ISRCTN11295199 https://doi.org/10.1186/ISRCTN11295199

Cognitive behavioral therapy for adolescents with thalassemia in Selangor

Submission date	**Recruitment status**	[X] Prospectively registered
19/11/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/11/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/02/2019	Circulatory System	[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional multi-center single-blinded randomised controlled parallel trial

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
17 Years

Sex
All

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 Lebuh Raya
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

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

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