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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

Registration date
02/10/2024

Overall study status
Completed

Last Edited
02/10/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

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)

Primary study design
Interventional

Study design
Multicenter quasi-experimental study

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)

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