# Development of Brief Cognitive Behavioral Therapy Workshop Study Protocol for Primary Care Attendees with Common Mental Disorders in Selangor, Malaysia

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The prevalence of Common Mental Disorders (CMD) in the primary care appears to be high, yet most of the individuals who can benefit from early and evidenced-based psychological approaches are limited. Barriers concerning stigma, lack of access to psychological interventions, high volume of primary care attendees, and poor awareness in mental health are among the factors that contribute to the accessibility of mental health treatments. The paper proposed a study protocol from past literatures' recommendations to integrate psychological interventions in the primary care setting. Implementation of the brief Cognitive Behavioral Therapy workshop (b-CBT) as the potential approach to address the issues and symptoms of CMD in the primary care clinics using a nonrandomized quasi-experimental study is proposed. The study will use a multivariate analysis of covariance (MANCOVA) to analyze the 84 prospective participants, using purposive sampling. The targeted identification of cognition, behavior and emotions from b-CBT model is expected to be able to address the symptoms relating to CMD. Results will show the potential changes of symptoms measured by Depression, Anxiety, and Stress Scale, 21 items (DASS-21) for three time-points (baseline, post-intervention, and one-month follow-up). The reporting guideline for the paper follows the TREND statement reporting guidelines.

*Keywords:* common mental disorders, brief cognitive behavior therapy, primary care, depression, anxiety

Common Mental Disorders (CMD) is characterized by depression and/or anxiety disorders in adults 18 years and older (World Health Organization, 2017). The World Health Organization (2017) reported that depressive disorders and anxiety disorders are prevalent and common among the general population across different cultures therefore, these two disorders can be referred to as CMD. CMD has undertaken the iteration of the Global Burden of Disease (GDB) studies (World Health Organization, 2017). In estimation, major depression is expected to be the largest contributor to the Global Burden of Disease (GBD) in 2030 (Chong, Abdin, & Vaingankar, 2012; Hassan, Hassan, and Kassim, 2018) while anxiety disorders were the sixth leading cause of GBD (Baxter, Scott, & Ferrari, 2014). The term 'CMD' therefore, depicted the two most common

mood disorders that are prevalent among the general population.

The National Health Morbidity Survey (NHMS) by the Malaysia Ministry of Health reported that the prevalence of Generalized Anxiety Disorder (GAD) and Major Depressive Disorder (MDD) among adults were 1.7% and 2.4% respectively (Ministry of Health Malaysia, 2017). In the primary care settings in Malaysia, it is estimated that the comorbidity of depression and anxiety symptoms ranges from 6.7 to 14.4% (Abdul Khaiyom, Mukhtar, & Oei, 2019; Mukhtar & Oei, 2011). With the relatively high percentage reported, it has been increasingly recognized that CMD is a common mental health conditions that impacted the public health community.

### *Utilization of Primary Care System*

Primary care is defined as the health care center for the delivery of integrated and accessible health care services (American Psychological Association, 2016). It includes providing the first line of treatment and cares for individuals with mental health issues, including CMD (American Psychological Association, 2016). Nevertheless, research reported that CMD can be overlooked by the general practitioners in the primary care setting due to the masked symptoms of physical and psychosomatic complaints of their conditions (World Health Organization, 2018). This condition can affect the individual to worsened their mental health due to early unrecognized signs and symptoms (Kutcher, Wei, & Coniglio, 2016).

The integration of mental health services to primary care has been encouraged by the World Health Organization (2011) and World Health Organization (2018) to improve the accessibility and availability of mental health care. Nevertheless, Seekles, Cuijpers, and Kok (2009) reported that the prospect of having primary care attendees who were 'filtered out' or not being referred from the primary care level to the tertiary care (i.e., psychiatric, and psychological services) can be high (World Health Organization, 2018) due to various factors such as poor mental health literacy (Cross & Hickie, 2017). Somatic symptoms reporting and presentation by the primary care attendees can be common at the primary care level, especially for individuals with mild- to moderate- levels of CMD, which exacerbates the unseen mental health issue that requires targeted psychiatric or psychological treatments (McCaffrey, Chang, Farrelly, Rahman, & Cawthorpe, 2017). Therefore, a targeted community mental health service as suggested by the World Health Organization (2011 & 2018) in the primary care are essential steps to allow for individuals with undetected mental health conditions to have a proper care pathway (Cross & Hickie, 2017; Ho, Yeung, Ng, & Chan., 2016).

### *Brief Cognitive Behaviour Therapy*

Studies have found that the psycho-educational brief Cognitive Behavioral Therapy (b-CBT) is able to function as a psychological evidenced-based intervention in addressing mild- to moderate- level of psychological conditions such as individuals with CMD (Brown & Cochrane, 1999; Gaynor & Brown, 2012). The b-CBT sessions has shown moderate to strong empirical support for treating CMD (Cape, Whittington, Buszewicz, Wallace, & Underwood, 2010; Christensen, Griffiths, Mackinnon, & Brittliffe., 2006; Mignogna, Hundt, Kauth, Kunik, Sorocco, Naik, et al., 2014). The structured b-CBT sessions for one-to-one psychotherapy has shown an effect size of 0.33 to 1.06 for depression and anxiety, respectively (Brown & Cochrane, 1999; Gaynor & Brown, 2012). In the b-CBT sessions, the content of the sessions includes psycho-education, behavioral activation, cognitive identification, thought challenging,

identification of cognitive distortions, and problem-solving (Cully & Teten, 2008). These techniques and skills can lead to psychotherapeutic interaction, allowing the individual to recognize, aware, and subsequently utilize self-management techniques to manage their emotions and behaviors (Cape et al., 2010).

### *B-CBT Workshop*

Studies have found positive results from utilizing CBT techniques with a workshop-based format or group format in the management of anger (Mignogna et al., 2014), sleep(Illman & Brown, 2016), and stress (Brown & Cochrane, 1999) previously. As anger, sleep, and stress are common emotional and physical conditions of CMD, the structured approach in b-CBT workshop appeared to be able to address targeted symptoms of CMD such as managing distressing emotions, building awareness of the problems, and learning a set of skills to manage one's problem faced (Mignogna et al., 2014).

In Malaysia, utilization of b-CBT workshop for the primary care setting has not been conducted thus far. To minimize resource and achieving high volume of reach to the primary care attendees (World Health Organization, 2017), the b-CBT workshop in the primary care level can address the needs of the setting and individuals who attends the primary care clinics.

Cully and Teten (2008) indicated that the implementation of b-CBT has improved CMD symptoms among individuals with a medical illness. Results in this study showed that participants whom obtained an average of 4 sessions of the b-CBT showed improved depression ($d$ = 0.33) and anxiety symptoms ($d$ = 0.37), with maintained effects at 8 and 12 months interval (Cully & Teten, 2008). The integrated b-CBT was concluded to be acceptable for participants as well as providers in the primary care setting (Cully et al., 2008).

### *Integration of Psychological Services to Primary Care*

The necessity to integrate psychological services to the primary care setting in long run can assist with improving the provision of services, planning, and implementation of strategies for the prevention of mental disorders, as well as reducing stigma, and discriminations (Brown & Cochrane, 1999; Li, Li, Thornicroft, & Huang, 2014; World Health Organization, 2011). Upscaling primary healthcare workers to apply psychosocial and behavioral skills to reduce CMD can address and target challenges and barriers to help-seeking, and other resource-intensive factors that could address and complement the gaps in the existing mental health system in Malaysia (Ministry of Health Malaysia (2017); World Health Organization (2018).

## Method

### *Study Intervention*

A b-CBT intervention is typically delivered over 4 to 8 weekly structured face-to-face sessions (Mignogna et al., 2014). It aims to identify thoughts and behaviors that contribute to distressing emotions, creating awareness of problems, and learning a set of skills to manage one's issue (Beck & Beck, 2019). In a b-CBT workshop, the modules in the b-CBT can be compressed to a 4-hour workshop, in group format from the traditional b-CBT intervention manual (Cully et al., 2008). The identification of module content for the b-CBT workshop will be extracted from the b-CBT manual from Cully and Teten (2008). The workshop will consist of short lectures on selected topics, in-session practices, and discussions. Based on a search procedure to identify published research examining the effects of b-CBT on adults with CMD from seven electronic databases: Scopus, PubMed, ScienceDirect, PsycArticles, MEDLINE Complete, Ebscohost, and SAGE, the keywords such as common

mental disorders, depression, anxiety, cognitive behavior therapy, and brief cognitive behavior therapy were included. The study framework has four main domains of interventions addressing the four issues from past literatures (Brown et al., 1999; Brown et al., 1999; Mignogna et al., 2014). The issues identified were (1) need for early intervention to address high prevalence of CMD; (2) need to use psychological evidenced-based approach; (3) need for awareness and recognition of symptoms of CMD; and (4) reduction of stigma and discrimination. The four main domains of intervention in addressing the issues are (1) access to the primary care level for early intervention; (2) using a validated evidenced-based approach that can be integrated and implemented in the primary care setting; (3) using psycho-education approach in the evidenced-based psychological intervention; and (4) using non-stigmatizing publicity to attract primary care attendees to attend. Table 1 indicates the framework for the study intervention.

*Table 1*
Framework for the study intervention

| **Issues identified** | **Domains of intervention** | **Proposed intervention** | **Aim of intervention** | **Expected outcomes** |
|---|---|---|---|---|
| Early intervention | Access in the primary care level | b-CBT | Recognition and self-help | Remissions of symptoms |
| Evidenced-based approach | Validated and reliable approach (CBT) | b-CBT | Recognition and self-help | Remissions of symptoms |
| Low MHL affects the efficiency of primary care attendees | Psycho-education | b-CBT | Targets recognition, self-help, and resources | Early identification and self-management |
| Stigma | Non-stigma/ non-medical publicity | Psycho-education | Awareness and recognition | Early identification and self-management |
| Volume of attendees | Accessibility | Large-scale workshop | Promote accessibility | Low cost, and a high volume of attendees |

*B-CBT workshop module development*

The extraction of the six components from Cully et al., (2008) include (1) psychoeducation on CMD; (2) thoughts challenging and maladaptive thought patterns; (3) cognitive distortions; (4) goal setting; (5) problem-solving skills; (6) behavioral activation.

In the study, the b-CBT workshop will start with general introduction from the facilitator and each participants on their name, age, and occupational background. The facilitator will follow a b-CBT workshop manual developed from the six components identified. The workshop module will begin with psychoeducation about the symptoms of depression and anxiety and the concept of cognitive triad

from CBT. Then, participants will learn about identification of negative automatic thoughts and thought challenging. The participants will follow with understanding the types of cognitive distortions and some basic problem-solving skills (i.e., the pros and cons table), and lastly behavioral activation (i.e., deep breathing). The entire session will allow participants to engage in structured discussion and practices facilitated by a facilitator.

Face and content validities on the proposed intervention will be examined through discussions with a group of expert panels including six clinical psychologist, one psychiatrist, and one family medicine specialist. Then, the study intervention will be piloted with a minimum of 10 participants from the primary care population. Revision and refinement of the intervention content will be made based on comments and suggestions from the group of expert panels and participants from the pilot study. Table 2 displays the mapping of b-CBT to outcome variables.

*Table 2*
*Mapping of b-CBT intervention module to outcome variables*

| **Session** | **Outcome variables** | |
|---|---|---|
| | Depression | Anxiety |
| Session 1:Psychoeducation on CMD | ✓ | ✓ |
| Session 2: Thought challenging and maladaptive thought patterns | ✓ | ✓ |
| Session 3: Cognitive distortions | ✓ | ✓ |
| Session 4: Goal setting | ✓ | ✓ |
| Session 5: Problem-solving skills | ✓ | ✓ |
| Session 6: Behavioral activation | ✓ | ✓ |

***Enhanced Usual Care Control Group***

Participants from the enhanced-usual-care (EUC) control group will receive the usual care that is provided to adults with CMD in the primary care setting. They will be attending a pharmacist's 2-hour lecture on medications that are important to address the CMD symptoms. The participants will be allowed to participate, maintain, or discontinue of the intervention at any point of the intervention duration. There will be no reinforcement or token of appreciation for participating in the treatment. Participants will be informed on the importance of obtaining treatment from the sessions. The participants from the EUC control group will receive an invitation to participate in the b-CBT workshop upon completion of data collection.

***Study Design***

This is a quasi-experimental, non-randomized, pre-post intervention study design, with a control group. A non-randomized approach will be used as the field study in the primary care setting may not be feasible to have adequate participants to complete randomization at the point of registration for the study intervention (Bemme & Kirmayer, 2020). When the participant number registered is amounted to a minimum of 6 participants, then the group session will be conducted. The control group and intervention group will take turn after each succession of the group session full accumulation. The intervention group and EUC control group will be assessed at baseline (T1), immediate post-intervention (T2), and one-month follow-up (T3).

***Study Population***

The study population will be primary care attendees aged 18 and above, has mild- to moderate- level of CMD assessed from the Depression, Anxiety, and Stress Scale-21 (DASS-21) (Lovibond & Lovibond, 1995), and has a history of attending any primary care clinics in the district of Hulu Langat, Selangor during the study period. Participants will be recruited at the registration counter of the primary care clinics using instruments (i.e., DASS-21) to screen for inclusion criteria.

Hulu Langat district in Selangor has been selected as the study as it is a mixture of an urban and sub-urban community. There are 14 primary care clinics in the district (Ministry of Health Malaysia, 2011). The location of the primary care clinics was also around the catchment area of tertiary mental health services, such as Hospital Kajang.

### *Sample Size*

The sample size estimation is based on the calculation from G*power (Faul, 2007). The total required number of participants for each group (intervention and EUC control group) will be 35. The present study expects a 20% attrition rate, therefore a sample size of 42 participants per group is needed. The total number of participants for both groups will be 84 participants. Figure 1 shows the participants recruitment and allocation flow chart using the TREND reporting guidelines for quasi-experimental design.

### *Inclusion and Exclusion Criteria*

The DASS-21 will be employed to identify prospective participants at the registration counter of the primary care clinics in Hulu Langat. Based on the inclusion criteria, participants must fulfill the cut-off score from mild to moderate condition of depression and/or anxiety. If participants fulfill the criteria of severe depression and/or anxiety, they will be referred to the psychiatric clinic nearby.

The exclusion criteria for the study includes participants who are screened and self-report that they have severe level of depression and/or anxiety and/or having severe psychiatric disorder and/or cognitive impairments (i.e., intellectual disability, schizophrenia, delusional disorder, and others).

### *Sampling Method*

A non-probability purposive sampling will be used as the participants must fulfill the criteria of having mild to moderate CMD symptoms. They must also be primary care attendees in the primary care clinics in Hulu Langat, Selangor.

### Instruments

The original 42-item DASS from Lovibond and Lovibond (1995) was modified to a 21-item. The DASS-21 has several reliability and validity published worldwide, including Malaysia (Musa, 2007; Nordin et al., 2017). The DASS-21 is a well-established instrument to measure symptoms of depression, anxiety, and stress in samples of adults (Antony et al., 1998) The Malay version of the DASS-21 (Lovibond & Lovibond, 1995) will be used to measure the symptoms of CMD as the national language of Malaysia is Malay Language.

The items that measure depression and anxiety will be extracted and used in the study. Only 14 self-reported items that measure depression and anxiety from the 21-items in DASS-21 will be used in the study. The DASS-21 has 4-point Likert scale ranging from 0 (Did not apply to me at all), 1 (Applied to me to some degree, or some of the time), 2 (Applied to me to a considerate degree or a good part of time), and 3 (Applied to me very much or most of the time) over the past week from the point of measurement (Lovibond et al., 1995).

### *Sociodemographic Information*

Sociodemographic information (e.g., gender, age, ethnicity, education level, income level, and marital status) will be collected for descriptive purposes.

### *Ethical Considerations*

The study was approved by the Ethics Committee for Research Involving Human Subject obtained from Universiti Putra Malaysia and the Malaysia Research Ethics Committee (MREC). Information sheet and consent form will be given to the participants involved in the study. Briefing on the intervention provided in the information sheet will be given. The participants will be able to have an informed discussion with the researcher team before the intervention began. Written consent from the participants who are willing to participate in the study will be obtained.

All the study-related materials (i.e., consent form and questionnaires) will be coded with an ID number to maintain participant's confidentiality. Information that contains personal identifiable information will be stored separately. Only group data will be released during publications.

### *Study Procedures*

Participants who fulfilled the criteria of mild to moderate level of CMD will be encouraged to attend the workshop titled "Stress Management Workshop". This title is used to achieve de-stigmatization of mental health as suggested by Brown et al., (2016). Participants can register themselves for the workshop via e-mail, social media, website, phone call, phone short message service (SMS), phone Whatsapp message, or a hardcopy list that will be placed at the main reception of each primary care clinics.

When participants register for the workshop, they will be screened again for the eligibility to the study. They will be informed of the intervention date.

Baseline measurement (T1) using DASS-21 will be obtained when participants attends the workshop,. Then, post-intervention (T2) measurements and one-month follow-up (T3) will be obtained using the same questionnaire.

The b-CBT workshops will be conducted by a professional clinical psychologist, using a b-CBT workhop manual prepared for the study. The manual is based on the b-CBT manual after modifications in the development process. In the session, four researcher team members will be present to assist with logistic and administration procedures.

## Data Analysis

Data will be analyzed using the IBM Statistical Package for the Social Sciences (SPSS) version 27 (IBM, Armonk, NY, USA). To assess the mean difference of the outcome measurements at three time-points (i.e., T1, T2, and T3), the multivariate analysis of covariance (MANCOVA) will be employed. Pairwise comparisons will be conducted to examine the specific differences between the groups when necessary.

## Discussion

The study will have theoretical and practical implementations as well as suggestions for policy development. With regards to theoretical implications, the study outcome is expected to identify specific theoretical approaches that can be helpful in improving the primary care attendee's CMD conditions (Beck & Beck, 2019). By utilizing the skills and techniques from the b-CBT workshop, the attendees are expected to benefit from self-management techniques when they have emotional issues (Brown et al., 1999). As for practical implications, the study is expected to be able to inform prevention programs such as psychoeducation, brief interventions, and awareness campaigns that are important to address CMD conditions. Upscaling of mental health

services can be important in a fast and busy setting to address high volume of attendees that may not have proper access to care (World Health Organization, 2011; World Health Organization, 2018). Lastly, findings are also anticipated to provide insight into the policy development in the country. Adaptation of evidence-based psychological intervention as a potential approach in changing and alleviating symptoms of CMD can reduce the burden of disease in the country. The study also follows the suggestions from the World Health Organization (2017 and 2018) in making psychological services and resources more available at the primary care level to ease frequent visits of primary care attendees due to targeted treatments (Brown et al., 1999).

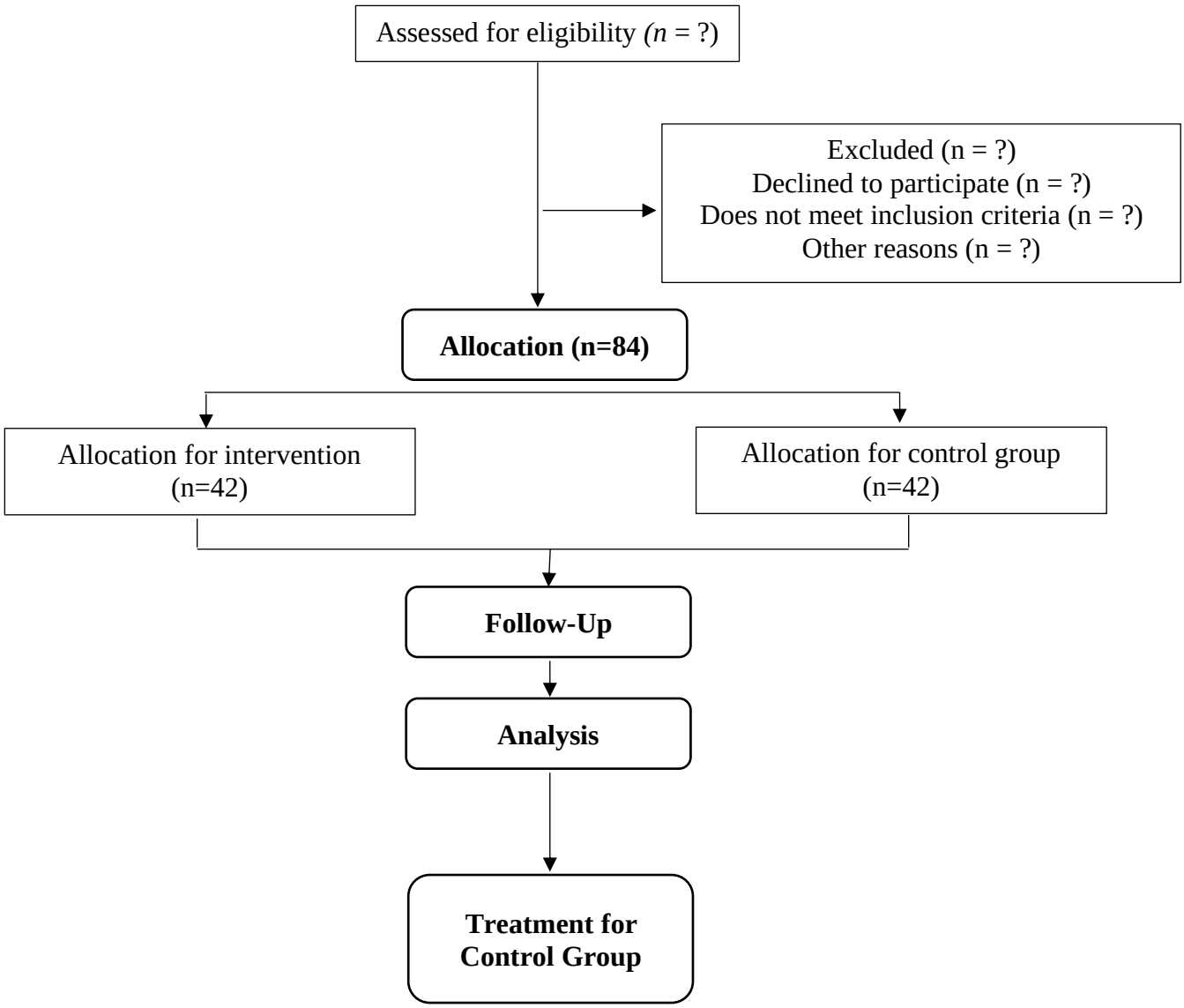


*Figure 1* Transparent reporting of evaluations with nonrandomized designs (TREND) flow chart

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