**PLEASE NOTE:** This trial has been registered retrospectively.

## Trial Description

### Title

Evaluation of the primary prevention program "Lebe Balance"

### Trial Acronym

[---]*

### URL of the trial

[---]*

### Brief Summary in Lay Language

This study examines the effectiveness of the primary prevention mental health program “Lebe Balance” which was developed in 2013 in cooperation with the German insurance company “AOK”. “Lebe Balance” aims to strengthen personal protective factors for stress-related mental illnesses by adapting evaluated psychotherapeutic interventions to a healthy population. The program is designed as a seminar based weekly program, lasting seven weeks for 1.5 hrs each seminar. All participants of the prevention courses between 11/13 and 06/14 were asked to take part in the study. Controls are drawn from a population of the insurance company's policy holders with statistically similar sociodemographic and health characteristics. A self-initiated participation in the evaluation study is not possible.

The aim of this study is to examine the outcomes of the program in terms of emotional distress, satisfaction in life, resilience and public health costs. The hypotheses are, that emotional distress and health costs decline while satisfaction in life and resilience rise in participants compared to controls. To investigate these hypothesis participants are asked to fill out a questionnaire prior to participation, after completion and 3 months follow-up. Controls are addressed at the same time points without receiving an intervention.

### Brief Summary in Scientific Language

**Background:**

Due to the enormous individual, societal and economic costs of mental illnesses, mental health promotion is of growing interest (see Jacobi, 2009). In terms of the biopsychosocial model of mental diseases, behavior oriented prevention aims at reducing psychological risk factors and raising psychological protective factors. The primary prevention program „Lebe Balance“ was developed in 2013 in cooperation with the German insurance company “AOK” (Bohus et al., 2013). It is based on the theoretical assumptions of the Acceptance- and Commitmenttherapy (ACT; z.B. Hayes et al.,2006); a behavioral approach, that doesn't address the specific symptoms of mental disorders, but teaches skills to enhance behavioral flexibility and value orientation. This approach was adapted to meet the
requirements of primary prevention. First, empirically supported protective factors for mental health are discussed directly (e.g. social networks and social support) or addressed via specific interventions (e.g. self-efficacy). Second, the program considers the fact, that motivation and intention building are not sufficient to initiate the behavior changes, which are substantial for effective prevention. Following the „Health Action Process Approach“ (HAPA) by Ralf Schwarzer (z.B. Sniehotta et al., 2005) this prevention program combines the implementation of valued behavior with the acquisition of problem-solving skills. The „Lebe Balance“ courses consist of 6 modules (1.5 hrs. each, presented weekly) with the main emphasis on the following topics: mindfulness, self-esteem, personal values, social networks and communication, behavior changes and one follow-up meeting (4-5 weeks after the last module) to maintain those changes. To enable lasting learning processes the basic principles of mindfulness and metacognitive awareness are addressed throughout all modules. For the time between meetings, the participants are given homework assignments, to improve the transfer of teaching content to daily life. The secondary aim is to examine the subjective satisfaction of participants as well as their compliance and transfer to daily life:

Do participants rate the topics as meaningful for their life and their mental health? Did they carry out the homework assignments and maintain behavior change (e.g. mindfulness practice)? Are there predictors for satisfaction with the course, compliance and transfer to daily life?

Research questions
The primary aim of this evaluation study is to examine (cost-) effectiveness of the “Lebe Balance” courses.

Hypothesis 1a: Satisfaction in life and resilience rise in participants compared to controls after completing the course (t1).
Hypothesis 1b: The changes in satisfaction in life and resilience remain stable until the 3-month-follow-up (t2).
Hypothesis 2a: Emotional distress declines in participants compared to controls after completing the course (t1).
Hypothesis 2b: The changes in emotional distress remain stable until the 3-month-follow-up (t2).
Hypothesis 3a: Participants have less direct and indirect health costs in the year after completing the course compared to the year before participation.
Hypothesis 3b: Participants’ direct and indirect health costs in the year after completing the course are lower than the health costs of the matched controls.

The secondary aim of the study is the examination of participant’s subjective experiences with the course, compliance and transfer of teaching to daily life:
- Do participants rate the topics as meaningful for their mental health and their life?
- Do they carry out their homework and keep a lasting practice in mindfulness.
- Can satisfaction with the courses, compliance and transfer be predicted by participant characteristics?

Method
The effects of the prevention courses are examined in a case-by-case matched control group design. All participants of the “Lebe Balance” courses offered by the “AOK-Baden-Württemberg” between 11/2013 until 06/2014 (approx. 5.000, expected response-rate 40-50%) are asked to take part in the study. Controls are drawn from the population of the insurance company’s policy holders (approx. 20.000, expected response-rate 40-50%, expected matching-attrition 50%).
Matching variables are sex, age, economic status, psychometric status and health costs. Outcome ratings are measured prior to participation, after completion and 3 months follow-up.

The outcome measures consist of questionnaire-based self-ratings:

- „Satisfaction with Life Scale“ (SWLS; Glaesmer et al., 2011)
- „Hospital Anxiety and Depression Scale“ (HADS-D; Herrmann, Buss & Snaith, 2007)

Literatur


Organizational Data

- **DRKS-ID:** DRKS00006216
- **Date of Registration in DRKS:** 2014/06/11
- **Date of Registration in Partner Registry or other Primary Registry:** [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2013-620N-MA**, Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg

Secondary IDs

**Health condition or Problem studied**
ICD10: Z73 - Problems related to life-management difficulty

Interventions/Observational Groups

- **Arm 1:** Study-group: Participation at the prevention course. The „Lebe Balance“ courses consist of 6 modules (1.5 hrs. each, presented weekly) with the main emphasis on the following topics: mindfulness, self-esteem, personal values, social networks and communication, behavior changes and one follow-up meeting (4-5 weeks after the last module) to maintain those changes.
  3 questionnaires (RS-11, SWLS, HADS) and questions about compliance and satisfaction with the course.

- **Arm 2:** Control-group: 3 questionnaires (RS-11, SWLS, HADS)

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Non-randomized controlled trial
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Control group receives no treatment
- Purpose: Prevention
- Assignment: Other
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

Measurement time points are previous to participation in the course (t0), after completing the course (t1= t0+10 weeks) and 3 months follow-up (t2 = t1 + 12 weeks).
This study is carried out with questionnaire-based self-ratings. The following measures are used at all three time points.
- „Satisfaction with Life Scale“ (SWLS; Glaesmer et al., 2011)
- „Hospital Anxiety and Depression Scale“ (HADS-D; Herrmann, Buss & Snaith, 2007)
The specific and unspecific health costs are drawn from the insurance company’s stock data.
Secondary Outcome

Secondary criteria are compliance, course satisfaction and lasting behavior changes in the study-group. These criteria are measured at t1 and t2 (maintaining of behavior change) via self-developed items.

Countries of recruitment

- DE Germany

Locations of Recruitment

- other Baden-Württemberg

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2013/10/28
- Target Sample Size: 4000
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

Participants of the prevention courses; matched controls (age, gender, health costs)

Exclusion criteria

Insufficient comprehension of the German language, impaired ability to judge or capacity to consent.

Addresses

- Primary Sponsor
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Sources of Monetary or Material Support

Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2015/11/01

Trial Publications, Results and other documents

- Paper <style fontName='DejaVu Sans' isBold='true'>Lyssenko, L., Müller, G., Kleindienst, N., Schmahl, C., Berger, M., Eifert, G., ... & Bohus, M. (2016). Effectiveness of a Mindfulness-Based Mental Health Promotion Program Provided by Health Coaches: A Controlled Multisite Field Trial. Psychotherapy and psychosomatics, 85(6), 375-377.</style>

* This entry means the parameter is not applicable or has not been set.
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