

Cognitive behavioral therapy for adolescents with thalassemia in Selangor

Submission date 19/11/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/02/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Thalassemia is a disease where the individual does not produce enough haemoglobin, which can lead to a variety of symptoms including severe fatigue, anaemia, weakness and shortness of breath. Rates of anxiety and depression amongst thalassemia patients and their caregivers has significantly increased. This has been shown to lead to non-adherence towards blood transfusion and iron chelation therapies amongst adolescents with thalassemia. Cognitive behavioral therapy (CBT) is a therapy for the treatment of anxiety and depression that has been shown to be effective. The aim of this study is to look at the effectiveness of CBT to treat thalassemia-related anxiety and depression.

Who can participate?

People aged 13-17 years with thalassemia major

What does the study involve?

Patients will be randomly allocated to one of two groups, the intervention group or the control group. The intervention group will receive a course of CBT over 4 weeks, with one session per week, along with the usual treatment for thalassemia-related anxiety and depression. The control group will receive the usual treatment only. Questionnaires and tests will be completed before the intervention, just after the intervention and 1, 3 and 6 months afterwards.

What are the possible benefits and risks of participating?

Participants may or may not benefit from receiving CBT. The data obtained from this study will help to improve the treatment or management of other participants with the same disease or condition.

There are no known risks to participants taking part in this study. In the case of increased in severity of the symptoms of anxiety and/or depression at any time, patients will leave the study and their case will be managed accordingly.

Where is the study run from?

Four hospitals in Selangor, Malaysia:

1. Hospital Serdang
2. Hospital Ampang

- 3. Hospital Selayang
- 4. Hospital Tengku Ampuan Rahimah

When is the study starting and how long is it expected to run for?
December 2018 to May 2019

Who is funding the study?
Fakulti Perubatan dan Sains Kesihatan, Universiti Putra Malaysia (Malaysia)

Who is the main contact?
Dr. Dayangku Hayaty bt Awg Dzulkarnain
yatyadzul@gmail.com

Contact information

Type(s)

Public

Contact name

Dr dayangku hayaty dzulkarnain

Contact details

Department of Family Medicine, Faculty Of Medicine and Health Sciences, Universiti Putra
Malaysia, Serdang
selangor
Malaysia
43400

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

41010

Study information

Scientific Title

Efficacy of cognitive behavioral therapy on psychological and clinical parameters among
adolescents with thalassemia in Selangor: a randomized controlled trial

Acronym

CBT THALASSEMIA

Study objectives

1. Cognitive behavioral therapy (CBT) and treatment as usual (TAU) in comparison with treatment as usual (TAU) alone are superior in reducing anxiety and depression among adolescents with thalassemia at short and long-term treatment.
2. There is a significant difference between the effect of CBT and TAU in comparison with TAU alone in improving thalassemia knowledge, clinical parameters, satisfaction, adherence and persistence to iron chelation therapy treatment (SICT) and quality of life among adolescents with thalassemia
3. CBT and TAU in comparison with TAU alone at the 6 month follow-up is superior in increasing the response rate, remission or relapsed of anxiety and depression, and attrition to the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Medical Research Registration Malaysia (waiting for approval after study was revised twice on 26/10/2018), reference number NMRR-18-1311-41010

Study design

Interventional multi-center single-blinded randomised controlled parallel trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please email yatyadzul@gmail.com to request a participant information sheet

Health condition(s) or problem(s) studied

Thalassemia in the adolescent population

Interventions

Participants are randomly allocated to either the intervention or the control group using random number sequences.

The intervention group will receive cognitive behavioral therapy (CBT) and treatment as usual (TAU). CBT is administered by the primary investigator, with adequate training from an experienced clinical psychologist. The CBT is specifically designed for thalassemia-related anxiety and depression. Participants will receive CBT once per week for at least 45 minutes for 4 weeks. The CBT sessions will focus on biological and psychological aspects of thalassemia, treatment adherence and how to manage thalassemia-related anxiety and depression. The 4 week treatment period may be increased if necessary for scheduling purposes (for example, due

to holidays or examination periods) up to 8 weeks.

TAU is provided by the doctors at the day care center of Hospital Ampang, Hospital Selayang, Hospital Serdang and Hospital Tuanku Ampuan Rahimah, Klang, Selangor in their regular consultations. It consists of a face-to-face session with a duration of up to 15 minutes to assess psychological and physical complaints. Doctors will provide advice in this session.

The control group will receive TAU only.

For both groups, psychological and clinical parameters will be assessed at the baseline, at the end of the treatment, and 1, 3 and 6 months post-treatment.

Intervention Type

Behavioural

Primary outcome measure

Short and long-term effectiveness of cognitive behavioral therapy (CBT) and treatment as usual (TAU) compared to treatment as usual (TAU), assessed using the following at the baseline, immediately post-intervention, and 1, 3 and 6 months post-intervention:

1. Beck Anxiety Inventory (BAI)
2. Beck Depression Inventory (BDI)

Secondary outcome measures

The following are assessed at the baseline, immediately post-intervention, and 1, 3 and 6 months post-intervention:

1. Thalassemia knowledge, assessed using a questionnaire including:
 - 1.1. 5 items on general knowledge of thalassemia
 - 1.2. 10 items on knowledge of thalassemia major
 - 1.3. 6 items on knowledge of thalassemia minor
 - 1.7. 2 items on knowledge of prevention of thalassemia major
2. The following clinical parameters, collected by self-report from participants and through medical records:
 - 2.1. Age of first diagnosis
 - 2.2. Type of thalassemia
 - 2.3. Age of first blood transfusion
 - 2.4. Frequency of blood transfusion
 - 2.5. Age of first iron chelation therapy
 - 2.6. Type of chelation
 - 2.7. Number of siblings with thalassemia
 - 2.8. Latest pre-transfusion hemoglobin level
 - 2.9. Latest serum ferritin level
 - 2.10. Presence of hepatomegaly and splenomegaly
3. Satisfaction, assessed using the Satisfaction with ICT questionnaire (SICT)
4. Adherence, assessed using the Satisfaction with ICT questionnaire (SICT)
5. Persistence to iron chelation therapy treatment, assessed using the Satisfaction with ICT questionnaire (SICT)
6. Quality of life among adolescents with thalassemia, assessed using the PedsQL 4.0 questionnaire
7. Response rate, assessed by the total numbers of participant return and completion of the questionnaire at all timepoints in comparison with the number of participants assigned to each arms
8. Remission/relapses of anxiety and depression, assessed using the total score of the BAI and

BDI at all timepoints post-intervention compared to these scores at the baseline
9. Attrition from the intervention, assessed by the total numbers of participants lost to follow-up compared to the number of participants recruited

Overall study start date

01/06/2018

Completion date

08/01/2020

Eligibility

Key inclusion criteria

Current inclusion criteria as of 22/02/2019:

1. Registered at the thalassemia day care center of their hospital
2. Confirmed diagnosis of thalassemia major
3. Aged 13-17 years
4. On regular blood transfusion
5. On iron chelation therapy
6. Beck Depression Inventory score >21
7. Beck Anxiety Inventory score >16
8. Able to read and write in English and Malay languages

Previous inclusion criteria:

1. Registered at the thalassemia day care center of their hospital
2. Confirmed diagnosis of thalassemia major
3. Aged 11-17 years
4. On regular blood transfusion
5. On iron chelation therapy
6. Beck Depression Inventory score >21
7. Beck Anxiety Inventory score >16
8. Able to read and write in English and Malay languages

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

85 in the intervention group and 85 in the control group

Key exclusion criteria

1. On medication for anxiety and/or depression
2. Anxiety and/or depression due to other medical illness
3. Exposure to cognitive behavioral therapy and/or counseling and/or psychological therapy
4. Co-morbidity (not due to thalassemia, blood transfusion or iron chelation therapy complications), including cancer, young hypertension, epilepsy, asthma
5. Illiterate

Date of first enrolment

01/01/2019

Date of final enrolment

30/04/2019

Locations**Countries of recruitment**

Malaysia

Study participating centre**Thalassemia Daycare Centre of Hospital Serdang**

Hospital Serdang
Jalan Puchong of Kajang
Selangor
Malaysia
43000

Study participating centre**Thalassemia Daycare Centre of Hospital Ampang**

Hospital Ampang
Jalan Mewah Utara
Pandan Indah
Selangor
Malaysia
68000

Study participating centre**Thalassemia Daycare Centre of Hospital Selayang**

Hospital Selayang Lebuhraya
Lebuhraya Selayang - Kepong
Batu Caves
Selangor
Malaysia
68100

Study participating centre

Thalassemia Daycare Centre of Hospital Tengku Ampuan Rahimah

Hospital Tengku Ampuan Rahimah

Jalan Langat

Klang

Selangor

Malaysia

41200

Sponsor information

Organisation

Universiti Putra Malaysia

Sponsor details

Department of Family Medicine,

Faculty of Medicine and Health Sciences, Universiti Putra Malaysia

serdang,selangor

Malaysia

43400

Sponsor type

University/education

ROR

<https://ror.org/02e91jd64>

Funder(s)

Funder type

University/education

Funder Name

Fakulti Perubatan dan Sains Kesihatan, Universiti Putra Malaysia

Alternative Name(s)

Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, FPSK, UPM

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Malaysia

Results and Publications

Publication and dissemination plan

1. Trial protocol - intention to publish after receiving approval from the Ministry of Health's Medical Research Ethics Committee and UPM's Medical Research Ethics Committee and received approval of trial registration
2. Systematic literature reviews and meta-analysis of psychological intervention for anxiety and depression in thalassemia
3. Publication of the complete trial results after completion of the study

Intention to publish date

30/04/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be/are available upon request from Dr. Dayangku Hayaty Awg Dzulkarnain (yatyadzul@gmail.com). The data will be dependently available (restricted to participant's consent and parents/legal guardian's consent for minor, approval from the Ministry of Health Ethics Committee, University Putra Malaysia Ethics Committee and the sponsor (Universiti Putra Malaysia)). The criteria for approval of data sharing needs to be consistent with the studied policy on sharing (for educational use, peer review journal, for the proposed research which is bona fide and methodologically sound). The data sharing agreement is issued and signed by the appropriate authorities upon release of the data. The data will be available for one month.

IPD sharing plan summary

Available on request