

Effectiveness of Acceptance and Commitment Therapy for patients with insulin-treated diabetes and depressive symptoms: ACT in Diabetes

No registrations found.

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

Summary

ID

NL-OMON23602

Source

Nationaal Trial Register

Brief title

ACT in Diabetes

Health condition

Diabetes Mellitus, depression, diabetes self-care behaviour, Acceptance and Commitment Therapy

Sponsors and support

Primary sponsor: Zuyderland Medical Centre, Heerlen

Source(s) of monetary or material Support: Zuyderland Medical Centre, Heerlen

Intervention

Outcome measures

Primary outcome

Depression: VAS by PsyMate (App for smartphone)

Diabetes self-care behaviour: Self-Care Inventory-revised (SCI-R) (blood glucose regulation)

Secondary outcome

Acceptance: Acceptance and Action Questionnaire- II (AAQ-II)

Cognitive fusion: Cognitive Fusion Questionnaire (CFQ13)

Study description

Background summary

Diabetes Mellitus (DM) is associated with a doubled risk of depressive symptoms compared to the general population. Concurrent diabetes and depressive symptoms are related to poorer emotional functioning, quality of life, self-care behaviours and health outcomes. Acceptance and Commitment Therapy (ACT) is a psychological intervention that mixes acceptance and mindfulness strategies with commitment and behaviour-change strategies in order to increase psychological flexibility, including acceptance and cognitive defusion (disentanglement from our thoughts). Several meta-analyses have shown the effectiveness of ACT. In diabetes, ACT has been proven effective on diabetes self-care, acceptance coping strategies and glycaemic control. ACT for patients with diabetes and depressive symptoms has not yet been studied. The aim of the present study is to examine the effectiveness of an ACT intervention on depressive symptoms and diabetes self-care behaviour in insulin-treated DM patients. In addition, we explore the underlying operating mechanisms of ACT.

Study objective

Firstly, we hypothesise that Acceptance and Commitment Therapy (ACT) for diabetes patients will reduce depressive symptoms and will increase diabetes self-care behaviour. Furthermore, we explore the underlying operating mechanisms of ACT. We hypothesise that ACT for diabetes patients will increase psychological flexibility, including acceptance and cognitive defusion.

Study design

This is a replicated randomised single-case experimental study. This means a low number of participants with highly frequent measurements.

Depression is measured daily during the base-line and the intervention period. Diabetes self-care behaviour, acceptance and cognitive fusion are measured weekly, during the baseline period and the intervention period. Total study period for each participant is 25 weeks. Moment of phase change from base-line to intervention phase is randomised. □ □

Intervention

Acceptance and Commitment Therapy (ACT) consisting of eight one-and-a-half hour individual sessions across ten weeks

Contacts

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Eligibility criteria

Inclusion criteria

1. age 18 to 65 years;
2. a diagnosis type 1 or type 2 diabetes mellitus > 6 months ago;
3. suboptimal glycaemic control (HbA1c \geq 7.5%/58mmol/mol)

4. intensive insulin treatment (at least 4 daily administrations regimen; or insulin pump therapy)
5. elevated depressive symptoms (CES-D \geq 16);
6. motivation for an 8-session psychological intervention focusing on acceptance in chronic illness (based on clinical judgement).

Exclusion criteria

1. severe psychiatric or somatic comorbidity that hampers participation (e.g. depression with strong suicidal ideation, psychosis, severe cognitive impairment, severe cardiac disease, end-stage cancer);
2. non-fluent in Dutch language, an intellectual disability or lack of verbal abstraction (based on educational level and clinical judgement);
3. earlier treatment based on ACT and/or MBCT;
4. ongoing other psychological treatment;
5. changes in antidepressive medication during the study period;
6. pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-03-2016
Enrollment:	3

Type: Unknown

Ethics review

Positive opinion

Date: 26-01-2016

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	NL5562
NTR-old	NTR5683
Other	: 15-N-172 METC Zuyd

Study results