



UNIVERSITI PUTRA MALAYSIA

***DETERMINATION OF THE EFFECTIVENESS OF UNIFIED GROUP
COGNITIVE BEHAVIOUR THERAPY FOR PATIENTS WITH
HETEROGENEOUS ANXIETY DISORDERS IN KLANG
VALLEY, MALAYSIA***

JAMILAH HANUM BINTI ABDUL KHAIYOM

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By

JAMILAH HANUM BINTI ABDUL KHAIYOM



**Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia,
in Fulfillment of the Requirements for the Degree of
Doctor of Philosophy**

February 2017

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DEDICATION

To all my patients with anxiety disorders,
may we continuously strive to live in the present.

“Men are disturbed, not by things, but by the view which they take of them.”

Epictetus – Greek Stoic Philosopher



Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfillment
of the requirement for the Degree of Doctor of Philosophy

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February 2017

Chairman : Associate Professor Firdaus Binti Mukhtar, PhD
Faculty : Medicine and Health Sciences

The prevalence rate of anxiety disorders both globally and in Malaysia has increased for the past decade. However, many patients with anxiety disorder remain under-treated or untreated. Based on the literature review, the problems were rooted in poor treatment delivery on this disorder (i.e., poor dissemination of treatments to the clinicians and limited availability of treatments for patients). Therefore, current study intended to provide solutions to this problem. There are two phases of study. Phase 1 involved the validation of measures used. While Phase 2 evaluate the effectiveness of Unified Group Cognitive Behaviour Therapy as an adjunct to pharmacological treatment (Treatment-As-Usual) (Group CBT+TAU) for patients with heterogeneous anxiety disorders in Klang Valley, Malaysia.

Patients diagnosed with heterogeneous anxiety disorders ($N=242$) were randomly allocated to receive either Unified GCBT+TAU ($n=81$), or Group Relaxation Training (GRT)+TAU ($n=81$), or TAU alone ($n=80$). The Unified GCBT+TAU and GRT+TAU consisted of eight and seven sessions, respectively. The primary outcome measure was the Beck Anxiety Inventory-Malay. The secondary outcome measures consisted of other symptom measures of anxiety (PAS-Malay and FQ-Malay), catastrophic cognition measures (CCQ-Modified-Malaysia and ACQ-Malaysia), a quality of life measure (WHOQOL-BREF-Malay), and a symptom measure of depression (Beck Depression Inventory-Malay). All the measures were validated in terms of its construct and its criterion prior to be used in the study. The participants completed the questionnaire battery at pre-treatment (week 0), middle of the treatment (week 4), post-treatment (week 8), and follow-ups (1-month, 3-month, and 6-month after the treatment).

General linear model (i.e., repeated measures MANOVA and mixed ANOVA) and an intention-to-treat with last observation carried forward model was used for data analyses. Participants receiving Unified GCBT+TAU improved more significantly and at a faster rate than the GRT+TAU group and TAU group. The effect size (Cohen's d) of the Unified GCBT+TAU group for the primary outcome measure was 1.61, ranging from 0.98 to 1.30 for the other secondary outcome measures. Meanwhile, the effect size of the GRT+TAU group for the primary outcome measure was 0.70, ranging from 0.12 to 0.54 for the other secondary outcome measures. On the other hand, the effect size of the TAU group for the primary outcome measure was 0.09, ranging from 0.02 to – 0.28 for the other secondary outcome measures. Furthermore, 70.1% and 36.7% of the participants receiving Unified GCBT+TAU and GRT+TAU, respectively, experienced either reliable or clinically significant change. Meanwhile, none of the participants in the TAU group experienced any reliable or clinically significant change from pre-treatment to post-treatment.

The findings suggest that Unified GCBT, when used in addition to TAU, is faster and more effective in reducing symptoms of anxiety disorders, decreasing catastrophic cognitions, increasing the quality of life, and reducing comorbid symptoms of depression among the patients with anxiety disorders in Klang Valley, Malaysia, when compared to GRT+TAU and TAU alone.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai
memenuhi keperluan untuk Ijazah Doktor Falsafah

**PENGESAHAN KEBERKESANAN TERAPI KOGNITIF TINGKAH LAKU
BERSEPADU SECARA BERKUMPULAN BAGI PESAKIT-PESAKIT
GANGGUAN KEBIMBANGAN DI LEMBAH KLANG, MALAYSIA**

Oleh

JAMILAH HANUM BINTI ABDUL KHAIYOM

Februari 2017

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Fakulti : Perubatan dan Sains Kesihatan

Kadar kelaziman gangguan kebimbangan di peringkat global mahupun Malaysia telah meningkat sejak sedekad yang lalu. Walau bagaimanapun, ramai pesakit yang mengalami gangguan kebimbangan tidak dapat mendapat rawatan yang sewajarnya. Berdasarkan kajian literatur yang dijalankan, masalah ini berakar umbi daripada kelemahan dalam penyampaian rawatan. Oleh kerana yang demikian, kajian ini bertujuan untuk memberikan penyelesaian kepada masalah ini. Terdapat dua fasa di dalam kajian ini. Fasa pertama melibatkan pengesahan skala yang digunakan. Manakala fasa kedua bertujuan mengesahkan keberkesanan Terapi Kognitif Tingkah Laku Bersepadu Secara Berkumpulan sebagai rawatan tambahan kepada rawatan farmakologi (Rawatan-Seperti-Biasa) (*Group CBT+TAU*) untuk pesakit-pesakit yang mengalami gangguan kebimbangan di Lembah Klang, Malaysia.

Pesakit yang didiagnos dengan gangguan kebimbangan heterogen ($N=242$) telah ditempatkan secara rawak untuk menerima sama ada *Unified GCBT+TAU* ($n=81$), atau *GRT+TAU* ($n=81$), atau *TAU* ($n=80$). *Unified GCBT+TAU* dan *GRT+TAU* masing-masing terdiri daripada 8 sesi dan 7 sesi. Skala penilaian utama adalah soal selidik *BAI-Malay*. Manakala skala penilaian sekunder adalah terdiri daripada soal selidik lain yang berkaitan dengan gejala kebimbangan (iaitu, *PAS-Malay* dan *FQ-Malay*), soal selidik pemikiran malapetaka (*CCQ-Modified-Malaysia* dan *ACQ-Malaysia*), soal selidik kualiti kehidupan (*WHOQOL-BREF-Malay*), dan soal selidik gejala kemurungan (*Beck Depression Inventory-Malay*). Semua skala telah disahkan dari sudut konstruk dan kriteria sebelum diguna pakai dalam kajian ini. Peserta kajian menyelesaikan semua soal selidik yang dinyatakan pada tempoh pra-rawatan (minggu 0), pertengahan rawatan (minggu ke-4), selepas rawatan (minggu ke-8), dan ketika tempoh penilaian susulan (1 bulan, 3 bulan, dan 6 bulan selepas rawatan).

Model *general linear* (iaitu *repeated measures MANOVA and mixed ANOVA*) dan model *intention-to-treat with last observation carried forward* telah digunakan untuk analisis data. Peserta yang menerima *Unified GCBT+TAU* menjadi bertambah baik pada kadar yang lebih cepat dan signifikan daripada kumpulan *GRT+TAU* dan *TAU* sahaja. Saiz kesan (Cohen *d*) kumpulan *Unified GCBT+ TAU* pada hasil penilaian utama adalah 1.61, manakala saiz kesan untuk hasil penilaian sekunder adalah antara 0.98-1.30. Sementara itu, saiz kesan untuk kumpulan *GRT+TAU* untuk hasil penilaian utama adalah 0.70, manakala saiz kesan untuk hasil penilaian sekunder adalah antara 0.12-0.54. Sebaliknya, saiz kesan untuk kumpulan *TAU* bagi hasil penilaian utama adalah 0.09, manakala saiz kesan untuk hasil penilaian sekunder adalah antara 0.02 hingga -0.28. Disamping itu, 70.1% dan 36.7% daripada peserta-peserta yang menerima *Unified GCBT + TAU* dan *GRT + TAU*, masing-masing, mengalami perubahan positif yang boleh dipercayai atau perubahan klinikal yang signifikan. Sementara itu, tidak ada peserta dalam kumpulan *TAU* yang mengalami apa-apa perubahan positif yang dipercayai atau perubahan klinikal yang signifikan di antara tempoh pra-rawatan dan pasca-rawatan.

Kajian ini mencadangkan bahawa *Unified GCBT*, apabila digunakan sebagai tambahan kepada *TAU*, lebih cepat dan lebih berkesan mengurangkan gejala gangguan kebimbangan, mengurangkan pemikiran malapetaka, meningkatkan kualiti hidup, dan mengurangkan gejala-gejala kemurungan sampingan di kalangan pesakit-pesakit psikiatri yang mengalami gangguan kebimbangan di Lembah Klang, Malaysia, jika dibandingkan dengan *GRT+TAU* dan *TAU* sahaja.

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I certify that a Thesis Examination Committee has met on 6 February 2017 to conduct the final examination of Jamilah Hanum binti Abdul Khaiyom on her thesis entitled "Determination of the Effectiveness of Unified Group Cognitive Behaviour Therapy for Patients with Heterogeneous Anxiety Disorders in Klang Valley, Malaysia" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the Doctor of Philosophy.

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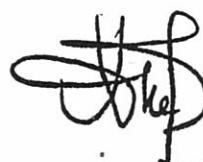
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LIST OF ABBREVIATIONS

| | |
|--------------------|--|
| ACQ-Malaysia | Agoraphobic Cognitions Questionnaire-Malaysia |
| AD | Anxiety disorders |
| Agora | Agoraphobia |
| BAI-Malay | Beck Anxiety Inventory-Malay |
| BDI-Malay | Beck Depression Inventory-Malay |
| BT | Behaviour therapy |
| BZD | Benzodiazepines |
| CBT | Cognitive Behaviour Therapy |
| CC | Clinical change |
| CCQ-Modified-Malay | Catastrophic Cognitions Questionnaire-Modified-Malay |
| CPG | Clinical Practice Guideline |
| DSM-IV-TR | Diagnostic and Statistical Manual of Mental Disorders (4 th ed.) –Text Revision |
| DSM-5 | Diagnostic and Statistical Manual of Mental Disorders (5 th ed.) |
| ES | Effect size |
| FQ-Malay | Fear Questionnaire-Malay |
| GAD | Generalized anxiety disorder |
| ITT | Intention-to-treat analysis |
| MAOIs | MAO inhibitors |
| MOH | Ministry of Health |
| NasSA | Noradrenergic and specific serotonergic antidepressant |
| PAS-Malay | Panic Agoraphobia Scale-Malay |
| PD | Panic disorder |
| PPA | Per-protocol analysis |

| | |
|-------------------|--|
| RC | Reliable change |
| RCT | Randomized controlled trial |
| RT | Relaxation Training |
| SAD | Social anxiety disorder |
| SP | Specific phobia |
| SNRIs | Serotonin-norepinephrine reuptake inhibitors |
| SSRIs | Selective serotonin reuptake inhibitors |
| TCA | Tricyclic antidepressants |
| USA | The United States of America |
| WHO | The World Health Organizations |
| WHOQOL-BREF-Malay | World Health Organization Quality of Life-BREF-Malay |
| WMH | The World Mental Health |

CHAPTER 1

INTRODUCTION

1.1 Background

Anxiety disorders (AD) has emerged as one of the most common mental illness exists around the world (Steel et al., 2014). The evidence was clear when the World Health Organizations (WHO) considered AD as one of the core disorders should be assessed in the World Mental Health (WMH) surveys apart from mood disorders and substance use disorders (Kessler et al., 2009). Based on meta-analytic reviews of 202 studies from 94 countries globally, the lifetime prevalence of AD was found to range in between 12.9% and 16.6%. In other words, about one in eight people to one in six people will experience an anxiety disorder in their lifetime (Somers et al., 2006; Steel et al., 2014). In the United States of America (USA), AD represents the single largest mental health problem with 18.1% prevalence rate (Kessler et al., 2005) and more than 19 million American adults having an anxiety disorder in a given year (National Institute of Mental Health (NIMH), 2005).

Apart from having high prevalence rate, AD (i.e., panic disorder, agoraphobia, social anxiety disorder, and social phobia) is also characterized by early age of onset (Kessler et al., 2005). The disorder is associated with the development of other psychiatric comorbidity particularly among ADs and depressive disorders (Brown et al., 2001), and has a prolonged chronic course with high relapse (Penninx et al., 2011). Due to its chronic nature, patients with AD tend to have poor quality of life (Olatunji, Cisler, & Tolin, 2007) and significant impairments in their roles functioning (i.e., social, family, and work) (Alonso et al., 2011; Hoffman, Dukes, & Wittchen, 2008; Senaratne et al., 2010). Furthermore, AD with other psychiatric comorbidity are also associated with increased risks of suicidal ideation, suicide attempts and completed suicide (Allan et al., 2015; Bentley et al., 2016; Kanwar et al., 2013).

However, mortality alone does not give a complete picture of the burden of disease borne by individuals in different population. The disability-adjusted life year (DALY) is a measure to calculate the overall disease burden, expressed as the number of years lost due to ill-health, disability, or early death. Using DALYs, the burden of disease that cause premature death but little disability (such as drowning or measles) can be compared to that of diseases that do not cause death but do cause disability (such as cataract causing blindness). One DALY represents the loss of the equivalent of one year of full health (WHO, 2017). According to Baxter and colleagues (2014), AD accounted for 390 DALYs per 100 000 persons in 2010, globally, with no distinct changes observed over time. Furthermore, AD is the sixth leading cause of disability (in terms of years of life lived with disability), in both high-income and low- and middle-income countries. (Baxter et al., 2014). Regarding gender, females accounted for 65% of the DALYs caused by AD, with the highest

burden in both men and women experienced by those aged between 15 and 34 years (Baxter et al., 2014).

The burden of AD was also reported in the increase of economic cost since 2005. In 2010, € 74.4 billion Euros was spent in Europe, which has been the second highest expenditure after mood disorder (Olesen, Gustavsson, Svensson, Wittchen, & Jönsson, 2012). The high economic cost owing to lost work productivity and high medical resource use (Hoffman, Dukes, & Wittchen, 2008). Apart from the economic burden, the social implications of AD is diverse and far-reaching. For example, AD is associated with lack of education and income-generation opportunities, limiting their chances of economic development and depriving them of social networks and status within a community (World Health Organization, 2011).

1.2 Statement of the Problem

Despite the size, burden, and costs of AD, many patients remain under-treated or untreated. Even if they were treated, the standard of evidence-based interventions in routine clinical practice could be disappointing (Baldwin et al., 2010).

Early and effective interventions can reduce the burden of AD (Baldwin et al., 2010), especially with the use of evidence-based psychological treatment such as group cognitive behaviour therapy (group CBT) which has been recommended as the first-line psychological treatment for AD (Baldwin et al., 2014; Katzman et al., 2014; MOH Singapore, 2015; National Institute for Health and Care Excellence, 2011; The Australian Psychological Society, 2010).

Despite the above, patients suffer from AD remain under-treated or untreated (Baldwin et al., 2010). Apart from minimal supports and lack of recognitions for psychological treatments for AD by Malaysia government, the barriers to the psychological treatment of AD were rooted from poor treatment delivery (i.e., dissemination of treatments to the clinicians and limited availability of treatments for patients). Norton and Philipp (2008) clearly argued that the poor dissemination of efficacious treatments be due to time and financial costs to teach and preparing clinicians for specific-diagnosis treatment procedures (e.g., group cognitive behaviour therapy for panic disorder). Even if the clinicians were ready to deliver effective treatments in a group format (i.e., less cost of involved), the issue of treatments availability persists due to the number of patients need to constitute a therapy group with the same diagnosis.

Looking at the growing number of patients with AD in Malaysia and the problem of very minimal number of mental health experts (Abdul Wahab Khan, 2008; Deva, 2004; Ng, 2012) to conduct group CBT for specific diagnosis of AD, current study aims to address the issue by evaluating the use of Unified Group CBT for heterogeneous AD.

1.3 Objective of the Study

The general objective for this study is to determine the effectiveness of Unified Group Cognitive Behaviour Therapy as an adjunct to pharmacotherapy among patients with heterogeneous AD.

The specific objectives of the study are:

1. To determine the effectiveness of a Unified Group Cognitive Behaviour Therapy+Treatment-As-Usual (Group CBT+TAU) (experimental group) for patients with heterogeneous AD compared to Group Relaxation Training+Treatment-As-Usual (Group RT+TAU) (comparison group) and Treatment-As-Usual (TAU) alone (control group) in reducing the symptoms of anxiety during mid-intervention, after the intervention, and at follow-up periods (i.e., 1-month, 3-month, and 6-month after intervention) in Klang Valley, Malaysia.
2. To determine the effectiveness of a Unified Group CBT+TAU for patients with heterogeneous AD compared to Group RT+TAU and TAU alone in reducing the catastrophic cognitions during mid-intervention, after the intervention, and at follow-up periods (i.e., 1-month, 3-month, and 6-month after intervention) in Klang Valley, Malaysia.
3. To determine the effectiveness of a unified Group CBT+TAU as an intervention programme for adult psychiatric patients with heterogeneous AD compared to Group RT+TAU and TAU alone in increasing the quality of life during mid-intervention, after the intervention, and at follow-up periods (i.e., 1-month, 3-month, and 6-month after intervention) in Klang Valley, Malaysia.
4. To determine the effectiveness of a unified Group CBT+TAU as an intervention programme for adult psychiatric patients with AD compared to Group RT+TAU and TAU alone in reducing the comorbid depressive symptoms during mid-intervention, after the intervention, and at follow-up periods (i.e., 1-month, 3-month, and 6-month after intervention) in Klang Valley, Malaysia.

1.4 Research Hypotheses

The research hypotheses for the current study are:

1. The Unified Group CBT+TAU is more effective than Group RT+TAU and TAU alone in reducing the symptoms of anxiety among patients with heterogeneous AD, in the middle of intervention, after the intervention, and at follow-up periods. Same as the above, Group RT+TAU is more effective than TAU alone.

2. The Unified Group CBT+TAU is more effective than Group RT+TAU and TAU alone in reducing the catastrophic cognitions, in the middle of intervention, after the intervention, and at follow-up periods. Same as the above, Group RT+TAU is more effective than TAU alone.
3. The Unified Group CBT+TAU is more effective than Group RT+TAU and TAU alone in increasing the quality of life, in the middle of intervention, after the intervention, and at follow-up periods. Same as the above, Group RT+TAU is more effective than TAU alone.
4. The Unified Group CBT+TAU is more effective than Group RT+TAU and TAU alone in reducing the comorbid depressive symptoms, in the middle of intervention, after the intervention, and at follow-up periods. Same as the above, Group RT+TAU is more effective than TAU alone.

1.5 Significance of the Study

Since the Unified Group CBT for patients with heterogeneous AD is relatively new, the results of the current study would be essential for the body of knowledge related to this treatment. Not to mention, the current study has taken into considerations the limitations of the methodology for previous studies to bridge the presence of gaps.

The use of Unified Group CBT+TAU for heterogeneous AD would benefit patients with AD to receive treatments in a more reasonable time. Moreover, through group discussions, they could learn from other team members, increase social support systems, and would have the opportunity to recognize common experiences shared.

The treatment protocol of Unified Group CBT was designed not only to reduce the symptoms of AD but also to reduce negative cognitions and depressive comorbidity symptoms. By reducing these elements, the treatment also would increase the quality of life of the patients. Furthermore, the components of treatment would prepare patients with knowledge about the nature of AD, skills related to the management of their anxiety symptoms and negative thoughts. Moreover, skills such as relaxation techniques, problem-solving, and relapse preventions would increase the chances of remission.

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