

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

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

Plain English Summary

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
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 hypothesis

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

Intentional

Secondary study design

Non randomised study

Study setting(s)

Community, University/medical school/dental school

Study type(s)

Other, Efficacy

Participant information sheet

Not available in web format

Condition

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 measure

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

Secondary outcome measures

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

Overall study start date

08/02/2024

Overall study end date

08/08/2024

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

20

Total final enrolment

20

Participant exclusion criteria

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

Recruitment start date

20/02/2024

Recruitment end date

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

Sponsor details

Pejabat Pengurusan, Aras 2 Blok A1

Fakulti Perubatan dan Sains Kesihatan

Universiti Malaysia Sabah, Jalan UMS

Kota Kinabalu

Malaysia

88400

+60 (0)88 32000 ext 611001

pejfpsk@ums.edu.my

Sponsor type

University/education

Website

<http://www.ums.edu.my/v5/>

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer peer-reviewed journal

Intention to publish date

01/01/2025

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)

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