mean baseline depression score among treatment group compared to a 40% reduction among controls, while 76% versus 41% for anxiety (−0.48 (95% CI: −0.61, −0.34)) (Bolton et al., 2014). Khan et al. had conducted a feasibility study for vulnerable women from conflict-affected areas in Pakistan, using trans diagnostic tools CBT-based Group Problem Management Plus (PM+). Outcome evaluation showed improvement of the depression and anxiety symptoms (Khan et al., 2019).

A large cluster-randomized clinical trial done in Zimbabwe reported an overall improvement in mental health symptoms among respondents at the 6th month to follow up after exposure to the lay health workers administered, primary care-based problem-solving therapy with education and support compared with the control group (Chibanda et al., 2016). CBT is one of

the potential interventions for the B40 population as their cognition is quite maladaptive and malfunctioning due to the persistent exposure to the poor living environment and financial strain.

As the pandemic progresses, physical distancing aimed at reducing contagion continues to limit in-person contact, worldwide mental health providers have been forced to adopt innovative approaches via technologies to provide continuation of care. Based on the post-disaster mental health management, technology-based tools, aimed at preventative and supportive to reduce acute distress through positive coping, are suitable for levels 1 and level 2 of mental health responses during the COVID-19 pandemic. Level one intervention includes an online platform for self-management of symptoms that is available to the public, but few have been tested empirically. Clinical video teleconferencing (CVT), which allows psychotherapists and patients to interact in real-time (i.e., "synchronously"), is the most widely studied tele-psychotherapy modality has been proven its efficacy by a large body of research. However, when these interventions were tested against face-to-face sessions in experimental studies, findings were not significant (Howells et al., 2016). Nevertheless, studies indicate CVT is feasible for psychotherapy treatment in terms of adherence (Morland et al., 2011), fidelity (Acierno et al., 2016), and competency in establishing rapport (Rosen et al., 2020). Providing care via tele-psychotherapy was in favour of privacy protection and reducing stigma for help-seeking (Rosen et al., 2020). The recent literature has shown that overall literature on internet-based cognitive behavioural therapy (iCBT) favours enhancing access to care, cost-effectiveness, and time efficiency(Webb et al., 2017). A more detailed review of the literature showed that guided iCBT programs have better outcomes than the unguided fully self-help program, later associated with higher dropout rates. Support and guidance can be provided in a variety of different forms, which entails automated emails sent to participants, weekly phone calls lasting for 3 to 5 minutes from therapists or research assistants providing encouragement, support, and clarification of iCBT lesson content and homework through a synchronized text-based

communication between clients and providers (Ruwaard et al., 2009; Titov et al., 2010; Webb et al., 2017).

The impact of COVID-19 is a long haul; major adversity and pandemic trauma are expected to affect the lives of the underprivileged. The existing literature has shown signs of maladaptation towards the negative effect of the pandemic in the community; thus, a resilient mindset is crucial to strengthen a positive attitude towards adversity and moderate negative determinants on mental health. Psychological resilience denotes the capability or ability of a person to maintain relatively stable psychological functioning despite psychological and physical burdens (Bonanno et al., 2010; Masten, 2001). Three main core psychological domains have been associated with resilience: secure attachment, positive emotions, and life purpose.

A meta-analysis has established that positive psychology interventions such as writing gratitude letters, practising optimistic thinking, replaying positive experiences, and socializing can mitigate the levels of depression (Sin & Lyubomirsky, 2009). Mathias et al. have piloted a fifteen weeks peer-led brief mental health and resilience intervention for young women in an urban slum in India, and the findings from the quasi-experimental study showed it has significantly improved depression, anxiety, and resiliency among the participants (Mathias et al., 2018).

Mindfulness meditation is one of the interventions that could promote positive emotion, which is essential for building resilience and greater well-being (Howells et al., 2016; Rutten et al., 2013). According to Kabat-Zinn (2003), mindfulness is defined as experiencing daily life by turning our attention and awareness to the present moment without judgment (Kabat-Zinn, 2003). Mindfulness is broadly divided into 3 mindfulness-based stress reduction, mindfulness-based cognitive behavioural therapy, and compassion mindfulness. Systematic review and meta-analysis did by Scott et al. (2019), mindfulness is beneficial to cardiovascular cases that mitigate stress that could reduce cardiovascular outcomes (Loucks et al., 2015; Scott-Sheldon et al., 2019). Howarth et al. (2019), in his systematic review, reported brief mindfulness of 30 min

or less on any one occasion, totalling no more than 100 min per week and lasting up to 4 weeks, is effective for anxiety and depression (Howarth et al., 2019).

Another researcher has reviewed studies targeted on normotensive to hypertensive subjects in community settings, and 3 out of 4 randomized controlled studies show mindfulness-based stress reduction is capable of reducing blood pressure levels (Goldstein et al., 2012). Breathing awareness meditation (BAM), is one of the primary exercises in MBSR that showed BP reduction among different populations. In one study that was carried out on a low socio-economic population, nine graders of African American ninth-graders (with a resting SBP >50th percentile and <95th percentile) were exposed to BAM, life skills training, or health education. Among the three behavioural intervention approaches, only BAM produced a significant decrease in 24-hour SBP (Wright et al., 2011). Botvin LifeSkills Training is another similar study which was conducted among high-risk African American ninth-graders at increased risk for essential hypertension compared the treatment effects; intervention BAM group demonstrate significant BP and heart rate reduction as compared to previous findings (Gregoski et al., 2011).

In Malaysia, a few small studies have been conducted among university students, cancer patients, and teachers. One of the prominent researchers has done a few studies on university students and found that the mindfulness 5-week mindfulness-based stress management (MBSM/Mindful-Gym) program was effective in improving stress, mental distress, and self-efficacy. Students from the intervention arm showed higher self-efficacy as compared to the control on follow-up (Phang, Mukhtar, Ibrahim, Keng, et al., 2015; Phang, Mukhtar, Ibrahim, Shian-Ling, et al., 2015). Other studies that were conducted in other populations were yet to be published, and the sample size was appeared to be small which posit difficult interpretation.

From the review paper by Singla et al., online psychology intervention research is emerging for LMIC whereby 60% (15 out of the 25 articles) of the articles were research belongs to online intervention. However, none of the study uses the mindfulness approach (Singla et al., 2017). In developed countries, mindfulness-based training is predominantly delivered face-to-face, with

a small number of online studies showing effectiveness for symptomatic relief of mental health issues (Cavanagh et al., 2013; Glück & Maercker, 2011; Howells et al., 2016; Huberty et al., 2019). Therefore, the online mode of delivery of the intervention to B40 for the current study is feasible given the current pandemic climate and high internet coverage in the Klang Valley.

Intervention for health literacy and mental health literacy leads to less stigmatization and enhance of help-seeking attitude. Based on a review paper, the most used methods of delivering health-related awareness and knowledge are traditional that include lectures, passive lessons, one-way delivery of information, distribution of pamphlets and leaflets, and health-education sessions using visual aids (Meherali et al., 2020). Even though sufficient evidence has shown traditional ways of delivering HL strategies through series of lectures and discussions have improved health-related knowledge, and outcomes (Brainard et al., 2016; Brijnath et al., 2016), the significant low literacy levels in LMIC challenged the efficacy of these interventions thus may lead to poorer health perceptions (Budhathoki et al., 2017; Jacobs et al., 2014)

Technology-based HL interventions are recent strategies to deliver health-related knowledge to target populations through technology in the LMIC (such as mobile devices, internet websites, digital devices) (Meherali et al., 2020). HL interventions that involve the internet or eHealth technologies have undoubtedly improved the community's access to health care information in recent years (Hur et al., 2015; Mackert et al., 2016). Overall, compared to control interventions, the interventions using technology reported significant positive outcomes in a variety of settings, for different diseases, and with diverse samples(Jacobs et al., 2014). Given the high rate of Internet penetration in the general population, more than 80% in the developed world, the Internet is an ideal medium through which to reach significant numbers of people at a relatively low cost (Brijnath et al., 2016).

Interestingly, one of the studies has shown higher education levels showed lower trust for the government, thus less likely to use health literacy applications (Mackert et al., 2016). A systematic review conducted by Singla et al. has observed gender gaps among the interventional

study subjects exclusively focused on women and lacking men involved in the treatment. This is a concern as men are prone to violence and substance abuse; they do pose a risk for women's mental health issues (Singla et al., 2017).

A limited study was done in Malaysia to examine the influence of mental health-seeking and mental health issuers. A cross-sectional study was conducted at an established Islamic spiritual healing center with 357 respondents. Younger age (OR .97, 95%CI .94–.99, p = .002), higher education level (OR 1.99, 95%CI 1.15–3.45, p = .014), and a more threatening view of the illness (OR 1.19, 95%CI 1.13–1.26, p ≤ .001) were found to confer risk of seeking help at this centre among attendees with a psychiatric diagnosis(Abdullah et al., 2016)

Poverty can also adversely affect children's mental health through family and community-level factors. Poverty exposes a family to a range of stressors such as food insecurity and housing problems. These stressors predisposed the parents to mental disorders and substance abuse, which can diminish their capacity to engage in positive parenting practices (e.g. warmth and responsiveness, nurturance, supervision) and increase the potential for child abuse and neglect. Low-income communities are often characterized by poor housing, limited resources, inadequate schools, and high crime and violence, all of which are associated with adverse mental health outcomes (Hodgkinson et al., 2017). Parental programs which aimed at providing positive social, emotional interactions and cognitive-behavioural skills allow parents to think about behaviour patterns and focus on solutions that could buffer the negative socioeconomic, mental health gradient. Barlow et al. (2014) has synthesized 48 studies that involved 4937 participants and covered three types of programs: behavioural, cognitive-behavioural, and multimodal. Overall, the group-based parenting programs led to statistically significant short-term improvements in depression, anxiety, stress, anger, and other mental health-related modalities. However, follow-up study at six months, only stress and confidence continued to be statistically significant (Barlow et al., 2014).

It is impossible to eliminate the hazardous effect of poverty experienced by the B40 population; however, an intervention that aimed to build their social and life skills could help them to attain a better quality of life. Good mental health will improve the motivation of B40's who are at risk of cardiovascular disease to seek help and better self-care in order to improve their health condition. Apart from that, a stable state of mind could help the B40 to buffer the emotional strain during an economic downturn. Therefore, it is a dire need to tackle the cycle of poverty.

2.0.2 Community-level

Based on the socio-ecological framework by Patel et al. (2018), the second level is a community-level intervention that emphasizes the role of social capital. Social capital is critical for social integration (a dynamic process by which members of a social group participate in dialogue or collaborate to achieve a shared social goal). Income inequality, therefore, undermines social capital and social integration, promoting social isolation, alienation and loneliness. Holt-Lunstad, among others, has synthesized 148 studies worldwide to assess the association between social relationships and health outcomes. The association was strongest for complex measures of social integration (OR = 1.91; 95% CI 1.63 to 2.23) in relation to mortality outcomes and concluded that social capital is crucial to promote social networking and connectedness (Holt-Lunstad et al., 2010). Whittington and Huppert (1996) had conducted a cross-sectional study and compared the changes in scores from a 7 years old longitudinal study; findings showed the 6% reduction in the prevalence of mental health issues is correlated with a one-point decrease in the mean scores of General Health Questionnaires (Whittington & Huppert, 1996). The study had concluded, the greater reduction was attributed to the community-based intervention. Therefore, apart from individual intervention, community-based intervention exert a collective effect on the overall reduction of the mental illness burden in the population (Friedli, 2009). In the recent systematic review by Anderson et al., peer support, community participation and engagement, skills training and animal has shown to have positive effect in improving the social networking among people who has mental illness in the community (Anderson et al., 2015). This

potentially cost-effective intervention focused in the community may increase social interactions sufficiently to constitute a protective social network (Wahlbeck et al., 2017).

Expanding mental health services in primary care clinics improved the access of services by the vulnerable population and closed the gaps in healthcare. Apart from that, it also improves the uptake of the screening of mental illness so that early intervention can be carried out. Interventions that promote the responsiveness of health services improve the interpersonal quality of care, thus reducing the barrier of non-compliance to follow-up for chronic illnesses (Bramesfeld et al., 2007). These also include intervention to improve the cultural competency to serve the vulnerable population such as people with chronic illness, gay, bisexual, and transgender (LGBT) populations, and racial/ethnic minority populations. Some interventions are mainly aimed at changing provider attitudes and beliefs through training or curriculums. Other studies aimed at reducing professional stigma toward people with serious or chronic mental illness. However, these studies are not reliable due to the moderate to high risk of bias and heterogeneity of the population. The lacking of measurement consensus has prohibited the meaningful interpretation of the efficacy of the intervention (Butler et al., 2016).

In our country, primary care has been covered quite extensively at the level of urban and rural settings. It is accessible by the B40 population. The mental health service at the primary care clinic encompasses screening and treatment cater mild to moderate neurotic cases. Despite the proximity to the community, some cases are still beyond the reach of mental health screening. This may reflect that there are other barriers to mental healthcare that warrant further exploration and attention.

2.0.3 Policy level

National or regional levels denote the neo-material hypothesis proposes that greater income inequality coexists with a wide range of material deprivations that are relevant to health. These entail inadequate investment for housing, education, and public transport as well as pollution control, healthy food availability, and accessibility of health care. Thus, greater inequality leads

to worse mental health outcomes. A worldwide survey was done in 2007 to assess the adequacy of mental health services in 17 developed and developing countries. Findings revealed a disturbingly high level of unmet need for mental health services worldwide but more in resource-low country countries (Wang et al., 2007). Policy pertaining to improving universal health care will be able to address the disparities in mental services. Primary care, which handles almost 70% of the common mental health diseases (Kessler et al., 2005), should be the gatekeeper in screening and offering preliminary intervention which is equitable for the low-income population. It also reduces the distance to get help which in turn overcomes the transportation barrier (Syed et al., 2013).

In some countries, labour policies are in place to enhance access to the labour market, reduce poverty, and have positive mental health effects. Retaining and reintegrating the workers in the job market, especially during the economic crisis, is essential to mitigate the suicide rate (Stuckler et al., 2009).

Evidence for social and welfare policies in tackling poverty issues has shown equivocal findings in a systematic review, even though some benefits were found in some conditional cash transfer and asset promotion programs (Lund et al., 2011). In fact, cash transfer programs are an important component of the social safety net in developing countries.

A study of the conditional cash transfer program in Mexico showed a significant improvement in children's behavioural issues and growth (Fernald et al., 2009). On the other hand, two randomized controlled studies involved an unconditional cash transfer program in Ecuador and Nicaragua showed moderate effectiveness in modifying parental behaviour via providing a better quality of food for the children and better utilization of health care (Macours et al., 2008; Paxson & Schady, 2007).

Jabatan Kebajikan dan Masyarakat (Department of Social Welfare Malaysia) has an unconditional cash transfer program that assists the disadvantaged population is based on the

life course concept. A study based on mixed methods has been done to assess the effectiveness of the program. The findings showed the monetary assistant (based on four programs: children, people with disabilities, older person, and general assistant) improve the state-level economic performance. While the findings from the qualitative studies showed, the beneficiaries reported improvement in quality of life. However, some interviewees reported the incentive is unable to buffer for the high cost of living (JKM, 2017).

Good housing and urban planning policies create the basis for social capital, which in turn is beneficial for population mental health and social cohesion. Even though experimental studies in these areas are scarce (Moore et al., 2018), the available observational data has supported that and well-built environment garnered good mental wellbeing. A large scale survey involving the urban residents (Quality of Life Survey, 2012) show that socioeconomic inequality in mental wellbeing was considerably narrower among respondents reporting good access to green/recreational areas, compared with those with poorer access (Mitchell et al., 2015). Other environment modalities like blue space may also benefit mental wellbeing; however, findings from the systematic review were inconsistent (Britton et al., 2018).

Apart from economic growth, the 11th Malaysia plan has emphasized the well-being of the nation. Part of these strategies aimed at improving the quality of life via poverty reduction and the means of improving healthcare delivery to the low social income group. Strategy A4 of the 11th Malaysia Plan 2016-2020 focused on measures that will be undertaken to reduce communicable diseases (CD) and non-communicable diseases (NCD), which includes the provision of preventive healthcare services and the promotion of a healthy lifestyle. These strategies also focused on improving the equitability of the healthcare delivery system via community participation to tackle the NCD issues in this country. Few policies underlie these strategies (MOH, 2016).

1. National Plan of Action for Nutrition of Malaysia (NPANM) III 2016-20252
2. National Strategic Plan for Tobacco Control 2015-2020

3. Policy Options to Combat Obesity in Malaysia 2016-2025
4. Salt Reduction Strategy to Prevent and Control NCD For Malaysia 2015-2020
5. National Strategic Plan for Active Living 2016-2025
6. Malaysia Alcohol Control Action Plan 2013-2020
7. National Strategic Plan for Cancer Control Program 2016-2020
8. Strengthening Chronic Disease Management At Primary Care Level through the Enhanced Primary Health Care (EnPHC) initiative.
9. National Community Health Empowerment (KOSPEN) initiative
10. National Mental Health Policy

Despite the comprehensive NCD-related policy, the implementation is challenged by inadequate interdepartmental collaboration, rising operating costs, inadequate evaluation and monitoring (Abdul, 2019). KOSPEN is a multi-components community outreach intervention program that was initiated to tackle the undiagnosed cases involving participants from the community settings. KOSPEN has adopted the concept of the influence of the environment to facilitate behaviour modification toward healthier lifestyles. However, an evaluation study done by Lim and others has revealed 54.0% among the communities never been participated in the programs, and the commonest reasons were no time. Apart from that, inadequate funding, training, and quantity of screening equipment were issues highlighted by the implementers (Lim et al., 2015). NCD Strategies at the national level were also lacking in the emphasis on psychosocial intervention in terms of enhancing resilience in the community. This is a survival skill that could assist the community in coping with adversity in low resources conditions.

The National Mental Health Service framework was established in 2001. This framework has a legal binding to Mental Health Act 2001 and Mental Health Regulations 2010, focuses mainly on the psychiatric treatment services starting from the tertiary centre, secondary centre down to primary care and the community mental health centre in life course manner. National Mental health policy was established in 2012 as a means of an extension of the mental health services

to cover strategies for prevention and promotion. The mental health policy is in line with the vision of the ministry of health to build a nation which composed of healthy individuals, families, and communities through a health system that is efficient, equitable, and accessible. For that, mental health care and mental health programs deserved due attention by proper health financing. Under the subheading of "Protection of vulnerable individuals", it was explicitly under mental health strategies, programs should be done for Women, Children, the elderly, prisoners, detained individuals, marginalized groups, and the very poor. However, it is not explicit neither types of evidence-based strategies nor interventions for the vulnerable population (MOH, 2012). Mental health prevention and promotion strategies were implemented through the mental health unit at the Ministry of Health. Even though the programs were comprehensive which covered individuals in life-course manners, it was limited by inadequate funding and outcomes evaluation.

2.0.4 Outcome of the intervention review

A way forward, it appears that individual level of intervention to mitigate mental health issues with re-enforcing of positive emotional and mental health confer robust evidence for the low-income population. Given the current pandemic climate, internet-based Interventions like CBT and brief mindfulness intervention offer promising psychosocial interventions that strengthen the resiliency at the personal levels to improve the mental health well-being among the B40 group in this country. Even though evidence showed parenting programmes and policy levels are also effective, it was not added in as it more sophisticated evaluation documentation within each household and more interpersonal social contact between the respondents, which is not feasible during the pandemic. To date, there is yet a suitable online manualized psychosocial intervention being tested at the low-income community settings in this country.

2.2 Conceptualized Psychosocial Intervention (Health Belief Model)

The current study was conducted based on Medical Research Council (MRC) framework, which was succinctly described in Chapter 1 under **subheading 1.7**. The psychosocial

intervention was developed based on the outcome findings from the cross-sectional study and the qualitative study. Psychosocial interventions for mental health and substance use disorders are interpersonal strategies that are targeted at the level of biological, behavioural, cognitive, emotional, interpersonal, social, or environmental factors in order to improve health functioning and well-being (Butler & Gonzalez, 2015). According to Zoonen et al., timely psychosocial intervention at the pre-clinical stage may avert the development of mental illness (van Zoonen et al., 2014) **Figure 2.2** .

Our psychosocial intervention will be aimed at improving mental health symptoms in order to achieve quality of life. Multiple components of the psychological intervention will be implemented to promote positive mental health by improving the depression and anxiety symptoms of B40 individuals who will be identified through mental health screening. The main components, which entail improving mental health literacy, self-help CBT-based intervention and brief mindful breathing, and providing help-seeking information, will be explained under each domain in the health belief model for promoting behavioural change towards improving health in the methodology**.**

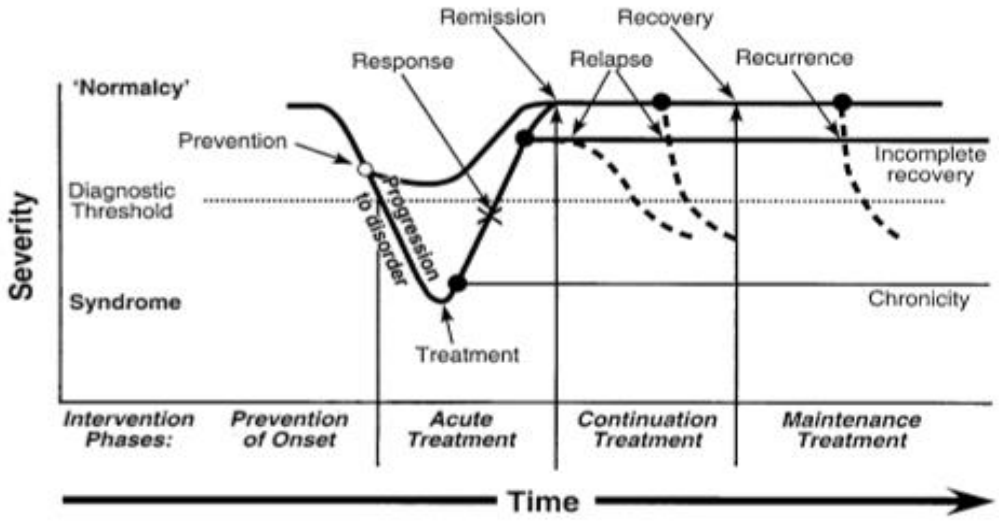

Figure 2.2: Intervention at the Pre-clinical stage may avert the mental illness progression. Adaptation from (Zoonan et al. 2014)

Health Belief Model (HBM) has been widely adopted to develop effective interventions that drive changes in health-related behaviours by targeting various aspects of the key constructs in the model (Glanz et al., 2008). The Health Belief Model was developed in the early 1950s by a group of socio-psychologists (Rosenstock & Hochbaum) from the US public health department to understand the reasons for failure of the public to accept the preventive and screening test proposed by the department.

The conceptual model was adapted from Abraham and Sheeran (2005) to explore the perceptions on health preventive behaviours among the B40 towards their current mental health status. HBM permit the understanding of the health belief system that could challenge an asymptomatic individual to take action. This model also guided the situational analysis (mixed methods approach) to identify the baseline risk factors pertaining to individual socio-demographic profiling, psychological characteristics, and recognizing the barriers or fascilitators to help-seeking.

The following section will further conceptualize the psychosocial intervention according to the targeted construct in the Health Belief Model (Figure 2.3).

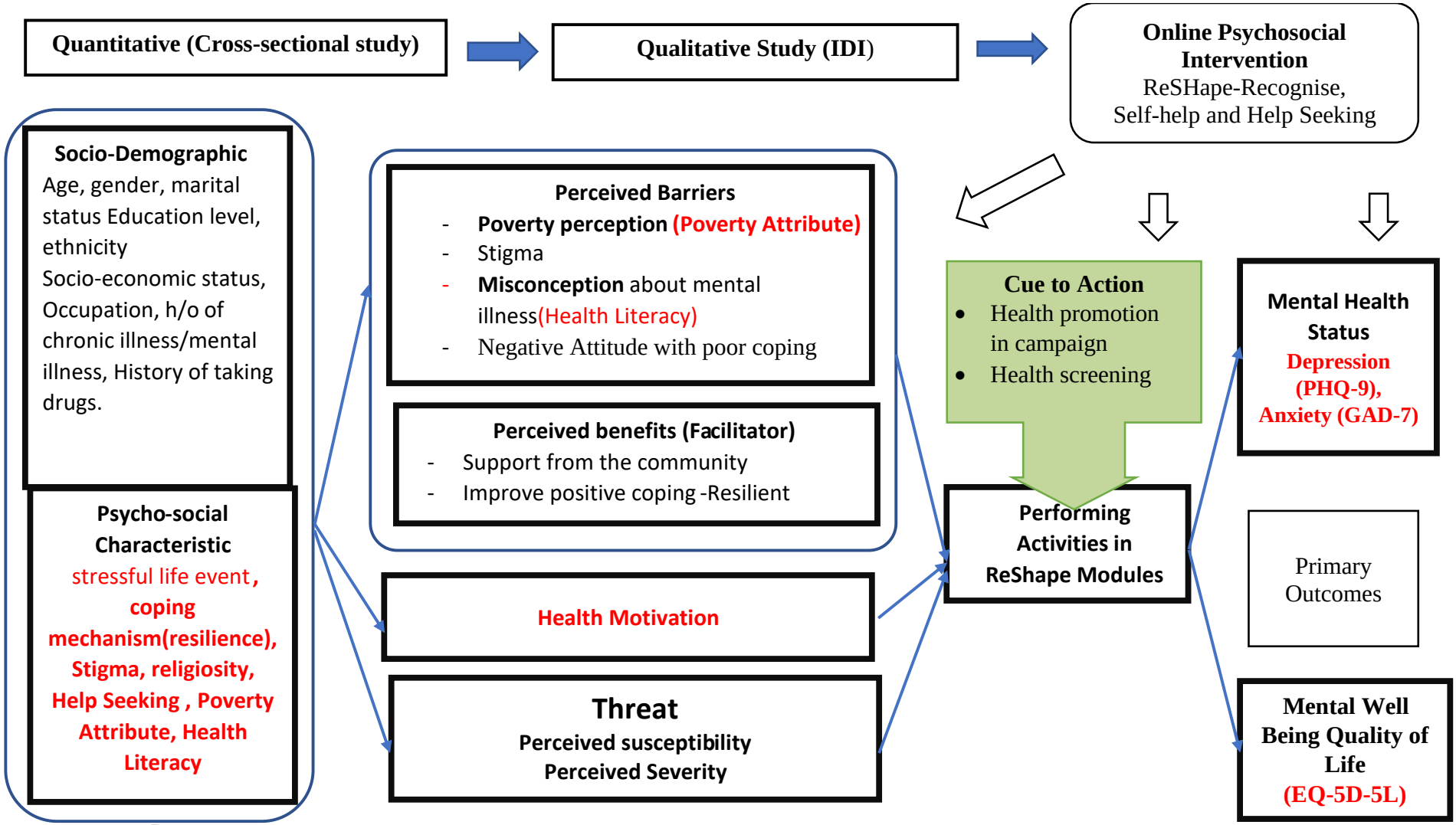

Figure 2.3: Adapted Health Belief Model and Its Relatioship To Research Structure (Abraham & Sheeran, 2015; Rosenstock, 1974)

3.0 Methodology

3.1 Psychosocial Intervention Module Development

Psychosocial Intervention Module development is to answer the **Objective 4** of this study, is a follow up of the mixed methods study before under the phase 1 development phase of the MRC framework. The module development intends to consolidate the evidence from the literature review and the findings from the situational analysis (mixed methods study) to form a standardized module guided psychosocial intervention through psychoeducation for the targeted low-income population.

As this is a health promotion psychosocial intervention based on health belief model (HBM), two main themes, barriers and facilitators derived from data integration will be mapped to form the domains for the module development.

It will be followed by setting of the objectives for each domain by using SMART approach .

3.1.1 Mapping the Components for the development of "ReSHape" online Modules

Mixed methods study in this research has proven, mental health issues are high and affecting the quality of life among the B40 community at the Petaling district. This warrant further psychosocial intervention.

The intervention will be developed to improve the mental health status and quality of life among the B40 community by improving their skill in recognising common mental health issues, self-help and help-seeking. This will be based on factors that emerged from the final data triangulation between quantitative and qualitative study, which comprised mental health literacy, resilience (self-reliance, religiosity and social support) and help-seeking. Poverty attribution is a factor to explain the perceptions of the poor with good coping factors like self-reliance helps them to thrive amid adversity.

The three components identified were mental health literacy and help-seeking, while the facilitator was self-reliant. The psychosocial intervention modules were formulated based on

the Health Belief Model (HBM) concept to drive a person to adopt healthy behaviours, and objectives of the main components were developed based on the SMART approach.

1. **Specific**:- Objectives specific for each module.
2. **Measurable:-** The comprehension of each module will be measured by pre and post-assessment and evaluation by using specific research tools (Primary and Secondary outcomes).
3. **Achievable:** A video tutorial (10 to 15 minutes) was sent to the participants the first week, followed by an assessment on the second week.
4. **Realistic:-** ReSHape Modules will be able to implemented and tested in the community
5. **Timely:**- these modules are expected to successfully delivered at the community settings

In the HBM model, improving mental health literacy helps to recognise the severity of the disease condition. Next, depression and anxiety symptoms can be alleviated by applying **self-help** approach through Cognitive Behavioral therapy **(CBT)** and mindful breathing exercise. Finally, with the mental health information and psychoeducation, the respondents will be prompt to **seek help**. **Specific:-** The specific objectives of each module guided the design of the activities.

3.1.1.1 Components that promote the Behavioral Change

a) Recognise the Need for Change

The first **Module 1 Recognise: Knowing Your Mental Health** is based on the limited mental health literacy, the misconception of mental health and lack of awareness of the available treatment among the B40 respondents. The aims are to provide essential information on the definition of mental health**,** contributory factors, symptoms of depression and anxiety, treatment options, the myth of mental health and the importance of mental health screening. Improving mental health literacy improves the public's stigmatising perceptions on mental health issues and encourages an individual to seek help. Mental health screening using PHQ-9 and GAD-7 helps an individual aware of the severity and susceptibility of their mental health issues. As described in the HBM, when individuals feel the threat of the disease, they will seek help.

b)Self Help

Depression and anxiety were elevated among B40, and the qualitative study showed most of the participants prefer self-help as one of their initial options to resolve the underlying mental health issues. This **Module 2 Self-help** comprises three submodules based on CBT concepts, and one module focuses on mindfulness breathing exercises. These are evidence-based psychosocial interventions to reduce symptoms of depression and anxiety while improving their positive coping

Based on the Beck (1979) Cognitive model, an individual emotion and behaviour are influenced by the perceptions environment. By applying the cognitive triad formulation suggested by , which comprises core beliefs, dysfunctional assumptions, and negative automatic thoughts, it assists in reconstructing the maladaptive cognition in mental health issues. Therefore The first three sub-module in ReSHape module 2 use Cognitive behavioural therapy (CBT) approaches to reduce depression and anxiety symptoms through three key strategies **a) Problem-oriented - goal setting, b) behaviour activation and c) Recognising and overcoming negative thoughts.** The ultimate aims of this module are to provide the B40 skills to understand their current ways

of thinking, behaving and equip them with the tools to change their maladaptive cognitive and behavioural pattern(Fenn & Byrne, 2013). Reducing negative thoughts increases the motivation in individual who has high symptoms of depression or anxiety(Beck, 1979).

The first **sub-module 2A is problem-oriented -goal setting**. Respondents were guided on recognising their strengths, identifying problems, and setting goals to reduce their issues in life that lead to mental strain. With that, the respondents were required to suggest three issues in life i.e, and not enough rest causes stress leads to unhealthy eating, leads to overweight; strategies to resolve their issues for the next three months is sleep early.

The subsequent **sub-module module 2B behaviour activation** provide respondents with skills to activate what they have planned. They are required to set up a digital calendar reminder and required to keep a record of what they have done and what not in a self-evaluation weekly form (Appendix G). This prompt an individual to take action on the subsequent week according to the planned activities.

At time, respondents may face the challenge of negative thoughts due to their daily stressful life, and the **sub-module 2C negative thoughts** help them identify the negative thoughts and overcome them guided by another self-evaluation form (Appendix H).

The low-income group is a stressful community with their hectic routine, the final module, Mindfulness breathing exercise, provides stress reduction techniques that bring them to focus. According to evidence, a mindful breathing session that lasts for 15 to 20 minutes, three to four times a week, reduce depression and anxiety symptoms.

Reducing negative thoughts stemming from underlying mental issues improves the respondents' motivation to adopt health promotion for their mental well-being. Harnessing the strength of the respondents mediate the respondent's motivation to overcome negative thought that equates as a barrier that is emphasized in the HBM.

c)Help-seeking

The quantitative study results showed equivocal findings for Mental Health help-seeking attitudes and were challenged by the reduced trust to see the professional. Therefore, this module seeks to create awareness of the dangerous sign of severe mental illness and when they should seek -help. Again, this is to raise the respondents' awareness on how severe their condition is that warrant them to seek the needed treatment.

In this module, respondents were provided with information on the credible organization they can seek for help and surf safely online.

3.1.2 Mode of delivery

An online / internet-based mode of delivery will be opted for ReSHape psychosocial intervention for its feasibility during the movement restriction amid the COVID-19 pandemic. This intervention research will be developed in REDCap to facilitate the delivery of the modules and data collection. REDCap, University Malaya is a secure web platform for building and managing for online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy (Harris et al., 2009)

3.1.3 Development of the activities and content

The specific objectives of the modules were translated into the Malay language by the native-speaking research assistant for the current study precede the drafting of the module's content. The content was worded in simple Malay language with minimal technical terms suitable for the literacy level of the B40 community, which is on par with 6th grade or standard six reading level and below. The investigators also sourced information from the Infosihat from the Ministry of Health, Malaysia, Health Education of England (HEE) and National Institutes of Health, USA. The contents of the modules were presented in PowerPoint and reviewed by an academician and a senior counsellor before it was converted to video format.

Attractive graphics will be added to each narration to enhance the understanding of the contents. A situational narrative or a case study will be created in modules 2A and 2B to portray the meaning of negative thought and overcome it. Each video was kept between 5-10 minutes. The videos will be uploaded to youtube first before they will be linked to ReDCap. The six modules will be delivered online through RedCAP over 12 weeks duration, whereby each respondent will be given one module link (started from the first module in the first week and ended with the last module at twelve-week) every fortnight through an email account or Whatsapp. Each respondent will be given ample time to clarify their doubts with the investigators and answer all the assignment before moving on to the subsequent module. The estimated duration for each respondent was 3-4 hours **Table 3.1**. Each respondent will be given a unique ID in the ReDcap, and upon completion of the modules, the link will be locked to avoid sharing of the link with other respondents.

Table 3.1 Relevant modules assignments, activities and duration for completing each module

MODUL		Activities	Estimated Duration
Modul 1 :Kenali Minda Anda		Video ,	10 minit
		Menjalankan Saringan Minda Sihat , Quiz berkenaan dengan Modul	20 minit
Modul 2: Membantu Diri	**2A: Daya Ketahanan Minda dan Menentukan Matlamat**	Video	10minit
		Quiz, Borang Menentukan Matlamat	20 minit
	2B: Mengambil Tindakan	Video	10-minit
		Quiz dan Borang Pemantauan Mingguan	45 -minutes
	2C: Mengatasi Fikiran Negatif	Video	10 minit
		Quiz dan Borang Pemantauan Pemikiran Negatif	35 minit
	2D: Kesedaran Pernafasan (Mindfulness)	Video +	10 minit
		Quiz dan Soal selidik Minfulness Awareness	35 minit
Modul 3 : Mendapatkan Bantuan		Quiz	15 minit
		Video	15 minit
Total			195 minit

3.2 Phase 2 Intervention : Feasibility and Evaluation Community-Based Intervention Study.

Phase 2 of this research involved the piloting and evaluation phase in the MRC framework, whereby the feasibility and effectiveness of ReSHape modules will be assessed through a community-based experimental study that will be incorporated into a logic evaluation model. Feasibility studies are commonly used to determine whether an intervention can be shaped to be relevant and sustainable for further testing in a bigger-scale study among the targeted population (Bowen et al., 2009). ReSHape modules will be tested in the community or in real-world settings, as mental health is not merely affected by individual behaviour but also closely related to socio-environmental factors. Therefore when intervention is done at the community level, it gives an interpersonal effect to drive the changes (Butler and Gonzalez 2015). And the areas of focus in the current feasibility study are the acceptability and the practicality of ReSHape modules to be used among the B40 community in the “real world” setting, guided by a process evaluation in the logic model to ensure fidelity. These are helpful information to troubleshoot any technical issues with the intervention module before implementing the community.

3.2.1 Study design

An online controlled pre-and post-quasi-experimental study will be piloted with an evaluation in a logic model to assess the feasibility and effectiveness of the ReSHape modules. Quasi-experimental is a cost-effective study design with good practicality for "real world" community-based intervention. ReSHape modules will be delivered through RedCAp online platform, as face to face intervention was impossible during the COVID-19 pandemic due to the movement control restriction at Petaling District. This study had been registered under ISRCTN25880061 (ISRCTN, 2021). The study will be conducted in Feb 2021 and ended in August 2021. The study will be reduced from 6 months to 3 months due to the shortage of funding.

The online quasi-controlled experimental study will be evaluated through process evaluation and outcome evaluation. Data collection will be conducted at pre-test T0 and post-test T1, after three months using validated tools (**Figure 3.1).** A post-test analysis at the post-intervention period will be conducted to look for differences between the intervention arm and the control arm. The feedback on the acceptability of the module's activities will be collected using a module evaluation form **(kindly email the principal investigator to view the form).**

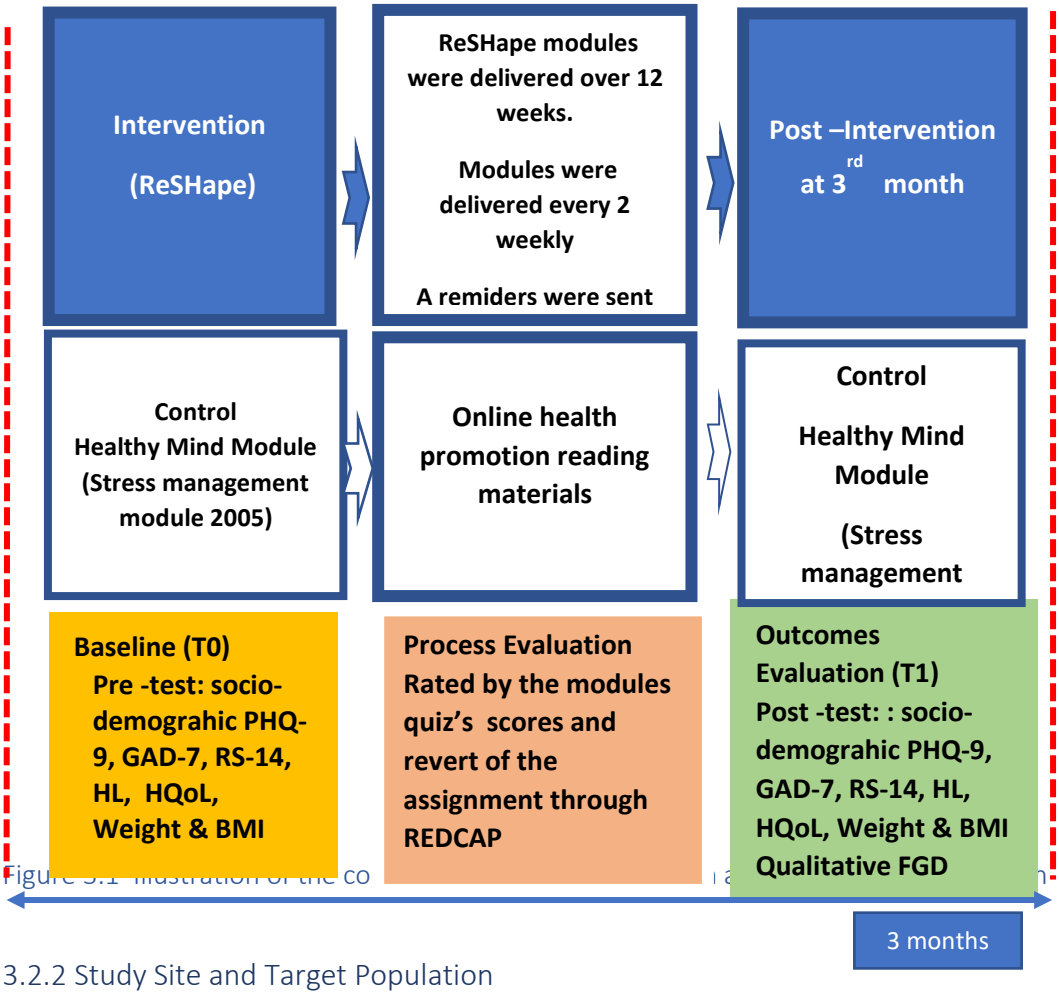

Figure 3.1 Illustration of the co a n

3.2.2 Study Site and Target Population

Eligible respondents from the low-socioeconomic households will be recruited from the four sub-districts of Petaling Districts, namely Sungai Buloh, Petaling Jaya, Damansara and Bukit Raja **(refer to Stuty site 3.3.1)**, through a social media campaign, whereby video of recruitment and electronic posters will be emailed to all the heads of the community. Preliminary screening for potential respondents will be done. Baseline assessment in Google form will be sent to the community leaders at the four sub-districts and filled by the low socioeconomic households.

Two medical officers trained in mental healthcare will be kept in standby and screened through the respondents' baseline assessment based on PHQ-9, GAD-7 and history of current mental illness. Eligible respondents will be recruited, and the consent form will be electronically signed in the REDCap database before data collection.

Since this is a controlled quasi-experimental study, no randomization will be done, respondents from Lembah Subang 1 were assigned to the intervention group, while respondents from Lembah Subang 2 will be put under the control group.

A letter of invitation, respondent's info sheets, and consent forms will be sent through RedCaps. Consent was obtained before the commencement of the study using the consent form attached in the ISRCTN registry.

3.2.2.1 Eligibility Criteria

Inclusion criteria

- The respondent is 18 years old and above. Mild to moderate score on PHQ-9 (≥5 < 10) and GAD-7 (≥5 <8) living in the three subdivisions of Petaling District.

Exclusion criteria

- Respondents that have difficulty communicating and understanding the Malay language will be excluded from the study.
- PHQ 9 ≥10 and GAD-7 ≥8 will referred for hospital assessment and will be excluded. Suppose the respondent has an unstable severe psychotic mental illness such as Schizophrenia, Bipolar and any form of psychotic illness based on DSM- VI diagnostic criteria. This is based on clinical assessment.
- In addition, if the participant were selected but refused to give consent are also excluded from the study

Withdrawal Criteria

- Respondent could withdraw anytime without being required to give any reason

3.2.3 Evaluation: Logic Model

The logic model in **Figure 3.2**, showing the work process of evaluation starting from the output, identification of the target population, activities that are leading to the intervention and outcomes of the intervention.

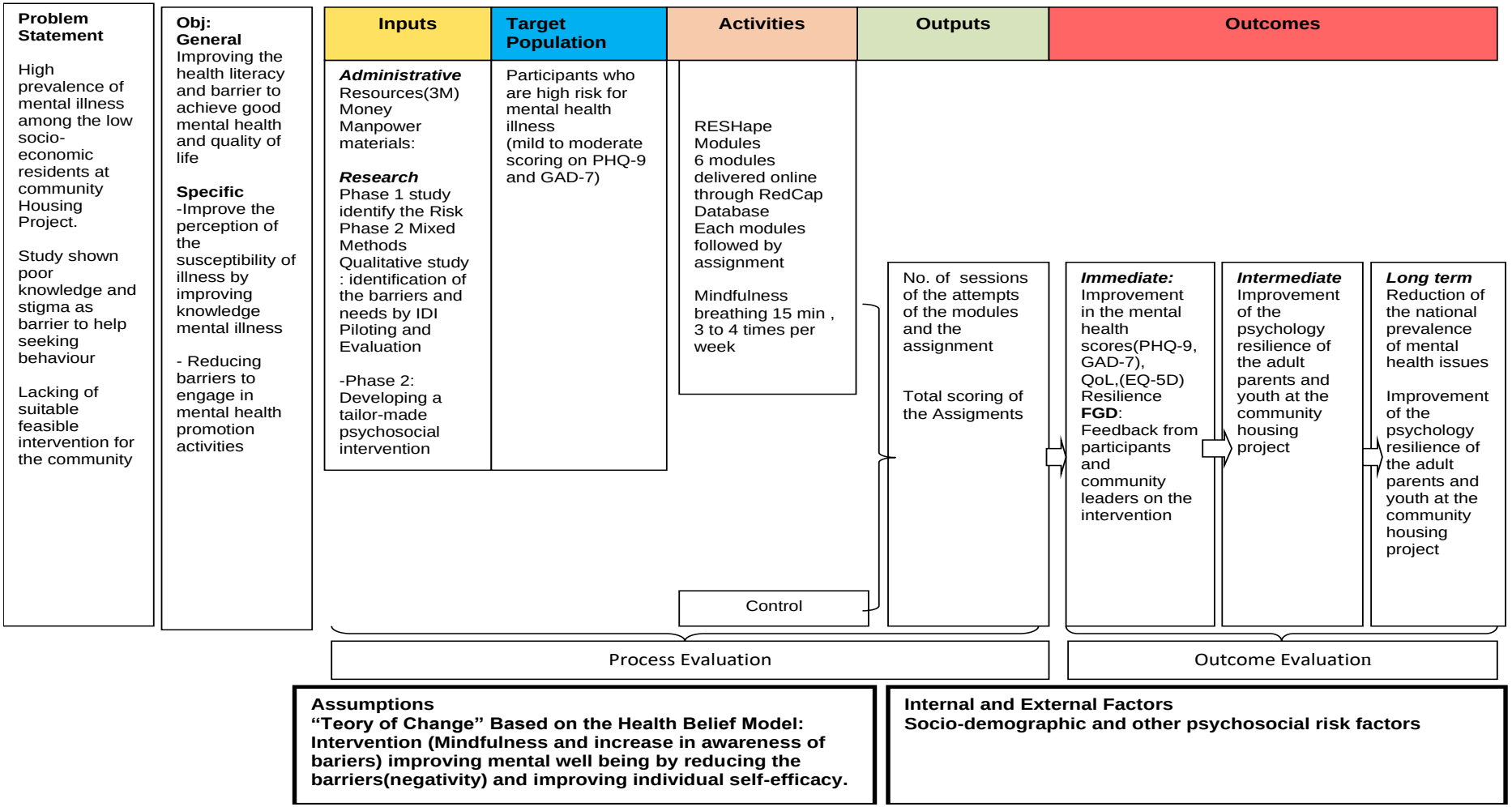

Figure 3.2: Logic Model for ReSHape Intervention

3.2.3.1 Intervention Group

Respondents selected in the intervention arm will be given the six ReSHape modules over three months, in which each respondent must complete each module and the related assignment (components of the modules were described in detail in table) in two weeks. The modules will be delivered through REDCap unique link via respondents' email and Whatsapp, in which each link is comprised of the narration of the components of the modules in videos and relevant quizzes. The understanding and the fidelity of the respondents' responses rely on the pre-post quizzes scores and submission of their assignments. Contents of the Self-Help Modules will be based on the cross-cultural elements derived from the mixed methods study output and evidence-based intervention described in the methodology **sub-heading 3.6** (Gillihan, 2020a, 2020b; Howarth et al., 2019; Mathias et al., 2018). Each respondent will be prompted through a reminder on WhatsApp to practice mindful breathing exercises at home. The mechanism of health-related behavioural change is driven by the components from the Health Belief Model **(HBM)**.

3.2.3.2 Control Group

Respondents selected in the control arm will be given a copy of Healthy Mind Modules, Let's TALK pamphlets and an educational video from the Malaysia Ministry of Health (MOH, 2005, 2018). And they will be given the intervention arm module or material at the end of the study **Figure 3.3**

3.2.3.1a Proses Evaluation

To determine whether programme activities have been implemented as intended. An analytical comparison of planned processes versus actual implementation, determination of strengths and weaknesses of the programme were conducted. Each participant will be monitored with a log from the REDCap online database on the completion of the training sessions and pre-test and post-test scoring of the modules quizzes. The percentage of the execution of tasks, attendance of the training sessions and pre-test and post-test/ quizzes scoring of the online modules will be taken as an indicator of the quality and fidelity of the Reshape intervention modules.

3.2.3.1a Outcome Evaluation

Outcome evaluation is to evaluate whether the psychosocial intervention worked on those who received the ReSHape intervention module. An online Quasi-experimental study will be conducted to evaluate the effectiveness. Standardized tools were utilised to record baseline data are as below:

Primary Outcomes : Patient Health Questionnaire (PHQ-9), Generalized Anxiety disorders (GAD-7), health-related quality of life (EQ-5L-5D)

Secondary Outcomes: Self-reported weight and height, Psychosocial indicators Resilience Scale 14-items (RS-14) and Health Literacy 12-items, Santa Clara Strength of Religious Faith is a 5-items, Poverty Attribution 21-items, Mental Help-Seeking Attitudes Scale (MHSAS) and Self-Stigma of Seeking Help (SSOSH) scale

Others: Socio-demographic

The data collection was conducted at baseline pre-test (T0), post-test (T1). The details of the instrument for this study have been described in length under methodology for a cross-sectional study.

3.2.4 Sampling

Details of the sampling methods were mentioned above under the **3.7.2 study site and Target Population.**

3.2.5 Sample size calculation

Based on Mathias et al. (2018) study on the effectiveness of resilience intervention to improve the mental status among young women in India and a local study for the effectiveness of mindfulness among university students, the effect size of the pre-test and post-test intervention were (d=0.42)(Phang, Chiang, et al., 2015). The sample size was calculated using G*Power version 3.1.9.4, and the estimated sample size was 50 cases in each arm (after inflated with a 20 % reserved rate). The initial required sample size for the entire study was calculated based on a 0.05 precision level and a 95 per cent confidence interval with the power of 80 per cent.

Experts in module development have suggested that the validation of the modules is similar to the validation for research instruments (Sidek, 2005). Therefore the sample size for validation of modules was 30 respondents, and a similar sample size was observed in other modules' development studies (Ahmad et al.; Talib et al., 2015)

3.2.6 Study Instruments

The baseline data from the intervention study and post-intervention qualitative study will be collected using the same instrument that was described under cross-sectional study . All the tools will be converted to an online survey in REDCap, and a pre-test was done before the actual data collection.

ReSHape Modules and the module activities evaluation form were created based on the objectives described under **sub-heading 3.1.** and the validation outcomes were presented in the subsequent sub-heading.

3.2.6.1 Sociodemographic Questionnaires

Sociodemographic questionnaires captured the background information of the respondents, which include the items stated below

a) Individual characteristics: age, gender, ethnicity and marital status.
b) Household information: years lived in the area, size of household
c) Socioeconomic status: education level, pre and post-covid monthly household income and employment status, ownership of assets (example: cash, car, houses, etc), ownership of communication tools.
d) Social capital: frequencies of interaction with the community

3.2.6.2 Health-related history Questionnaires

Health related history section captured the substance used, previous stressful life event, weight (Kg) and height (m) of the respondents.

The participants administered substance usage checklists to assess if the respondents took any non-prescribed substances from the most typical substances list, such as tobacco, alcohol, cannabis, cocaine, amphetamine-type stimulant inhalant, sleeping pills, hallucinogens, opioids and other substances. Respondents have to answer "yes" or "No" if they have ever taken these substances.

The stressful life event checklist was constructed based on a literature review (Maideen et al., 2015; Rosmalen et al., 2012). Respondents were required to answer "yes" or "no" to the events they perceived as a major events that caused emotional distress to them in their lifetime. A face validation was performed for this list with a panel of experts comprised of psychiatrists, family physicians, and public health specialists from the investigator's Master of Public Health (MPH) mental health study among the preschool caregivers (Min Fui, 2019) History of assault, loss of loved one, abuse during childhood, severe marital problems, severe family problems, serious injury or accidents are the events that were inquired about in the questionnaire. Respondents who answered "yes" to any life events will take as positive for life events in the binary category

Presence of Chronic Diseases. Diseases were self-reported by the participants based on the diagnosis by medical professionals. Chronic diseases are conditions that last one year or more and require ongoing medical attention or limit activities of daily living, or both (CDC, 2021). Some items included chronic illnesses list are hypertension, diabetes mellitus, heart diseases, stroke, mental illness, cancer, etc. Respondents have to indicate "yes" if they have a particular chronic illness. Any "yes" to the item will prompt the enumerator to cross-check with the respondents' home-based treatment card. They will be guided with a list of chronic diseases adopted from PARTNER's study protocol (Appendix G).

3.2.6.3 Patient Health Questionnaire 9 items (PHQ 9)

The Patient Health Questionnaire 9-item (PHQ-9) is a Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) based instrument designed to identify recent symptoms associated with major depression during the past two weeks. It is a subset of the PRIME-MD diagnostic instrument for common mental health disorders. This is a widely used free of charge tool that has been translated to various languages and tested in various populations (Teymoori et al., 2020). The original English version of the instrument was validated by Kroenke et al. among clinical settings respondents with good internal reliability. PHQ-9 consists of 9 items with four points scales, with each item scored from 0–3 and an overall range score of 0–27. The scores have been further classified according to the severity of depressive symptoms: increasing severity: minimal (0-4), mild (5-9), moderate (10-14), severe (15-19), and very severe (20 or greater). This is a practical tool for intervening depression, as each severity level of the scoring was given the possible intervention in the PRIME-MD (Kroenke et al., 2001).

This study adopted the total scoring methods to identify depression instead of algorithm scoring methods, as the former has better diagnostic performance (Manea et al., 2015). The scoring classification mentioned above was used, and in the present study, the cut-off point of ≥ 5 indicates the presence of mild to severe symptoms of depression and scores of ≥ 10 indicates moderate to very severe depression that requires referral for further clinical assessment. This cut-off was used in the final inferential statistic analysis, selection of the feasibility study subjects and cases for referrals

The Malay and English version of PHQ-9 was validated in Malaysia, with results showing good internal validity (Cronbach's α =.70) (M. S. Sherina et al., 2012). The Malay version was used in conducting a large local community and national level research in this country(IPH, 2019b; Kader Maideen et al., 2014).

3.2.6.4 Generalised Anxiety disorders (GAD-7)

Anxiety scale 7-item (GAD-7) is also part of the PRIME-MD diagnostic instrument based on DSM-IV construct for generalised disorders. This instrument inquires about the anxiety symptoms of the respondents for two weeks duration. The English version of GAD-7 was first validated by Dr Spitzer et al. (2006) among the adult patients at the primary care settings with the excellent internal consistency of (Cronbach's $\alpha = 0.92$), and Test-retest reliability was also good (intraclass correlation=0.83). This is a seven items instrument with four points rating scales with the scoring system of 0 = "not at all", one = "several days", two = "more than half the days", and three = "nearly every day". The total score ranged from 0 to 21. The score has been classified into five intervals of severity in the order of minimal (0-4), mild (5-9), moderate (10 -15) and severe (16-21)(Spitzer et al., 2006).

Using the total scoring method, two-level cut-off points will be utilised for the bivariate analysis of the cross-sectional study, ≥5 for mild to severe anxiety disorders and ≥8 for probable anxiety disorders, which require a referral for clinical assessment. This cut-off was used in the final inferential statistic analysis, selection of the feasibility study subjects and cases for referrals

The Malay version was validated by Sherina et al.; results showed good internal reliability (Cronbach's $\alpha = .74$) (Sidik et al., 2012). GAD-7 was also tested in one large prevalence study in Selangor and a national level survey (Kader Maideen et al., 2015).

3.2.6.5 European Health-Related Quality of Life, EQ-5D-5L

EQ-5D-5L is a standardised measure of Health-Related Quality of Life (HRQoL) developed by the Euro-Qol Group to provide a simple, generic questionnaire for clinical

and economic appraisal or population health status surveys. The EQ-5D-5L is part of the EQ-5D family of instruments.

EQ-5D-5L comprised the descriptive system (EQ-5D) and a visual analogue scale (EQ-VAS) that required a few minutes to complete.

The descriptive system is divided into five dimensions, providing information on the respondent's perceptions of their health status, including mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension is rated based on five response levels which include 1 = no problems, 2 = slight problems, 3= moderate problems, 4 = severe problems or 5 = unable to/extreme problems(Oemar & Janssen, 2013).

For instance, if a respondent scored 12345 for the mobility domain, the interpretation is no problems with mobility, slight problems with self-care (washing or dressing), moderate problems with doing usual activities, severe pain or discomfort and extreme anxiety or depression. Each health state can potentially be assigned a summary index score based on societal preference weights for the health state. This health state index scores generally range from less than 0 (where 0 is the value of a health state equivalent to dead; negative values representing values as worse than dead) to 1 (the value of full health), with higher scores indicating higher health utility(Oemar & Janssen, 2013). Each country has its own standardised value set, generated through a local study. The value set for Malaysia was published by Shafie, Vasan Thakumar, Lim, Luo, et al. (2018).

Visual analogue scale (EQ-VAS) records the respondent's overall current health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine and 'The worst health you can imagine. The EQ-VAS provides a quantitative

measure of the patient's perception of their overall health. The respondents need to mark on a scale ranging from 0 to 100.

This tool has been utilised worldwide with multi-language translation (Cheng et al., 2021). It was also tested in the bottom 40% of the income group through a local social welfare registry E-kasih involving the low-income households, people with disabilities and the aborigines in Malaysia (Wan Puteh et al., 2019). As the B40 population has variations in literacy level, the brevity of the tool helps them answer the question effortlessly. A Malay version of EQ-5D-5L has been selected because it is the national language and has acceptable reliability (Shafie, Vasan Thakumar, Lim, Luo, et al., 2018). Another study targeted clinical cases showed excellent Cronbach's alpha (0.85) for five dimensions of the descriptive system. (Tran, Ohinmaa, & Nguyen, 2012).

3.2.6.6 Health literacy

Health literacy is needed to gauge participants' knowledge, perceptions, judgement, and preventive steps on health. European Health Literacy Consortium refers to Health literacy as people's knowledge, motivation and competencies to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life-course (WHO, 2013). Through a literature search, there are many health literacy tools being used in research. Newest Vital Sign (Weiss et al., 2005), Rapid Estimate of Adult Literacy in Medicine (Davis et al., 1993), and the Test of Functional Health Literacy (Baker et al., 1999) are tools that are commonly being utilised for clinical subjects.

A tool to measure health literacy at the general population level is needed for this study. European Health Literacy Survey Questionnaire (HLS-EU-Q) 47 items has been

developed recently (Sørensen et al., 2013) and was validated across six Asian countries, including Malaysia (Duong et al., 2017) with Cronbach's alpha > 0.90. The Short Form of Health Literacy Questionnaire 12-items (HL-SF12) is also available and has been found to be a valid and reliable tool to assess health literacy (Duong et al., 2017), particularly in a large-scale study. HL-6, which was derived from the HL-SF12, was decided by the expert in the main MRUN committee to measure the capability of the low-income population in processing the health information for the prevention of disease.

Each item of The HL-6-items is rated with a four-point Likert scale that assesses the perceived difficulty of performing each item, where very difficult=1, difficult=2, easy=3, and very easy=4. The mean score is calculated if at least 5 of the six items are completed. Three levels for the scale entailed: inadequate HL (≤ 2), problematic/limited HL (>2 - <3), and sufficient HL (≥3).

This questionnaire was validated during a pilot study on seventy respondents with similar characteristics, showing excellent reliability of Cronbach α > 0.90. Another unpublished data showed that HL-6 is a valid and reliable tool to measure the health literacy of cases attending primary settings. Confirmatory analysis (CFA)revealed good fit indices (Chi-square: 6.713 p > 0.459, RMSEA = 0.000, CFI= 1.000, TLI= 1.001) with good concurrent and convergent validity. The tool also showed good internal validity with Cronbach's Alpha of more than 0.87.

A health literacy questionnaire was chosen instead of the mental health literacy tool as it measures other chronic diseases awareness as well, which is more suitable in this community with a high burden of NCD.

3.2.6.7 Poverty Attribution 21-item (PA-21)

Poverty Attribution 21-item is used to measure the perception of low-income respondents on the cause of poverty. This is a new tool that Professor Rozmi Ismail developed through the adaptation of various tools to meet the needs of the local cultural diversity of the bottom 40 group (Halik et al., 2012; Ljubotina & Ljubotina, 2007; Nasser & Abouchedid, 2001; Nishimwe-Niyimbanira, 2014; Wollie, 2009). There are four domains, namely structural support, socioeconomic support, individualistic and fatalistic. The scale has a rating of 1 to 5, and the formula for calculation of the scoring is as below:

Total PA score = structural support (Q1- Q5) + socioeconomic (Q6-Q10)+ Individualistic (Q11-Q15) + fatalistic (Q16 -Q21).

The total score of PA will be adopted to assess the relationship with the study's outcomes. The 17-item instrument has been validated by Rozmi et al. 2019 in the Malay language among low-income adults in Selangor Malaysia; results showed the internal validity for structural attribution (Cronbach's Alpha = 0.773), individualistic attribution (Cronbach's Alpha = 0.752) and fatalistic attribution (Cronbach's Alpha = 0.662)(Hassan et al., 2019). Another improved version, PA 21-item in the Malay language, was designed by the same author and was tested among the low -socioeconomic showed Cronbach's Alpha of 0.60 to 0.87 for the four domains (Ismail et al., 2019). Validation of the tool in the pilot study for the current study has shown an excellent Cronbach's Alpha of more than 0.90.

3.2.6.8 Resilience Scale (RS-14)

The full scale of Resilience Scale 25-items was developed by Dr GM. Wagnild, PhD, RN and Dr Heather M. Young, PhD in 1993 (Wagnild & Young, 1993). The full items instrument yielded an excellent Cronbach's Alpha of 0.91. This scale was

subsequently tested in various populations, and the range of internal validity was between 0.72 to 0.94(Wagnild, 2009). The shorter items of the Resilience Scale, RS-14, were developed for the feasibility of clinical cases. The 14 items scale was validated and has attained a high Cronbach's alpha of 0.93. Each item was rated on 7 points scale with a maximum total score of 98 and a minimum of 14. This tool also allowed further classification of the total scoring of RS according to high (91-98), moderate (74-81) and low (57-64). Each score level comes with its interpretation and the action to be taken to improve resiliency (Wagnild, 2014).

Based on the review paper by Windle et al. 2011 19 tools were developed to measure resilience among the clinical and general population (Windle et al., 2011). Through literature exploration, the Resilience Scale 14-items and Connor-Davidson Resilience Scale 10-items (CD-RISC) were the most common tools used in the local research. However, only Resilience Scale 14-items in Malay translation were tested in the local study with good internal consistency of 0.86 (Narayanan & Cheang, 2016; Windle et al., 2011). In addition, these tools have been used in observational studies related to health promotion and lifestyle, which is an ideal tool for the current study.

3.2.6.9 Santa Clara Strength of Religious Faith (SCSRF-5)

Santa Clara Strength of Religious Faith is a 5- item Questionnaire utilised in this study to elicit the strength of religiosity among the low-income group. The original version was developed by Plante et al. in 1977. Subsequently, a shorter version, the 5-items Santa Clara Strength of Religious Faith, was developed for better feasibility for conducting bigger epidemiological studies involving cancer patients (Plante & Boccaccini, 1997).

This tool was selected as it applies to all the religions in this country as compared to a more frequently used tool Duke University Religion Index (DUREL). The 10-item of SCSRF is highly correlated with other established tools, namely Age Universal Religious Orientation (AURO), the Intrinsic Religious Motivation Scale (IRMS) and the Duke Religious Index (DUREL). It has a good Cronbach's Alpha coefficient of 0.95 and high split-half reliability of 0.92. The 5-item of Santa Clara's Strength of Religiosity was equally reliable as it was highly correlated with 10-item questionnaires >0.95. This tool was well-validated among the adult population (Pakpour et al., 2014).

Respondents will be required to answer a self-reported 4 points Likert scale Santa Clara Strength of Religious Faith Questionnaire 5 item (SCSRFQ-5). A score of 1 to 4 points will be given to each item (1 = strongly disagree, 2= disagree, 3= agree, and 4 = strongly not agree). The cut-off point based on the sample median will be adopted for the analysis (Plante & Boccaccini, 1997).

Based on the investigator's master research project, the Cronbach's Alpha coefficient for the SCSRFQ-5 Malay version was found to be 0.829, with an average intraclass correlation of coefficient of 0.822 (Min Fui, 2019). This tool was piloted in the current study, and the internal validity was 0.786.

3.2.6.10 Mental Help-Seeking Attitudes Scale (MHSAS)

Mental Help-Seeking Attitudes Scale (MHSAS) is a 9-item instrument that Dr Joseph H. Hammer developed to evaluate respondents' perception of seeking help from professionals for their mental health issues(Hammer et al., 2018). This is a semantic scale, and a higher score indicates a more positive attitude towards seeking help. The original instrument has an internal consistency of ($\alpha = 0.94$), Whereas Malay MHSAS, which were validated among the B40 population, has a Cronbach's Alpha of 0.892 (Ibrahim et

al., 2019). The total score will be to establish the relationship with the binary outcomes of mental health status and quality of life score.

3.2.6.11 Self-Stigma of Seeking Help (SSOSH) scale

This study instrument was designed by Vogel et al. to measure self-stigma as an important factor to deter people from engaging in therapy. This tool has 10-items with 5 points scale. English version of the scale has a unidimensional factor structure with excellent reliability (Chronbach's $\alpha = 0.91$), while the Malay SSOSH has been validated among the B40 in Malaysia with an acceptable internal consistency of Cronbach's alpha = 0.667 (Ibrahim et al., 2019). The higher scores indicate higher self-stigma. The total score was used to establish the relationship between mental health status and quality of life score binary outcomes.

3.2.6.12 Addressing Significant Scoring for PHQ-9 and GAD-7

PHQ-9 and GAD-7 are screening tools for the assessment of depression and anxiety. Any high scores from these questionnaires warrant further clinical consultation by the family physician or psychiatrist to confirm the underlying disorders—enumerators at the fieldwork are required to call the investigator, a medical officer or counsellor. Respondents were referred to the nearest clinic or hospital if the score was >=10 for PHQ-9 and >=8 for GAD-7 for further assessment to confirm the underlying disorders and for treatment initiation.

For mild depressive and anxiety symptoms cases (Scores of < 5), they were given the nearest health facilities contacts and online psychosocial support for them to get help when their symptoms worsened and to repeat screening tests (refer to Figure 3.6 on the workflow and referral pathway). Based on Kroenke et al., scores less than five almost always signified the absence of a depressive disorder (Kroenke et al., 2001)

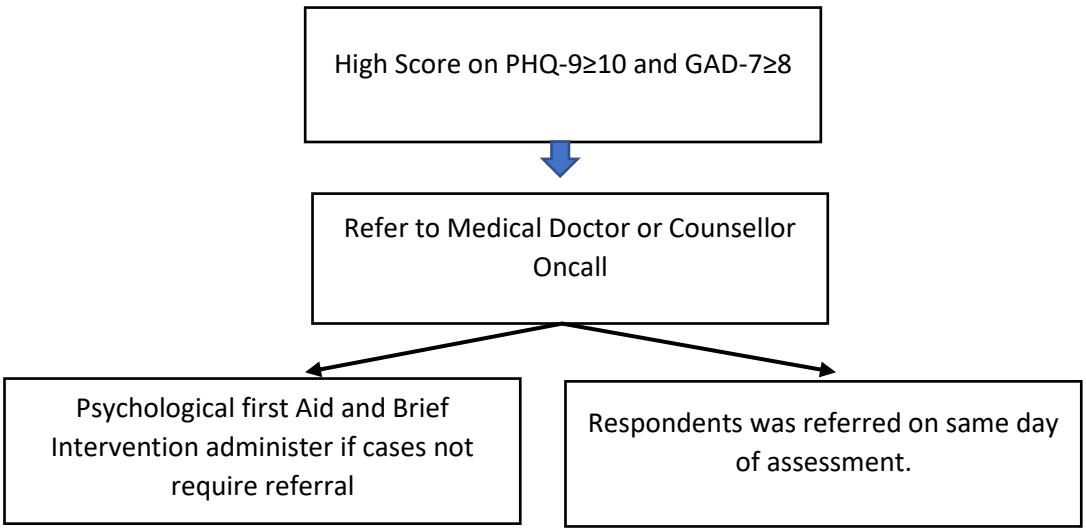

Figure 3.6 Referral Pathway for this study

3.2.6.1 Content Validity of ReSHape Module

To ensure the relevant, suitability and accuracy of the ReSHape's Module content, face validation by the relevant experts was done. There were six experts appointed to evaluate the validity of the constructs and module contents **(Letter of appointment APPENDIX J).** Experts are those who have the expertise and experience to ascertain the suitability of the newly developed modules. The criteria for selection of expertise are (i) Expertise:- B40 related to research or involvement in module development or outreach work with B40 community or (2)knowledge related to the field mental health among the low social income group or (3) working in the area of health promotion. The profile of the panels is shown in **Table 3.3**:

Table 3.3 Profile of the panel of Experts

No	Qualification	Field of Expert
1.	Academician at Psychology Unit Of Psychology and Human Wellbeing Research Centre Faculty of Social Sciences and Humanities, National University	Psychologist (counselling) - Positive Psychology - (Family Relationship) - Mental health related Module development
2.	Senior Lecturer at the Institute of Training , Ministry of Health (MOH)	Psychologist (Counselling) - Experience practitioner with low-income clients (Mindfulness Breathing Exercise) - Major in Family counselling
3.	Final year PHD candidates Major in Counselling	Major in Counselling - Extensive involvement in B40 research

		- Developer of Poverty Attribution questionnaires - B40 modules development
4.	Kepong District level Non-communicable Disease Coordinator	Senior Medical Officer (UD 54) - Community outreach programme with low income group community at Projek Perumahan Rakyat - Coordinating Mental health programme for 3 major clinics at Kepong District Office
5.	Senior Health Promotion Officer , the Institute for Health Behavioural Research (IHBR), National Institute of Health (NIH)	Senior Health Promotion officers - COMBI and Community outreach programme with low income group community at Projek Perumahan Rakyat.
6.	Representative from the B40 Community	Bachelor Holder and frequent involvement in survey as participants

Numerous local studies and academicians have conducted module validation based on the criteria recommendation by Russell (1974) (Ahmad et al.; Fuad et al., 2019; Sidek, 2005; Talib et al., 2015). The validation of the modules comprised of, a) Module Content Meet the population target; b) The contents of the Modules can be implemented c) Time is sufficient to complete the modules ; d) Module Content can alter the negative thought of the B40 community e) Module Content successfully reduces the depression and anxiety symptoms.

Therefore, two sets of questionnaires (a) Content Validity questionnaires for panels of experts and (b) reliability of the modules, were validated in this study**(kindly request from the Principal Investigator through email),** based on Russel's (1974) recommendation. Together with the list of objectives, videos and manual of the ReSHapes modules, these questionnaires were sent to the experts for assessment. The six experts have filled up the Content Validity questionnaires, which required them to rate their agreement according to 5= strongly agree, 4= agree, 3= unsure, 2= disagree, and 1 = strongly disagree, based on five criteria shown in **Table 3.4.**

Content Validity Index (CVI) is the most widely reported approach for content validity in instrument or module development, which can be computed using the Item-CVI (I-CVI) with the formula shown below **Table 3.4** (Rodrigues et al., 2017; Sidek, 2005). All of the modules have a score of CVI of more than 0.80 based on the Russell (1974) criteria, indicating ReSHape module has good validity. The feedbacks from the panels were implemented in the modules **Table 3.5**

Table 3.4 Content Validity Index (CVI) from the panel experts for ReSHape Module

No.	Items	CVI	Relevant
1.	Module Content Meet the population target	0.97	Relevant
2.	The contents of the Modules can be implemented	0.86	Relevant
3.	Time is sufficient to complete the modules	0.97	Relevant
4.	Module Content can alter the negative thought of the B40 community	0.83	Relevant
5.	Module Content successfully reduce the depression and anxiety symptoms thus improve the well-being	0.97	Relevant

$$\frac{\text{Total Scores Given By Experts}}{\text{Total maximum scores contents}} \text{ X 100\% = CVI (formula)}$$

Table 3.5 : Feedbacks from the panel experts for ReSHape Module prior to commencement of the feasibiluty study?

Experts	Feedbacks
Expert 1	The explanation is clear, and easy to understand. Please utilise more images or graphics to illustrate facts/information Review the use of the word catastrophic or castatropic, at 3.25 minutes. It is better to use the english word (catastrophic), because there is no Malay translation for this term in ***Dewan Bahasa dan Pustaka.*** "
Expert 2	Agree with the description shown in the knowing your mind module.
Expert 3	Overall, a good description. Improvements in terms of clarity on how the intervention / quiz will be conducted briefly so that participants are prepared and motivated with what they will learn.
Expert 4	Module presentation can be improved by using more interesting applications and software. Module content is easy to understand and clear.
Expert 5	Work with NGO or the ministry involved and address the issue promptly

3.2.6.2 Reliability of ReSHape Module

Since ReSHape module is a tool for the current intervention study, therefore just like any research, the researcher must elicit the reliability of the instrument. A research tool with high reliability denotes how good is the research tool in producing consistent or stable effects on the repeated trials.

According to (2005), a questionnaire to evaluate the reliability of modules (APPENDIX J) can develop based on the objectives of each of the module activities to evaluate the acceptance and agreement of the respondents to the module. The validation of this questionnaire was vetted by the same expert mentioned above. The lowest CVI was 0.77, and the highest was 0.93. **Table 3.6**

Table 3.6: Content Validity Index (CVI) and feedbacks from the panel experts for Reliability Questionnaires

No.	Items	CVI	Relevant
1.	**Module 1 : Knowing Your Mental Health**	**0.87**	**Relevant**
2.	**Module 2: Self-Help**	**0.90**	**Relevant**
3.	**Sub-module 2A-2C: CBT**	**0.90**	**Relevant**
4.	**Sub-module 2D: Mindfulness Breathing**	**0.90**	**Relevant**
5.	**Module 3 Seeking Help**	**0.90**	**Relevant**

In order to assess the reliability of the module, a feasibility study needs to be conducted at Projek Perumahan Rakyat (PPR) Lembah Subang One. Through purposive sampling, forty-five low-income respondents were recruited to test for the reliability of the intervention modules.

3.2.7 Data Collection and Management

The current intervention study's data collection and management will be online using REDCap(Research Electronic Data Capture), a secure, web-based application designed to support data capture for research studies, hosted at University Malaya. REDCap's streamlined process for rapidly creating and designing projects with various tools tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and standard statistical packages (SPSS, SAS, Stata, R). In addition, REDCap has a longitudinal data collection setting that provides a built-in project calendar, a scheduling module and the creation of arms for trials treatment administration, i.e. ReSHape modules video can be uploaded followed by a link for assignments and quizzes.

Other features entail indicating the completion of the module by the respondents, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Finally, REDCap has its collection of electronic questionnaires in the Shared Library REDCap; this expedites the setting up of the survey.

3.2.7.1 Study Variables (Indicators) and Data Dictionary Codebook

The below table illustrates the independent and dependent variables for the intervention study.

It also highlights the **primary and secondary outcomes indicators** for outcomes evaluation **Table 3.7**.

Table 3.7: Study variables, definitions, coding and scales

Dependent Variables	Coding	Definition	Scale of Measurement
Primary Outcomes			
1. Major Depression (PHQ- 9)	bmphq_1 to bmphq_9	Construct Based on DSM VI Assess Depression in 2 weeks Cut-off point ≥ 10 for clinical depression Denotes current Prevalence of Major Depression (M. S. Sherina et al., 2012)	Continuous 0= not at all 1= several days 2= more than half the days 3= almost every day Severity depending on the incremental of the scores Categorical 0 =No < 5 1=Yes≥ 5
3. Generalised Anxiety Disorders.(GAD-7)	bmgad_1 to bmgad_7	Construct Based on DSM VI Assess Anxiety in 2 weeks time. Cut-off point ≥ 8 for clinical depression Denotes current Prevalence of Generalised Anxiety Disorders. (M. Sherina et al., 2012)	Continuous 0= not at all 1= several days 2= more than half the days 3= almost every day Severity depending on the incremental of the scores. Categorical 0 =No < 5 1=Yes≥ 5
4. Health Related Quality of Life (EQ-5D-5L)	eq5d_mb_5l_mal_mal eq5d_sc_5l_mal_mal eq5d_ua_5l_mal_mal eq5d_pd_5l_mal_mal eq5deq5d_ad_5l_mal_mal eq5d_ad_5l_mal_mal EQ_2CAT	Measuring health related quality of life Descriptive System (Health Status) Visual Analogue (Current health)	Continuous and categorical EQ_index 0= no problem 1=problematic Scale (ED-VAS) 0=Bad (<65) 1=Fair (65-79) 2=Good (80-89) 3=Excellent (>90)
Independent Variables	Coding	Definition	Scale of Measurement
Secondary Outcomes			

18.	Resilience Scale-14 items	RS_14_1- RS_14_14	Quantifying resilience (measure of stress coping ability). The higher the scoring the greater is resilience	Continous 1=strongly disagree 2= disagree 3= less than moderate 4=Moderate 5= more than moderate 6=agree 7= strongly agree Categorical 0=high (91-98) , 1=moderate (74-81) and 2=low (57-64)
19.	Substance use	assist_1 assist_1a-1k	Checklist on ever use of substances.	0=no 1=yes
20.	Poverty Attribution (PA-21)	AP_1 to AP_21	4 domains namely Stuctural, socio-economic, individualistic and fatalistic	Continuous 1=strongly disagree, 2=disagree , 3=some how agree, 4= agree and 5=strongly agree.
21.	Health Literacy 12-items	HL_1 to HL_12	Quantifying knowledge, perceptions, judgement and preventive steps pertaining to health Gen-HL index=0-50 categorised into four groups: inadequate=(0-25), problematic=(25-33), sufficient=(33-42) excellent= (42-50).	Continuous and categorical HL-Index scores were calculated and classified into different level 0= inadequate(0-25) 1= problematic (25-33), 2= sufficient(33-42) 3= excellent (42-50).
22	Mental Help Seeking Attitude Scale	mhsas_9_1- mhsas_9_9	The MHSAS is a 9-item instrument designed to measure respondents' overall evaluation (unfavorable vs. favorable) of their seeking help from a mental health professional if they found themselves to be dealing with a mental health concern. A higher score indicates a more positive attitude toward seeking help.	Semantic Scale Unfavorable Favourable 1 → 7
	Self-Stigma Of Seeking Psychology Help	ssosh_10_1- ssosh_11_1	Measurement of Self stigma on professional help seeking	1=strongly disagree 2=disagree 3= not sure 4= agree

				5= strongly agree
23.	Weight Height	weight_kg height_cm	Reported by respondents	Continuous Weight: KG Height: metres
Socio-demographic variables				
1.	Gender	b02_gender	As indicated in the respondent's identification card	Categorical 1=Male or 2=Female
3.	Age	b01_age	As indicated in the respondent's year of birth in the identification card	year of birth
4.	Ethnicity	b05_race	As stated by the respondents	Categorical 0= Malay 1= Chinese 2=Indian 3 = others
5.	Marital status	b06_marital_status_status	As stated by the respondents	Categorical 0=Single, 1=married , 2=divorced and 3=separated 4= widowed
7.	Religiosity	b023_i_pray_daily b024_i_looktomyfaithas b025_i_considermyselfact b026_i_enjoy_being_around b027_myfaithimpacts_many	Self-reported 4-points likert scale Santa Clara Strength of Religious Faith Questionnaire 5 items (SCSRFQ-5). A cut -off point based on the sample median(Plante & T. Boccaccini, 1997). Min = 5 Max= 20	Continous and Categorical A score of 1 to 4 points will be given to each item (1= strongly disagree, 2= disagree, 3= agree and 4 = strongly not agree).
8.	Education level	b07_highest_education_leve	As stated by the respondents	0= Not Schooling , 1= Primary, 2= Secondary , 3= Diploma ,4 =certificate, 5= Degree and above
9.	Household Income Before and during covid	b010_mthly_income (before pandemic) b010_mthly_income_2 (during pandemic)	As stated by the respondents The breakdown of the categories were based on the latest national socio-economic status categories. (HRDF, 2019)	Continous and Categorical 0=<RM 1700, 1= RM1700 to 2700, 2= RM2701 to 3700, 3= RM 3701 to 4700, 4= RM 4700-5700 and 5= >RM 5701
10.	Size of Household	b09_total_households	As stated by participant	Continous to Categorical 0=< 4, 1=≥ 4

11.	Years-live in residential area	b04_year_started_to_reside	As stated by participant	Continous to Categorical 0=≤ 4 years,1=> 4 years
12	Job category	Before Covid-19 b012_job During Covid-19 b012_job_2	As stated by participant	0=no 1=yes
13.	Home ownership	b015_own_house	Socio-economic Status	0=no 1=yes
14	Asset Ownership	b015_own_house b016_vehicles_kenderaan b017_land b019 Tunai /barang Kemas b018_ochird b020 Saham b021_others_lain_lain3	Socio-economic Status	0=no 1=yes
15	Community Connectedness	jiran_kerap	Social capital	1= always 2=once a week 3= once a month 4= very rare 5= never
16.	Stressful life Event	b030-b043	Inventory of Stressful life events. Refer to Socio-demographic questionnaires (Appendix)	Categorical 0=no , 1=yes
17	Chronic Illness	b029_any_past_medical_illn hpt dm jantung buahpinggang kanser asma stroke mental lain_kronik	As reported by respondents any chronic illness more than 1 year or longer. List of chronic illness were provided to guide the participants(Kader Maideen et al., 2014)	Categorical 0=no 1=yes
18.	Substance use	assist_1 assist_1a-1k	Checklist on ever use of substances.	0=no 1=yes

Process Evaluation Indicators				
1.	Module 1 : Knowing your mental health	modul_1_a- modul_1_e	Assessment the comprehension of the modul 1 content.	0= False 1=True
2.	Modul 2A	hw_image_aktiviti1 Apakah aktiviti yang akan anda buat untuk memperbaiki isu ? Aktiviti 1: Contoh : mula mencari bantuan kewangan, cari maklumat atas talian, tanya ketua komuniti... resilien_aktiviti1 kekuatan minda untuk capai Aktiviti 1 Contoh kuat imam, minta kekuatan dari tuhan... hw_image_v3 Apakah Elemen (Isu-isu) yang perlu dibaiki? Elemen /isu no 2: isu kesihatan, kurangkan rokok , kurang senam ... hw_image_aktiviti2 Apakah aktiviti yang akan anda buat untuk memperbaiki isu ? Aktiviti 2: Contoh bersenam selalu/ berhenti rokok... resilien_aktiviti2 kekuatan minda untuk capai Aktiviti 2	Identified the major issues and suggest solution to overcome based on the resilient strength	Open ended

		Contoh sebelum ini anda orang yang berdisiplin		
3	Modul 2B	modulquiz_2b_a- modulquiz_2b_b https://docs.google.com/forms/d/e/1FAIpQLScneTULuCPu4aYHajYu6ZcPbNnflrO3L0hHxpGbiviGNarAHg/viewform?usp=sf_link APPENDIX	- Behaviour Activation - Weekly monitoring form for activities	0= False 1=True
4	Modul 2C	modul_2c_a- modul_2c_b https://docs.google.com/forms/d/e/1FAIpQLSe2EwdTv6497vwex695cbmN77QdRRZDT8VymOL4GhrQFifu1Q/viewform?usp=sf_link APPENDIX	- Understanding negative thought and overcome it	0= False 1=True
5	Modul 2D	modulquiz_2d_a- modulquiz_2d_e Mindful Attention Awareness Scale (MAAS) maas_1a- maas_15a	To assess the understanding of mindful breathing and practice of the mindfulness breathing	1= almost always 2= frequently 3=very frequently 4=some what infrequent 5=very infrequent 6= almost never
6.	Modul 3	modulquiz_3_a- modulquiz_3_e	To be aware of the reliable source to seek help	0= False 1=True

3.2.7.2 Data analysis

The preliminary raw data will be retrieved from REDCap and was organised before it is imported to STATA version 17.0 for statistical analysis. All the data interpretation will be based on the significant level of 0.05 with a power of 80%.

a. Descriptive Analyses

Preliminary descriptive data analyses involved exploration of the dataset to understand the data structure, distribution of the values, identification of extreme values, and missingness within the dataset. Subsequently, descriptive statistics will be used to compare the intervention and control groups' baseline characteristics. The results will be presented in counts and proportions for categorical data. Normally distributed data is presented in mean and standard deviation, while skewed data will be summarised with median and interquartile range (IQR).

In order to establish baseline equivalent, respondents characteristics between the treatment and the control group's respondents will be assessed using an independent t-test for normally distributed continuous data, Mann-Whitney U test for skewed data and chi-square test for categorical data.

b. Missing Data

The overall missing values will be analyzed using the multiple imputation function in SPSS version 23. The steps in multiple imputations will be followed through, and the missing pattern will be identified as missing at random (MAR). Five imputed datasets will be generated for the monotone missing pattern. The aggregation function in SPSS version 23 will be used to pool the five imputed datasets for univariate analysis and multivariable analysis.

Inferential Analyses

In univariate analysis, paired T-test or Wilcoxon Signed Rank Test will be applied to identify the difference in scores for primary and secondary outcomes of interest for Time-0 and Time-1 in this study. An intergroup mean difference will be calculated based on the formula

mentioned below to confirm the difference between the intervention and the control group's primary and secondary outcomes variables shown in Table 3.15.

Intergroup mean difference = [(mean pre^{I} – mean $post^{I}$) – (mean pre^{C} – mean $post^{C}$)], where pre^{I} = pre-intervention in intervention group;

$post^{I}$ = post-intervention in intervention group;

pre^{C} = pre-intervention in comparison group and

$post^{C}$ = post-intervention in comparison group.

In multivariable analyses, three types of inferential analyses will be considered. They are repeated measures ANOVA, ANCOVA, generalised linear mixed model (GLMM) (Mixed Model Repeated Measure (MMRM) or logistic GLMM). A mixed model general linear model design like repeated measures ANOVA and ANCOVA helped address differences between two independent measures while also exposing subjects to repeated measures (Green & Salkind, 2011; Leppink, 2018). However, they only allowed listwise deletion and last observation carried forward (LOCF) for dropout cases. This may lead to reduced power and biases in the estimation. Therefore, given the missingness for dropout 20%) and small sample size, MMRM or logistic GLMM is superior in conserving the power of the current dataset. MMRM or logistic GLMM is also a likelihood-based statistical approach for handling repeated non-independent measures data collection overtime points. This model uses an unstructured time and covariance structure that (1) avoids model misspecification and (2) its unbiasedness for data that are missing completely at random (MCAR) or missing at random (MAR)(Bell & Rabe, 2020; Mallinckrod† et al., 2008). GLMM was chosen for analysis instead of GEE, as the formal is an extension of MMRM, providing a more consistent estimate of the fixed effects and given MAR for missingness in the current dataset (Liu and Zhan, 2011;Davis, 2014).

All primary and secondary outcomes variables will be treated as continuous variables and analysed using MMRM. Whereas EQ-5D (residuals were non-normal distributed when modelled with MMRM) will be dichotomised based on median (0= 'no problem' index ≥0.928 1= "problematic" index < 0.928) and analysed with logistic GLMM. Interaction terms were created and tested for the first-order main effect. Final models were assessed for assumptions compliance regarding the normal distribution of the residuals, homoscedasticity and random effect coefficient(Schielzeth et al., 2020). Model fitness was evaluated using the likelihood-ratio test, AIC, BIC and coefficient of determination r^2.

3.7.8 Appraisal Tools and Reporting

The mixed methods and the intervention studies will be appraised using evidence-based tools, Mixed Methods Appraisal Tool (MMAT) Version 2018 (Hong et al., 2018) and the Transparent Reporting of Evaluations with Non-randomised Designs (TREND), checklist, respectively (Des Jarlais et al., 2004). Critical appraisals are essential as an integral of good practice to ensure no potential threats to the validity of the research findings.

3.7.9 Ethical consideration

Ethical approval was obtained from the University of Malaya Research Ethics Committee (UMREC). The protocol for this study was registered with the International Standard Randomised Controlled Trial Number (ISRCTN), an approved database by WHO, and was given a unique registration number (ISRCTN25880061). The benefits will be received by the respondents are health Promotion will be given to the participants. Referral for counselling and treatment. Whereas some respondents may may experience some emotional discomfort when answering certain questions in the mental health assessment questionnaires. Respondents can choose to stop answering the questions and contact the researchers as stated at the end of this information sheet.Other ethical issue concerned was the confidentiality of respondents with high scores for depression and anxiety symptoms rated by the screening tool. Given the high perceived self-stigma for mental health issues, two researchers will solely handle the referral

letter for respondents. Participants will be called and reassured of the need for referral to the nearest health clinic or hospital. The referral letter will be emailed to the respondents.

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