

# An efficacy study of modified dialectical behavioral therapy skill training program for alcohol addiction in Sabah

<b>Submission date</b> 01/10/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/10/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Dialectical behavioral therapy (DBT) is a method of psychotherapy and nonpharmacological treatment in the field of psychiatry and mental health problems. Many studies have shown that psychotherapy treatment is effective in the treatment of mental health issues. The DBT method is also effective in helping with stress problems in everyday life. DBT contains four components: mindfulness, interpersonal effectiveness, resilience, and emotion regulation. These four skills will help you either in the form of individual therapy or in the form of group therapy. It was found that addiction is closely related to the individual's stress level. The team is now conducting a study using DBT to help with alcohol use disorders in the population of Sabah. The aim of this study is to investigate the effectiveness of DBT skills training and its cultural adaptation to alcohol addiction in Sabah.

### Who can participate?

Patients aged 18-70 years old with an alcohol use disorder, able to speak and write Malay, currently actively using alcohol, with no serious medical or psychiatric illness, and not undergoing any forms of psychotherapy.

### What does the study involve?

If you agree to take part in this study, you will participate in a DBT therapy course together with other participants for 3 months. It will be a weekly hourly training session (total of 12 sessions, 1.5 hours per session) – the dates of the sessions will be allocated by the therapists and discussed with you later. You will receive phone calls between sessions for reinforcement training (reinforcement coaching). You will need to answer questionnaires and surveys before, 6th week, and after the training, then 1 month, and 3 months after the training sessions.

### What are the possible benefits and risks of participating?

There are neither severe side effects nor harmful risks. If you participate and fulfil the requirement, you receive logistic coverage from the research team for the sessions. The therapy may provide clinical benefits to you in addressing your stress and addiction issues. You will also help the study team to gain knowledge in the field of this study.

Where is the study run from?  
University of Malaysia Sabah (Malaysia)

When is the study starting and how long is it expected to run for?  
February 2024 to August 2024

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Thong Vie Cheong, thongvc@ums.edu.my

## Contact information

**Type(s)**  
Public, Scientific, Principal investigator

**Contact name**  
Dr Vie Cheong Thong

**Contact details**  
Pejabat Pengurusan, Aras 2 Blok A1  
Fakulti Perubatan dan Sains Kesihatan  
Universiti Malaysia Sabah  
Jalan UMS  
Kota Kinabalu  
Malaysia  
88400  
+60 (0)178998191  
thongvc@ums.edu.my

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
JKEtika 1/24 (12)

## Study information

**Scientific Title**  
Clinical trial for the efficacy of dialectical behavioral therapy skills training for alcohol use disorder in Sabah

**Study objectives**

There will be significant improvement in alcohol addiction severity post intervention

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 08/02/2024, Universiti Malaysia Sabah Medical Research Ethics Committee (Faculty of Medicine and Health Sciences, Universiti Malaysia Sabah, Jalan UMS, Kota Kinabalu, 88400, Malaysia; +60 (0)88320000; pejfpsk@ums.edu.my), ref: JKEtika 1/24 (12)

### **Study design**

Multicenter quasi-experimental study

### **Primary study design**

Interventional

### **Study type(s)**

Other, Efficacy

### **Health condition(s) or problem(s) studied**

Alcohol use disorder

### **Interventions**

Modified Dialectical Behavior Therapy (DBT) Skills Training Program: a weekly hourly training session (total of 12 sessions, 1.5 hours per session) – the dates of the sessions will be allocated by the therapists. Participants will receive phone calls between sessions for reinforcement training (reinforcement coaching) and will need to answer questionnaires and surveys before, 6th week, and after the training, then 1 month, and 3 months after the training sessions.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Alcohol addiction severity measured using the Addiction Severity Index at pre-, 6th week, post, and 1 month after intervention

### **Key secondary outcome(s)**

Coping skills measured using DBT- Ways of Coping Checklist at pre-, 6th week, post, and 1 month after intervention

### **Completion date**

08/08/2024

## **Eligibility**

### **Key inclusion criteria**

1. 18-70 years old
2. Active alcohol user
3. Alcohol Use Disorders Identification Test (AUDIT) score >8
4. Healthy without acute medical illness

- 5. Not undergoing any other psychotherapies
- 6. Able to read and write in Bahasa Melayu

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

70 years

**Sex**

All

**Total final enrolment**

20

**Key exclusion criteria**

- 1. Having acute medical or psychiatry illness requiring intervention
- 2. Not able to read/write in Bahasa Melayu

**Date of first enrolment**

20/02/2024

**Date of final enrolment**

01/03/2024

**Locations****Countries of recruitment**

Malaysia

**Study participating centre**

St Pius X Church

Kampung Bundu Tuhan

Ranau

Malaysia

89260

**Sponsor information**

**Organisation**

Universiti of Malaysia Sabah

**ROR**

<https://ror.org/040v70252>

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Dr Thong Vie Cheong ([thongvc@ums.edu.my](mailto:thongvc@ums.edu.my))

All information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, the subject's identity will not be revealed. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study may be archived for the purpose of analysis, but your identity will not be revealed at any time. With your permission your family doctor will be informed of your participation in the study.

All the results of this study will be treated in complete confidentiality to the extent permitted by law. The yield of this study shall be analyzed as a group of data and shall be given to Universiti Malaysia Sabah for research purposes if necessary and may be published or given to regulatory authorities of Malaysia.

The data will be kept available for at least period of 5 years for audit purposes.

**IPD sharing plan summary**

Stored in non-publicly available repository, Available on request