

# Evaluation study 'Customized Care'.

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-OMON26076

### Source

Nationaal Trial Register

### Health condition

loneliness  
low mental health  
social isolation  
low SES

## Sponsors and support

**Primary sponsor:** University of Twente, Enschede  
Arcon, Borne

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

## Intervention

## Outcome measures

### Primary outcome

Positive mental health (Dutch MHC-SF, Lamers et al., 2011).

### Secondary outcome

1. Loneliness;

2. Depression;
3. Consumption of care;
4. Purpose in Life;
5. Resilience;
6. Social participation;
7. Health-related quality of life.

## Study description

### Background summary

Rationale:

The Dutch welfare state focuses traditionally on the support of people in solving their problems. However, there is a group of citizens who keep falling back on state support. It is therefore necessary to develop new approaches with a focus on mental health promotion (i.e., happiness, self-realization, and social integration). We propose that the intervention 'Happiness route' will improve the mental health of this group.

Objective:

The primary objective of this study is to evaluate how effective the intervention 'Happiness route' is in promoting positive mental health in comparison to a control condition that consist of a optimized care-as-usual. Secondary objectives are to assess the effectiveness of the intervention in terms of decreasing loneliness, depression, and consumption of care as well as increasing purpose in life, resilience, social participation, and health related quality of life. Furthermore, we will study if the effect of the intervention is different for participants and counselors with different characteristics. Last, we examine how the intervention is evaluated by counselors and participants.

Study design:

A multi-centered, randomized controlled trial will be carried out with two parallel groups. In the experimental condition, the intervention 'Happiness Route' will be carried out. In the control condition, a short home visit program, intended to optimize care-as-usual, will be

provided. Questionnaires will be filled out by the participants at three points in time: at the intake, 3 months after the intake (i.e., when the intervention is completed), and at follow-up 9 months after the intake.

#### Study population:

The population in this study consists of adults (18 years or older) with a low socio-economic status (SES), who are socially isolated and have health limitations. Participants are recruited in ten municipalities throughout the Netherlands. Recruitment will be performed by an outreaching approach through professional intermediaries who are in frequent contact with the target group.

#### Intervention:

The 'Happiness route' builds on insights from economic theory ('nudging', i.e., a gentle push in the right direction) and from positive psychology ('mental health promotion'). Participants are encouraged in a behavioral intervention to carry out an intrinsically motivating activity for which they receive a one-time budget (max. €500,-). Between two and five sessions will take place at the home of the participant with a maximum of 1,5 hours per session. The control group will receive two home visits to optimize their care-as-usual.

#### Main study parameters/endpoints:

The main study parameter is positive mental health, as measured with the Mental Health Continuum – Short Form (MHC-SF). Other parameters are loneliness, depression, self-reported and actual consumption of care, purpose in life, resilience, social participation, and health related quality of life. Three questionnaires will be filled out by the participants – during the intake and after 3 and 9 months.

#### **Study objective**

1. The intervention 'Happiness Route' is effective in promoting positive mental health in comparison to a control condition that consists of optimized care-as-usual;
2. In comparison to the control condition, the intervention 'Happiness route' is effective in decreasing loneliness, depression, and consumption of care and in increasing purpose in life, resilience, social participation, and health related quality of life;
3. The effect of the intervention does not differ for participants with different characteristics (age, gender, and cultural background);

4. The effect of the intervention does not differ for trained counselors with different characteristics (work experience, work satisfaction, and adherence to the program);
5. The evaluation of the program is positive from the counselors and participants point of view.

## **Study design**

1. Intake;
2. Three months after the intake;
3. Nine months after the intake.

Measurement instruments are the Mental Health Continuum -Short Form (MHC-SF), the Loneliness Scale, the Center for Epidemiologic Studies Depression Scale (CES-D), the Purpose in Life scale, the Dutch version of the Resilience Scale (VK+) en the EuroQol (EQ5D).

## **Intervention**

The "Happiness route" builds on insights from economic theory ("nudging", i.e., a gentle push in the right direction) and from positive psychology ("mental health promotion"). Participants are encouraged in a behavioral intervention to carry out an intrinsically motivating activity for which they receive a one-time budget (max. €500,-). Between two and five sessions will take place at the home of the participant with a maximum of 1,5 hours per session.

The control group will receive two home visits to optimize their care-as-usual.

## **Contacts**

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### **Scientific**

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## Eligibility criteria

### Inclusion criteria

1. Age:  $\geq 18$  years;
2. Social isolation: A score of 3 or higher on the loneliness scale (de Jong Gierveld & Van Tilburg, 1999);
3. Low socioeconomic status (SES): A low educational level (VMBO/LBO/MULO/MAVO or less) and/or few financial means (we use the CBS budget approach which includes income for basic means as well as participation, i.e., 1.000euro per month for a single household and 1370 euro for a couple; CBS, 2011);
4. Health limitations, i.e. at least one health limitation on the EQ5D (Brooks, 1996).

All inclusion criteria must be fulfilled: A participant must be an adult with a low SES (low education or few financial means or both), who is social isolated, has health limitations, and is capable of taking part in the study.

### Exclusion criteria

1. High positive mental health: A high score on the Mental Health Continuum-Short Form (Lamers et al., 2010). To avoid ceiling effects, we use a score of more than one standard deviation above the mean of the Dutch population (i.e., 4.83 or higher) to exclude candidates;
2. Serious depression: A score of 26 or higher on the Center for Epidemiology Depression Scale (CES-D) (Radloff, 1977; Bouma et al, 1995);
3. Crisis situation: Candidates who are in a (psychiatric) crisis, or who are addicted to alcohol or drugs, or who are homeless or who have high debts, judged by the counselor during the intake;
4. Insufficient linguistic and cognitive skills to be able to fill in the questionnaires, judged by

the counselor during intake.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2012
Enrollment:	260
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	02-04-2012
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	NL3225
NTR-old	NTR3377
Other	ZonMW : 200210013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A