# A prospective study to a blended ACT e-health training in curative treated breastcancer patients with distress: results and patient reports.

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

## Summary

### ID

NL-OMON44742

**Source**
ToetsingOnline

**Brief title**
Living to the full with breastcancer

### Condition

- Other condition

**Synonym**
distress, feeling uncomfortable

**Health condition**

distress-klachten

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Canisius Wilhelmina Ziekenhuis
**Source(s) of monetary or material Support:** Er is geen financiering voor het onderzoek.

## Intervention

**Keyword:** ACT, blended e-health, breastcancer

## Outcome measures

### Primary outcome

Primary outcome of the study is the level of well-being, measured by the MHC-sf

and the level of distress, measured by the HADS.

- Is there a significant increase in the level of well-being?

- Is there a significant decrease in the leve of distress?

### Secondary outcome

Secundary outcome of the study are the subscales from the MHC-sf.

Is there a significant increase in the level of emotional well-being?

Is there a significant increase in the level of psychological well-being?

Is there a significant increase in the level of social well-being?

As well there wil be investigated if the level of psychological flexibility and

engaged living will increase. When training is finished patients will be asked

to evaluate the training.

Is there an increasing level of psychological flexibility?

Is there an increasing level of engaged living?

How do patients evaluate the training?

How do the participants evaluate the training?

# Study description

### Background summary

Living to the full is already investigated in people with mild anxiety and mooddisorders in general population. These studies showed positive results, as well in training as in blended form. Well being increased, distress decreased. It is not clear yet if these results can even be finded in breastcancerpatients.

### Study objective

Aim of this study is getting a first indication from the effects described above (decrease distress, increase wellbeing). We will investigate if the effects found in general population even can be found in breastcancer patients and if there is a ground to set up an RCT in and implement the program in clinical practice.

### Study design

It's a prospective study without a controlgroup. We will include 50 patients.

### Intervention

Training Living to the full with breastcancer. This is a twelf week training, patients do it by there self, at home behind there computer. They will get information about Acceptance and Commitment Therapy and do exercises. There will be also planned five face to face contacts with a psychologist at the department Medical Psychology in CWZ on fixed moments: at the start, three times during the training and at the end of the training.

### Study burden and risks

We estimate that there are no risks for included patients. The estimated burden is limited. Included patients will be asked to respond three times, the estimated time to fill in the questionnaires is 15 to 30 minutes.

# 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

Breastcancer patients who has been treated curative.

## Exclusion criteria

Severe psychopathology (for example suicidality).
Younger than 18 years old.
Breastcancerpatients treated palliative.

# Study design

### Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-07-2016 |
| Enrollment: | 50 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 28-10-2015 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 18-05-2017 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL54429.091.15 |