# ACT your way: A transdiagnostic intervention for multiple disorders in transitional-age youth

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Psychiatric disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55941

**Source**
ToetsingOnline

**Brief title**
ACT your way: a transdiagnostic intervention for TAY

### Condition

- Psychiatric disorders NEC

**Synonym**
Psychopathology, various psychological problems

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Utrecht
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** (Cost)effectiveness, Acceptance and commitment therapy, Transdiagnostic intervention, Transitional-age youth

## Outcome measures

### Primary outcome

The two main primary outcome measures are psychological flexibility (measured with de AFQ-Y) and the number of diagnoses (measured with the SCID-5-Junior, a semi-structured diagnostic interview).

### Secondary outcome

Secondary outcomes are the presence of the primary disorder, psychopathology, global functioning, quality of life, individual and societal functioning, emotion regulation, personality problems, autonomy, stress, perfectionism, self-esteem and self-compassion. Other study parameters are demographic information, type and severity of problems, psychopathology of parents, information about previous treatments and life events, treatment expectancy, satisfaction with treatment, therapeutic alliance, information about drop-out, treatment integrity and content of the treatment. Costs are registered in a cost questionnaire.

# Study description

### Background summary

Transitional-age youth (TAY; aged 15 to 25) has recently been identified as a group in need of special attention in mental health services. Studies show that TAY experience more psychological problems than other age groups. An effective intervention for this specific age group seems warranted. However, there is a lack of interventions specifically developed for this age group. We propose a

transdiagnostic intervention, ACT your way, that can be used for a wide variety of psychological problems and can also be used for chronic and/or recurrent problems in this specific age group.

### Study objective

The primary aim is to evaluate the effectiveness of ACT your way, by comparing ACT your way to treatment as usual (TAU) in TAY. The secondary aim is to evaluate the cost-effectiveness of ACT your way, by comparing ACT your way to TAU in TAY. The third aim is to examine for whom ACT you way works best (moderation analyses). The fourth aim is to investigate which factors mediate ACT your way changes (mediation analyses).

### Study design

The study is designed as a multi-center, randomized controlled trial. Participants are randomly assigned to the ACT your way or TAU condition. Six multiple informant (adolescent/young adult, parent, therapist) assessments will be conducted: prior to the intervention (pre-treatment), after 3 sessions (mediator 1), after 6 sessions (mediator 2), after 9 sessions (mediator 3), immediately after the intervention (post-treatment) and 6 months after the intervention (6-month follow-up). Assessments will include diagnostic interviews, questionnaires and ratings (i.e., therapist and observational ratings).

### Intervention

ACT your way is an intervention based on Acceptance and Commitment Therapy (ACT), that is not directed primarily at symptom reduction but at changing the underlying mechanism of psychopathology, namely psychological inflexibility. ACT you way consists of twelve weekly sessions. Therapists will be trained in using ACT your way.

### Study burden and risks

In our opinion, the risks associated with participation can be considered negligible. The burden consists of structured clinical interviews and online questionnaires, which are partly included in the standard diagnostic process of the patient. The intervention that is offered, is independent of participation, patients will receive this intervention whether or not they participate.

## Contacts

### Public

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

## Inclusion criteria

(1) A primary diagnoses of any disorder (e.g., anxiety disorder, OCD, trauma, depressive disorder, dysthymic disorder, ODD, CD or any combination of these)
(2) Aged 15 to 25 years
(3) Referred to one of the participating mental health institutions.

## Exclusion criteria

(1) Insufficient knowledge of the Dutch language
(2) Acute suicide risk
(3) Drug abuse
(4) Absence of TAY or parental permission (for participants younger than 16)
(5) Estimated IQ below 80
(6) Unstable medication (i.e. the medication should be set before the start of

the intervention and should remain stable)

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2022 |
| Enrollment: | 144 |
| Type: | Anticipated |

# Ethics review

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| Approved WMO Date: | 27-01-2022 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 04-05-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 28-12-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

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| Approved WMO Date: | 05-05-2023 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 02-11-2023 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23521
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL78679.041.21 |
| Other | NL9642 |
| OMON | NL-OMON23521 |