

Effect of Exercise during CBT on Adolescents with a major Depression

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23354

Source

Nationaal Trial Register

Brief title

CBT-EXERCISE-YOUTH-DEPRESSION

Health condition

Depression

Sponsors and support

Primary sponsor: GGZ Delfland

Source(s) of monetary or material Support: GGZ Delfland

Intervention

Outcome measures

Primary outcome

Main study parameters/endpoints: the daily mood level of the patient; measured with a daily journal in which the patient registers his/her mood level on a scale of 1-10 with 1 "as sad as can be" and 10 "as happy as can be".

Secondary outcome

In addition the treatment satisfaction of the patient is measured with the Session Rating Scale, consisting of 4 items.

In order to establish whether CBT and exercise together results in a significant decrease of depression symptoms, the degree of depressive symptoms is measured pré, post en follow-up. For this a validated depression questionnaire is used, the Beck Depression Inventory-II, Dutch revised version, consisting of 21 items.

Study description

Background summary

Rationale: depression among adolescents is a major social problem. According to the Central Bureau of Statistics in the Netherlands (2017) nearly 4% of all youngsters aged 12 to 18 years old (about 37.000 adolescents) stated that they endured a depressive state during six months or longer in 2016.

The most appointed psychological treatment for depression, CBT, is only of mediocre effect (Weersing et al., 2017). An important treatment component in the therapy of depression is activation: the person has to get active again. Exercise on its own, without therapy, has a moderate positive effect on decreasing depressive symptoms within adolescents (Carter et al., 2016). Running therapy proved to be an effective intervention in decreasing depressive symptoms in adults (Bongers & Dijkerman, 2013). Among adolescents the first findings are positive as well.

Also it has been established that exercise, alongside CBT, has an additional effect on decreasing depressive symptoms in adults with a depression (Abdollahi et al., 2017). A combination of CBT and exercise could possibly lead to better results in adolescents as well, compared to the administration of CBT or exercise alone.

Objective: does exercise during CBT increase the treatment effect in patients aged 13-18 years old with a mediocre or major depression.

Additionally the treatment satisfaction of the patients is measured during the sessions with exercise compared to the session without exercise.

Study design: single case experimental design with alternating treatment interventions (ABC SCED). Every subject always gets treatment as usual: CBT during 12 individual sessions according to an evidence based treatment protocol.

During half of the sessions the patient is asked to perform a simple, moderately intensive exercise activity.

Patients register daily outcomes of their mood level(s). After every treatment session they fill in a short treatment satisfaction survey. And they also fill in a validated depression survey (pré, post and follow-up).

Study population: boys and girls aged 13-18 years old with a mediocre or major depression with CBT without medication as first choice of treatment.

Intervention:

CBT= a validated depression treatment protocol of 12 weekly individual sessions of 45 minutes, based upon the multidisciplinary guidelines of depression among children and youth. This treatment is care as usual and the same kind of treatment as is offered to patients that do not participate in this study.

Exercise activity= during half of the CBT sessions every patient is instructed to perform a moderately intensive exercise activity over a period of 30 minutes, stepping on a stepper. The intensity is determined by the so called "talking test", which holds that the patient is able to converse with the therapist during the exercise without getting exhausted. In this manner the exercise does not interfere with the CBT.

Main study parameters/endpoints: daily mood level of the patient; measured with a daily journal in which the patient registers his/her mood level on a scale of 1-10 with 1 "as sad as can be" and 10 "as happy as can be".

In addition the treatment satisfaction of the patient is measured with the Session Rating Scale, consisting of 4 items.

In order to establish whether CBT and exercise together results in a significant decrease of depression symptoms, the degree of depressive symptoms is measured pré, post en follow-up. For this a validated depression questionnaire is used, the Beck Depression Inventory-II, Dutch revised version, consisting of 21 items.

Hypothesis:

Primary hypothesis= exercise during CBT increases the mood more than only administering CBT.

Additional explorative hypothesis= exercise during CBT leads to a higher treatment satisfaction in the patient, compared to administering CBT only.

Analyses:

In order to determine whether exercise during CBT is more effective than CBT only both regression lines are analysed qualitatively and quantitatively. For the qualitative analyses a Single-Case Visual Analysis (SCVA) is used. And the quantitative analyses are performed with the method ALIV; actual and linearly interpolated values (Manolov & Onghena, 2017). This in order to establish whether exercise during CBT is more effective than CBT alone according to the overall results of the mood levels of the patient during the weeks that CBT, respectively exercise during CBT is administered. The same qualitative and quantitative analyses are performed to establish whether the treatment satisfaction of the patient is higher during the CBT sessions with exercise in contrast to CBT sessions without exercise.

Study objective

Primary hypothesis: exercise during CBT increases the mood more than only administering CBT.

Additional explorative hypothesis: exercise during CBT leads to a higher treatment satisfaction in the patient, compared to administering CBT only.

Study design

The study period (start to finish) is 112 days. During each day the patient registers his/her

daily mood level. After every session he/she fills in the Session Rating Scale. And there is a pré, post and follow up measurement (at the start of the baseline phase of 2 weeks, at the end of the intervention phase of 12 weeks and at the end of the follow up phase of 12 weeks) of the severity of depressive symptoms.

Intervention

CBT treatment protocol: a validated depression treatment protocol of 12 weekly individual sessions of 45 minutes, based upon the multidisciplinair guidelines of depression among children and youth. This treatment is care as usual and the same kind of treatment as is offered to patients that do not participate in this study.

Exercise activity: during half of the CBT session every patient is instructed to perform a moderately intensive exercise activity over a period of 30 minutes, stepping on a stepper. The intensity is determined by the so called "talking test", which inholds that the patient is able to converse with the therapist during the exercise without getting exhausted. In this manner the exercise does not interfere with the CBT.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria

- Age: 13 years or older and younger than 18 years at the start of treatment.
- Willingness to perform a physical effort: the patient is willing to perform an exercise with a moderate intensity during a period of 30 minutes. In addition: the exercise intervention isn't very heavy or stressful. The patient will not be overloaded physically and there aren't any risks of injury or accidents anticipated.

- BMI: healthy BMI (healthy weight).
- Degree of depressive symptoms: a mediocre or major depression according to the DSM-5 classification system and the BDI-II-NL-R overall score (mediocre= 20-28, major= 29-63).
- Type of depressive disorder: a depressive disorder, mediocre or major, a single episode of recurring episodes, without psychotic symptoms, not in remission. And a persisting depressive disorder, mediocre or major, early onset, with or without (actual) periodic depressive episode(s), without psychotic symptoms, not in remission.
- Co-morbidity: no co-morbidity / no other psychic disorder(s).

Exclusion criteria

Exclusion criteria

Age: younger than 13 years or older than 18 years at the start of treatment.

- Willingness to perform a physical effort: the patient is not willing to perform an exercise with a moderate intensity during a period of 30 minutes.
- BMI: unhealthy BMI (unhealthy weight; over- or underweight).
- Degree of depressive symptoms: a light depression according to the DSM-5 classification system and the BDI-II-NL-R overall score (light= <20).
- Type of depressive disorder: other depressive-mood disorders according to the DSM-5 classification system.
- Co-morbidity: other psychic disorder(s).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-09-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

An IPD plan (description) hasn't been formulated yet.

Ethics review

Positive opinion

Date: 06-09-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL8003

Other METC Erasmus MC : MEC-2019-0375 (research approved by METC Erasmus MC by decision d.d. 2-7-2019).

Study results

Summary results

The manuscript will be published internationally and a spin-off will be published in a national magazine. Internationally the aim is to publish the manuscript in the "Journal of Clinical Child & Adolescent Psychology", which published case studies before. On a national level the magazine "Psychologie & Gezondheid" or "Tijdschrift voor Gezondheidswetenschappen" will be approached.