

# **BRAVO: The process evaluation of a 7-step strategy for the implementation and continuation of a multicomponent lifestyle strategy in two worksite settings.**

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## **Summary**

### **ID**

NL-OMON28764

### **Source**

Nationaal Trial Register

### **Brief title**

BRAVO

### **Health condition**

This project aims to study the process of implementation and continuation of the BRAVO-strategy (see below) in two different worksite settings (i.e. healthcare and education). In addition, the effects of BRAVO on lifestyle and sickness absence of workers will be studied, since positive results will enhance the willingness of companies to implement BRAVO. The BRAVO-strategy is a detailed 7-step implementation method for implementing lifestyle interventions that focus on five main topics: physical activity, smoking, alcohol, nutrition and relaxation (i.e. BRAVO). Both participating intervention departments within the two companies are solely responsible for the implementation and continuation of the BRAVO-strategy according to their integral health policy

## **Sponsors and support**

**Primary sponsor:** ZonMw

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2509 AE Den Haag  
The Netherlands

**Source(s) of monetary or material Support:** ZonMw

Postbus 93 245  
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## Intervention

## Outcome measures

### Primary outcome

The main outcome measure of this study is to evaluate the natural process of implementation of the BRAVO-strategy in two different and contrasting worksite settings by structurally monitoring the implementation process (process evaluation).

### Secondary outcome

Secondary outcome measures are self-reported (determinants of) physical activity, smoking, alcohol and food intake and perceived work stress and work engagement, sick leave data and direct and indirect costs of the implementation of the BRAVO-strategy and accompanying BRAVO-interventions. Furthermore, the tertiary outcome measure data on body composition will be taken into account, but only when a health check is performed by the company.

## Study description

### Background summary

Rationale:

An unhealthy lifestyle reduces the health of workers and causes productivity loss. Adopting and maintaining a healthy lifestyle is one of the components to ensure long-lasting vitality and productivity of older workers and to prevent overweight and work disability. Growing evidence has been found for the effectiveness of interventions to promote a healthy lifestyle at the worksite. Nevertheless, only few Dutch companies are actually implementing such effective interventions.

Objective:

This project aims to study the process of implementation and continuation of the BRAVO-strategy (see below) in two different worksite settings (i.e. healthcare and education). In addition, the effects of BRAVO on lifestyle and sickness absence of workers will be studied, since positive results will enhance the willingness of companies to implement BRAVO.

The specific research questions are: (a) What are the determinants of failure and success for implementation and continuation of the BRAVO-strategy in two different and contrasting worksite settings?; (b) To what extent do management and employees know, adopt and adhere to the individual components of the BRAVO-strategy?; and (c) What are the effects of the BRAVO-interventions on lifestyle behaviour of workers and sickness absence as indicators of successful implementation?

#### Study design:

This study is an action research in the form of an observational, controlled quasi-experimental multicentre study, with a researcher embedded in the project structure.

#### Study population:

All employees from the intervention and control departments of the academic hospital and higher educational institute will participate in the study (n=2000).

#### Intervention:

The BRAVO-strategy is a detailed 7-step implementation method for implementing lifestyle interventions that focus on five main topics: physical activity, smoking, alcohol, nutrition and relaxation (i.e. BRAVO). Both participating intervention departments within the two companies are solely responsible for the implementation and continuation of the BRAVO-strategy according to their integral health policy. For the process evaluation relevant stakeholders (management, project group, company physician) in the intervention group will be invited to participate in (1) focus group interviews at T0 and T2, and (2) semi-structured in-depth interviews at T0, T1 and T2. Questionnaires for employees to measure intervention effect have to be fulfilled at baseline, at 6 and 12 months after the start of the intervention.

#### Main outcome measures:

The main outcome measure of this study is to evaluate the natural process of implementation of the BRAVO-strategy in two different and contrasting worksite settings by structurally monitoring the implementation process (process evaluation). Secondary outcome measures

are self-reported (determinants of) physical activity, smoking, alcohol and food intake and perceived work stress and work engagement. Furthermore, the tertiary outcome measure data on body composition will be taken into account, but only when a health check is performed by the company.

Nature and extent of the burden and risks associated with participation, benefit and group-relatedness:

The interventions will be part of the participants' own normal working life and are not expected to impose a high burden. It is expected that the participants and the companies will benefit from the program in the sense of a healthier lifestyle and a more pleasant working environment.

## **Study objective**

N/A

## **Study design**

All participants in the control and intervention group will be invited by their employer to complete a web-based questionnaire (i.e. TNO lifestyle scan with feedback for users) and when provided a health check (physical examination performed during PAGO) at baseline (T0). After obtaining the baseline data, the control group will continue their normal working routine whereas the intervention group will be exposed to different interventions at worksite level. Both groups will receive the same questionnaires. The first follow-up measurement will take place at 6 months (T1) after the start of the intervention. The purpose of this first follow-up measurement is to see whether the intervention had a beneficial effect on employees lifestyle related to the BRAVO lifestyles, self-reported BMI and other secondary outcomes. The participants will be asked to fill in the same questionnaire as for the baseline measurement. This procedure will be repeated for the second follow-up measurement at twelve months (T2) after the start of the interventions. The purpose of the second follow-up measurement is to see whether the magnitude of the effect of BRAVO-interventions remained the same, increased or declined compared to the control condition within the company (i.e. faculty of society and law and division of heart and lungs). At T2, the intervention group will receive additional questions about the content of and their satisfaction with the implemented interventions. Besides the questionnaire at three moments in time, participants in the intervention group will be approached to participate in a focus group interview at T0 and T2 to determine possible success and failure factors of the implementation of the BRAVO-strategy and accompanying BRAVO-interventions. Parallel to these focus group interviews, semi-structured in-depth interviews with employees and project members (i.e. steering committee, project group, working groups) will be performed at T0, T1 and T2 by the researchers. Participants will be approached using the company communication channels. Furthermore, data on sickness absence of the previous year will be requested by the researchers from the participating companies at T0 and T2. Finally, data for cost-

effectiveness (CEA) and cost-utility (CUA) will be obtained from project members.

## **Intervention**

The BRAVO-strategy is a detailed 7-step implementation method for implementing lifestyle interventions that focus on five main topics: physical activity, smoking, alcohol, nutrition and relaxation (i.e. BRAVO). Both participating intervention departments within the two companies are solely responsible for the implementation and continuation of the BRAVO-strategy according to their integral health policy. For the process evaluation relevant stakeholders (management, project group, company physician) in the intervention group will be invited to participate in (1) focus group interviews at T0 and T2, and (2) semi-structured in-depth interviews at T0, T1 and T2. Questionnaires for employees to measure intervention effect have to be fulfilled at baseline, at 6 and 12 months after the start of the intervention.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

All employees within the intervention and control departments from both companies will be included in the study. Other specific inclusion criteria for the employees are:

1. A contract for the duration of at least one year;
2. A signed informed consent at baseline;
3. A completed baseline questionnaire;
4. 18 years or older and mentally competent;
5. No participation in other long term health promotion programs other than usual care for both participating departments as well as the participating employees.

## Exclusion criteria

Physical limitations for moderate intensity physical activity (e.g., symptoms of cardiovascular disease, respiratory disease and orthopaedic disorders, pregnancy).

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

**Control:** N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	25-11-2010
Enrollment:	2000
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	20-04-2011
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	NL2723
NTR-old	NTR2861
Other	METC UMCU / ZonMw : 11-101/C / 50-5140598-019;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A