

Evaluation study "Customized Care"

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Primary ObjectiveThe 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 consists of optimized care-as-usual. This objective...

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|------------------------------|---------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Lifestyle issues |
| Study type | Interventional |

Summary

ID

NL-OMON41235

Source

ToetsingOnline

Brief title

Evaluation study "Customized Care"

Condition

- Lifestyle issues

Synonym

health limitations, poor well-being, social isolation

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: ZONMW;preventieprogramma 4

Intervention

Keyword: Happiness, Intervention studies, Mental health, Prevention

Outcome measures

Primary outcome

Positive mental health is the primary outcome. It is measured with the Dutch Mental Health Continuum - Short Form (MHC-SF; Lamers, Westerhof, ten Klooster, Bohlmeijer, & Keyes, 2011; Lamers, Glas, Westerhof & Bohlmeijer, 2012; Westerhof & Keyes, 2008). The MHC-SF is a 14-item questionnaire that measures three core dimensions of positive mental health (Keyes, 2002) that also match the three dimensions of the definition of the World health Organization (2004): emotional well-being (3 items), psychological well-being (6 items), and social well-being (5 items). Participants are asked to rate the frequency of feelings they have experienced in the past month. Items are scored on a 6-point scale ranging from *never* to *every day*. Higher scores indicate better well-being. The instrument has good psychometric properties (Lamers, Westerhof, ten Klooster, Bohlmeijer, & Keyes, 2011; Lamers, Glas, Westerhof & Bohlmeijer, 2012; Westerhof & Keyes, 2008) and is sensitive to change (Fledderus, Bohlmeijer, Smit & Westerhof, 2010; Korte, Bohlmeijer, Cappeliez, Smit, & Westerhof, 2011).

Secondary outcome

The following well-validated instruments will be used to measure secondary outcomes:

Loneliness: the eleven-item loneliness scale developed by De Jong Gierveld and Van Tilburg (1999);

Depression: the Dutch version of the Center for Epidemiological

Studies-Depression Scale (CES-D; Radloff, 1977, Bouma et al., 1995);

Consumption of care: items from the TIC-P (Hakkaart-van Roijen et al., 2002).

Vektis, the Dutch information centre for care, will compare the use of health care between the experimental and control group;

Purpose in life: the purpose in life scale developed by Ryff (1989; Ryff & Keyes; 1995);

Resilience: Dutch Resilience Scale (Wagnild & Young, 1993; Portzky et al., 2010);

Social participation: items that assess (volunteering) work, social contacts and activities, derived from several nationally representative surveys, such as CBS-POLS and LISS.

Health-related quality of life: The Dutch version of the EuroQol EQ5D (Brooks, 1996);

Study description

Background summary

Social relevance

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. This asks for a new approach that focuses on promoting positive mental health, i.e. happiness, self-realization and social integration (WHO, 2005). This is acknowledged in social work (VWS, 2010; VNG, 2010) as well as in public health (Raad voor de Volksgezondheid en Zorg, 2010). The *Happiness Route* provides a short behavioral intervention to promote positive mental health. It uses an outreaching approach to recruit participants and encourage them to carry out an intrinsically motivating activity for which they receive a one-time budget (maximum €500,-).

Scientific relevance

The Happiness Route is based on recent economic theories (*nudging*) and

psychological theories (*positive psychology*). The economic theory proposes that it is important to provide citizens a *nudge*, i.e., a gentle push in the right direction (Thaler & Sunstein, 2008; Tiemeijer, Thomas & Prats, 2009). Whereas the default nudge in the Dutch system is *What is your problem?*, the Happiness Route, provides the nudge: *What do you want to do in life?*. This nudge is based on insights from positive psychology that focus on the promotion of mental health. Meta-analyses show that the promotion of mental health will lead to considerable health gains for the individual and society (Chida & Steptoe, 2008; Howell, Kern & Lyubomirsky, 2007; Lamers, Bolier, Westerhof, Smit & Bohlmeijer, 2011; Lyubomirsky, King & Diener, 2005; Pressman & Cohen, 2005). Experimental studies have shown that it is possible to increase positive mental health through behavioral interventions (Bolier, Haverman, Westerhof, Riper, Smit & Bohlmeijer, under review; Sin & Lyubomirsky, 2009). As there is an abundance of studies showing that engagement in goal-directed activities is important for positive mental health (Westerhof & Bohlmeijer, 2010 provide an overview), the Happiness Route stimulates intrinsic goal engagement through the positive *nudge*.

Selected population

The intervention aims at a group that experiences an accumulation of risk factors for a low positive mental health: lower socioeconomic status, social isolation, and health limitations (Diener, Suh, Lucas & Smith, 1999; Veenhoven, 1996; Walburg, 2008; Westerhof & Keyes, 2010).

New information added by the study

Existing studies on positive psychological interventions were small, carried out in experimental settings, and with rather privileged groups. The present study will belong to the 10% largest trials on positive psychological interventions (Sin & Lyubomirsky, 2009). It is among the first to examine such an intervention in a practice-based research setting with several partners in the field of social work. Our study is also among the first to target individuals with an accumulation of risk factors for low levels of mental health (low SES, social isolation and health problems). It will thus provide new insights in the possibilities for mental health promotion in a naturalistic setting.

Study objective

Primary 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 consists of optimized care-as-usual. This objective contributes to our knowledge on the promotion of positive mental health in a practice-based research setting.

Secondary Objectives

There are four secondary objectives:

1. How effective is the intervention Happiness route in comparison to the control condition in terms of decreasing loneliness, depression, and consumption of care and in increasing purpose in life, resilience, social participation, and health related quality of life?
2. Is the effect of the intervention different for participants with different characteristics (age, gender, and cultural background)?
3. Is the effect of the intervention different for counselors with different characteristics (work experience, work satisfaction, and adherence to the intervention programme)?
4. How is the intervention evaluated by counselors and participants?

Study design

Design

A multi-centered randomized controlled trial will be carried out with two parallel groups:

1. Experimental condition: the Happiness Route.
2. Control condition: Optimized care-as-usual.

The experimental condition in this study will be compared to the control condition. The trial is practice-based and pragmatic in that we study the effects in a naturalistic setting. As we want to compare the Happiness Route intervention with care-as-usual, two home visits from a professional will make sure that the care the participants in the control group receive is optimal.

Instruments

Participants will fill out questionnaires at three measurement points: during the intake, 3 months and 9 months later. They need about 45 minutes to fill out the questionnaire at each of these measurement points.

Counselors will fill out a questionnaire after their training. This will take about 20 minutes to complete. Furthermore, counselors will fill out a log file for each participant after each session. This will take about 15 minutes per session.

Setting

The study will be carried out in the field of social work and care in ten municipalities in the Netherlands. The municipalities cooperate under responsibility of the alderman of welfare and care (wethouder welzijn en zorg). A municipal officer who is under direction of the alderman will be the local project leader. The recruitment of participants is done by intermediaries who work in local institutions in social work and care. Trained counselors are responsible for the intake and the delivery of interventions. The intervention and the study will be carried out at the homes of the participants.

Intervention

Experimental condition: Happiness Route

The intervention builds on the existing intervention Happiness Route (Toolkit Geluksbudget, 2008) but is formalized and strengthened with the help of existing intervention methods in positive psychology. The intervention consists of five stages: (1) mutual definition of the situation by the participant and counselor based on the findings from the intake, (2) goal orientation, (3) choice of an activity, (4) planning and carrying out the activity, and (5) early evaluation and feedback in a *booster* session. The counselor will make use of evidence-based methods during each phase. between two and five sessions will take place at the home of the participant, with a maximum of 1,5 hours per session. The stages are flexibly divided over the number of sessions. The whole process is completed within three months, before the second questionnaire will be filled in.

Control condition: Home Visiting Program

After the intake, participants receive two home visits to make sure that participants are provided with the best possible care as usual.

Study burden and risks

Participation in the study is not expected to have any risks. The predecessor to the behavioral experimental intervention *Happiness Route* (Geluksbudget) has been delivered to more than 400 adults without any negative effects. Participation is voluntary. There is only a very minor burden for participants in filling out three questionnaires. This will take about 45 minutes at each of the three measurement occasions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age: ≥ 18 years
- Social isolation: a score of 3 or higher on the loneliness scale (de Jong Gierveld & Van Tilburg, 1999)
- Low socioeconomic status: a low educational level (VMBO/LBO/MULO/MAVO or less) 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 1370euro for a couple; CBS, 2011).
- Health limitations, i.e. at least one health limitation on the EQ5D (Brooks, 1996)

Exclusion criteria

- High positive mental health: a high score on the Mental Health Continuum-Short Form (Lamers et al., 2010) - one standard deviation above the mean of the Dutch population, i.e. 4.83 or higher, to avoid ceiling effects.
- Serious depression: a score of 26 or higher on the Center for Epidemiology Depression Scale (CES-D) (Radloff, 1977; Bouma et al, 1995).
- Crisis situation: candidates who are in a (psychiatric) crisis or addicted to alcohol or drugs, or homeless, or having high debts, judged by the counselor during the intake
- 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 |
| Primary purpose: | Prevention |

Recruitment

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|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-09-2012 |
| Enrollment: | 256 |
| Type: | Actual |

Ethics review

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|--------------------|------------------------|
| Approved WMO | |
| Date: | 01-05-2012 |
| Application type: | First submission |
| Review commission: | METC Twente (Enschede) |
| Approved WMO | |
| Date: | 16-05-2013 |
| Application type: | Amendment |
| Review commission: | METC Twente (Enschede) |
| Approved WMO | |
| Date: | 27-11-2013 |
| Application type: | Amendment |
| Review commission: | METC Twente (Enschede) |
| Approved WMO | |
| Date: | 07-08-2014 |
| Application type: | Amendment |
| Review commission: | METC Twente (Enschede) |
| Approved WMO | |
| Date: | 19-02-2015 |

Application type: Amendment
Review commission: METC Twente (Enschede)

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 |
|----------|-----------------|
| CCMO | NL39774.044.12 |
| Other | NTR (TC = 3377) |