

# An online tailored intervention targeting heavy drinking in students in secondary vocational education (MBO students)

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28135

### Source

Nationaal Trial Register

### Brief title

What Do You Drink (WDYD)+

### Health condition

Adolescents, young adults, alcohol

## Sponsors and support

**Primary sponsor:** TNO Child Health (Netherlands Organization for Applied Scientific Research)<br>

Trimbos-institute (Netherlands Institute of Mental Health and Addiction)<br>Radboud University Nijmegen

**Source(s) of monetary or material Support:** ZonMw (The Netherlands Organization for Health Research and Development)<br>

TNO Child Health, the Vocational Education and Training (VET) council (in Dutch: MBO-raad), Testjeleefstijl foundation

## Intervention

## Outcome measures

### Primary outcome

- Mean weekly alcohol consumption (continuous);
- Frequency of binge drinking (dichotomous and continuous);
- Frequency of heavy drinking (dichotomous).

The frequency of binge drinking was measured as the number of days in the past week on which participants had drunk four (women) or six (men) or more glasses of alcohol (continuous) and the percentage of participants that had drunk four (women) or six (men) or more glasses of alcohol at least once per week (dichotomous)

The frequency of heavy drinking was measured as the percentage of participants drinking more than the mean weekly alcohol consumption rate of 0 (girls and boys <18 years), 7 (females ≥18 years) or 14 (males ≥18 years) glasses of alcohol.

Timepoints: EMA (i.e., daily measurement for 7 consecutive days) every six weeks starting at baseline and ending 43 weeks after baseline (in total 56 EMA's: 8 times x 7 days).

### Secondary outcome

Mood, attitude, intrinsic motivation, self-efficacy, coping planning and intentions towards drinking less alcohol than usual.

Timepoints:

- EMA (i.e., daily measurement for 7 consecutive days) every six weeks starting at baseline and ending 43 weeks after baseline (in total 56 EMA's: 8 times x 7 days) for mood, intrinsic motivation and self-efficacy.
- Online surveys at baseline, and 2 weeks and 6 months follow-up (i.e., after the intervention period) for attitude, intention, coping planning.

## Study description

## Background summary

In the Netherlands, 70% of the students drink too much alcohol. Lower educated students engage in heavy drinking more often and start drinking earlier than higher educated peers. Since evidence-based interventions targeting heavy drinking in lower educated students are lacking, this project will develop and test an improved version of “What Do You Drink” (WDYD). This online just-in-time adaptive tailored alcohol intervention (WDYD+) will be implemented in Test Je Leefstijl (TJL), a web-based lifestyle monitor for secondary vocational education students (i.e., MBO-students). WDYD, a single-session web-based brief alcohol intervention, has already proven its potential in college students.

Because MBO-students indicated their need for more thoughtful and tailored feedback, computer tailoring is used as one of the two core change techniques in WDYD+. The second technique is Motivational Interviewing (MI). MI suits best among those ambivalent about behavior change; a state prevalent among 90% of heavy drinking lower educated students. Both computer tailoring and MI have proven effective, and combining them in a pure online intervention (i.e., without real-life person contact) is highly innovative. A first test, applied in another context, showed positive effects at 12 month follow-up.

TJL is completed by more than 20 000 MBO-students yearly. A link to WDYD+ will be embedded in TJL for heavy drinking MBO-students. By embedding WDYD+ in the existing structures of TJL, implementation is ensured. Trimbos Institute will continue ownership after the study.

The research questions are:

1. Is exposure to WDYD+ more effective in changing alcohol drinking (primary outcome) and determinants (secondary outcomes) in heavy drinking MBO-students in the Netherlands at short and long-term follow-up (i.e., 2 weeks and 6 months after the intervention period) and over time compared to those exposed to the usual feedback module on alcohol drinking of TJL?
2. To what extend are heavy drinking MBO-students appointed to WDYD+ exposed to the intervention (i.e., program fidelity) and how do they evaluate WDYD+ (i.e., usability and acceptability) compared to those exposed to the usual feedback module on alcohol drinking in TJL?

The effectiveness of WDYD+ will be evaluated by a 2-arm parallel-group Randomized

Controlled Trial (RCT). MBO-students aged 16 to 24 years who are heavy drinkers, according to the TJL-assessment, will receive a link to the study app and will be randomly assigned to the experimental or control group (N = 655 students/arm) after providing informed consent. Students in the experimental group will receive just-in-time adaptive tailored alcohol feedback during a period of 3 months. Outcomes are assessed at baseline (i.e., at the start of the intervention) and at 2 weeks and 6 months follow-up (i.e., after the intervention period) by online surveys. Ecological Momentary Assessments (EMA; 56 times) will be held to control for the fluctuating nature of alcohol drinking and contextual factors.

Taking WDYD as a point of departure is a logical step since it has shown potential when applied to other students. We proposed a 3-stage improvement and adaptation process:

- 1) Systematic development of WDYD+: Refinement of change objectives and methods, combining the core change techniques for online application, iterative tests and refinement based on consultations with MBO-students, MBO-schools and (alcohol) behavior experts.
- 2) Conducting a 2-arm parallel-group RCT: After the baseline assessment, a random sample of heavy drinking MBO-students who visit TJL will be appointed to WDYD+ next to the current feedback module offered by TJL. Students in the control group will be appointed to the current feedback module offered by TJL. After the intervention period of 3 months, participants will receive 2 surveys (at 2 weeks and 6 months after completing the intervention). Participants will additionally receive 56 EMA's between baseline and 43 weeks after baseline.
- 3) Effect and process evaluation (data-analyses), communication of the results (publication and presentations), and implementation of WDYD+ within TJL.

To ensure adequate fit, MBO-students will be intensively involved in an iterative developmental process. Additionally, MBO-schools (Nova College and Deltion College), the Vocational Education and Training (VET) council (in Dutch: MBO-raad), and the TJL Foundation (owner of TJL) will advise on its compatibility with the existing school curriculum and student care structures. Alcohol expertise and ownership is preserved by collaboration with the Trimbos Institute, the owner of WDYD(+) and full member of the project team.

## **Study objective**

We hypothesized that exposure to WDYD+ (experimental arm) is more effective in changing alcohol drinking (primary outcomes) and its determinants (secondary outcomes) at 2 weeks and 6-month follow-up (i.e., after the intervention period), compared to exposure to the usual feedback module on alcohol drinking in Testjeleefstijl.nu (TJL; control arm). We expected a difference in effect size (cohen's d) of 0.20 on heavy drinking (primary outcome) among the experimental group compared to the control group.

## Study design

MBO students who engage in heavy drinking according to Testjeleefstijl.nu will receive an invitation to participate in the study by means of a link to the study app. Those who enter the app and provide informed consent will be randomized into one of two conditions (experimental or control condition) and will receive a baseline questionnaire measuring primary and secondary outcomes, and socio-demographic variables (i.e., sex, age, ethnicity, MBO level, MBO sector, MBO pathway, MBO school year). The experimental arm will receive just-in-time adaptive tailored feedback for a period of 3 months. Both conditions will receive ecological momentary assessments (EMA; i.e., primary outcomes, mood, intrinsic motivation, self-efficacy towards drinking less alcohol than usual). The EMA's (a daily measurement for 7 consecutive days) will be held every six weeks starting at baseline and ending 43 weeks after baseline (In total 56 EMA's; 8 times x 7 days). Additionally, both conditions will receive an extended survey at 2 weeks and 6 months follow up (i.e., after the intervention period) measuring attitudes, coping planning, intention at both time points. At 2 weeks follow-up, the experimental condition additionally receives questions about the use and acceptability of WDYD+, and the extent to which WDYD+ fulfills the psychological needs for autonomy, relatedness and competence; the control condition will additionally receive questions about the use and acceptability of alcohol feedback in Testjeleefstijl.nu, the extent to which the alcohol feedback in Testjeleefstijl.nu fulfills the psychological needs for autonomy, relatedness and competence, and questions to check for contamination (i.e., exposure to WDYD+ via participants in the experimental condition).

In sum, the effectiveness of WDYD+ will be examined at 2 weeks and 6 months follow-up (i.e., after the intervention period) as well as by EMA's (daily assessment of 7 consecutive days every 6 weeks starting from baseline and ending 43 weeks after baseline).

## Intervention

Students who give informed consent will be randomly assigned to the experimental condition (just-in-time adaptive tailored feedback about alcohol drinking, and usual alcohol feedback in Testjeleefstijl.nu) or control condition (usual alcohol feedback in Testjeleefstijl.nu). Participants in the experimental condition will receive the tailored feedback over a period of three months by means of an app.

## Contacts

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## Eligibility criteria

### Inclusion criteria

- MBO students aged 16 to 24 years who are heavy drinkers. Heavy drinking is defined as:
  - 1) drinking more than the low-risk drinking guidelines (Health Council of the Netherlands) recommending for adolescents (aged 16-17 years) to drink no alcohol and for adults to drink a maximum of 1 (women) or 2 (men) glasses of standard alcohol units daily and/or
  - 2) binge drinking, that is, drinking 4 or more (women) or 6 or more (men) standard alcohol units at one occasion.

### Exclusion criteria

- No MBO students aged 16 to 24 years who are heavy drinkers

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	21-08-2017
Enrollment:	1310
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	16-08-2017
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	NL6441
NTR-old	NTR6619
Other	ZonMw : 531001105

## Study results