

Implementation and evaluation of the online self-help intervention "This is your life" in primary care: A pretest-posttest study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43295

Source

ToetsingOnline

Brief title

Implementation and evaluation of "This is your life" in primary care

Condition

- Other condition

Synonym

Physical symptoms and low or moderate well-being

Health condition

iedereen die last heeft van lichamelijke klachten en een verminderd welbevinden

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Stichting Agis

Intervention

Keyword: Chronic somatic symptoms, Online self-help, Positive psychology, Well-being

Outcome measures

Primary outcome

The primary outcome is the level of well-being, measured with the MHC-SF.

Secondary outcome

Secondary outcomes are resilience (BRS), depression (HADS-D), anxiety (HADS-A), positive and negative affect (PANAS), use of talents (SUS), self-compassion (SCS-SF) and positive relations (subscale of the PGGS). Additional variables include socio-demographic characteristics (i.e. sex, age, nationality, marital status, work- and living situation, education) and symptom-related characteristics (e.g. type of symptoms, time, received care).

Study description

Background summary

In recent years, the number of chronically ill people has increased rapidly. In 2011, approximately 5.3 million people in The Netherlands suffered from one or more chronic illnesses. Following a diagnosis with a chronic illness, many people experience a reduction in well-being and quality of life. In addition, people with a chronic illness are at increased risk of mental health problems, such as depression or anxiety. Consequently, next to medical care, it is important to pay attention to the (positive) mental health of the chronically ill. Unfortunately, existing interventions targeted at this population focus primarily on teaching self-management skills and not so much on resilience and

well-being. Positive psychology offers several intervention strategies for cultivating positive adaptation and resilience in people with chronic illnesses. Hence, the University of Twente developed a positive psychological online self-help intervention titled "This is your life" which has the potential to enhance well-being and resilience in adults with chronic somatic symptoms.

Study objective

The objective of the study is three-fold, namely:

- To develop a blended care protocol which can be used for implementing the online self-help intervention "This is your life" among adults with chronic somatic symptoms in primary care settings.
- To evaluate the feasibility of this blended care protocol in primary care.
- To gain insight in the possible effects of the online self-help intervention "This is your life" as blended care on levels of well-being and resilience of adults with chronic somatic symptoms.

Study design

Pilot study with a one sample pretest-posttest design.

Intervention

All participants have free access to the online self-help intervention "This is your life", following completion of the baseline assessment. This self-help intervention is focused on strengthening participants' resilience and well-being. The content is based on the self-help book "This is your life, experience the effects of positive psychology". The intervention comprises 8 lessons. Participants are asked to complete 4 or more lessons. Each lesson focuses on a specific theme, such as positive emotions, self-compassion or positive relations. The lessons about positive emotions and self-compassion are obligatory. The other lessons are optional. Each lesson starts with a brief introduction video, in which the theme and its relation to well-being is explained. Subsequently, the participant is provided with multiple exercises. Participants have 3 months to follow the intervention. They receive guidance from a practice nurse of their GP.

Study burden and risks

Participants are asked to complete at least 4 of the 8 lessons. However, participants decide for themselves how much time they spend on the intervention. They can follow the intervention online, and do more lessons or spend more time on exercises if they wish. Participants receive guidance from the practice nurse of their general practitioner. In total, this takes about 90 minutes.

Assessments take place before the start of the intervention (baseline), and after 3 months (posttest). Filling in the questionnaires takes approximately 20 to 30 minutes each time. Participants are screened before they are included in the study, which takes approximately 5 to 10 minutes. Finally, 6 to 10 participants are asked to participate in an interview which takes about 30 minutes. In total, measurements will take maximum 1 hour and 40 minutes to complete.

Based on the results of a recent randomised controlled trial on the effectiveness of "This is your life" as guided bibliotherapy, we do not expect any (significant) risks from participation.

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

- The participant is 18 years or older.
- The participant has chronic somatic symptoms of any kind.
- The participant experiences low to moderate well-being, as determined by the Mental Health Continuum-Short Form (MHC-SF).
- The participant has access to a computer, laptop or tablet/iPad with an adequate Internet connection.
- The participant possesses an e-mailaddress.
- The participant has sufficient computer skills.
- The participant is motivated to complete at least 4 lessons of the online self-help intervention in a 3-month period.
- The participant is able to read and write Dutch.
- The participant provides informed consent.

Exclusion criteria

- The participant experiences a high level of well-being (flourishing), as determined by the Mental Health Continuum-Short Form (MHC-SF).
- Presence of moderate to serious depressive or anxiety symptoms: score >14 on the depression scale and/or score >14 on the anxiety scale of the Hospital Anxiety and Depression Scale (HADS).

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated): 25-04-2016

Enrollment: 65

Type: Actual

Ethics review

Approved WMO

Date: 29-03-2016

Application type: First submission

Review commission: METC Twente (Enschede)

Approved WMO

Date: 21-04-2016

Application type: Amendment

Review commission: METC Twente (Enschede)

Approved WMO

Date: 23-09-2016

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	NL56952.044.16