

# **LYMFOcare: The impact of providing feedback on patients\* symptoms and health-related quality of life and offering a self-management website on the self-management of patients with lymphoma. A randomized controlled population-based registry trial.**

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To assess the impact of access to feedback and access to an internet-based self-management intervention after primary treatment of lymphoma by increasing self-management and decreasing distress. We hypothesise that patients who have access to...

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Approved WMO        |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | Lymphomas NEC       |
| <b>Study type</b>            | Interventional      |

## **Summary**

### **ID**

NL-OMON42473

### **Source**

ToetsingOnline

### **Brief title**

LYMFOcare

### **Condition**

- Lymphomas NEC

### **Synonym**

haematological malignancy, Hodgkin and non-Hodgkin lymphoma

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Integraal Kankercentrum Nederland (IKNL)

**Source(s) of monetary or material Support:** Jonker-Driessen Stichting

## Intervention

**Keyword:** feedback on quality of life, lymphoma, self-management, web-based psycho-education

## Outcome measures

### Primary outcome

self-management and psychological distress.

### Secondary outcome

Anxiety and depression, health care utilization, psychological empowerment, health-related quality of life (HRQoL) generic and specific, symptoms, illness perceptions, personal control, coping, satisfaction with information provision, remoralization, and fatigue.

## Study description

### Background summary

Since cancer patients survive longer, health-related quality of life (HRQoL) and other patient reported outcomes (PROs) are more and more recognized to be important. Particularly because many lymphoma survivors continue to face physical and psychosocial problems after completion of primary treatment. There is increasing recognition to improve information disclosure and cancer survivorship care. Providing web-based feedback on patient reported outcomes to patients has the potential to help detect unmet needs and symptoms leading to better control and monitoring of such issues, serve as a guide to discuss issues (empowerment), and facilitate individualized information provision and care. To diminish anxiety, depressive symptoms, emotional processing symptoms, and physical symptoms, interventions with cognitive behavioural therapy aspects

through E-health has been proven to be effective as for example shown by the internet-based self-management BREATH intervention for breast cancer patients. However, no evidence exists concerning the access to feedback and access to an internet-based self-management intervention on adjustment after cancer for patients with lymphoma.

## **Study objective**

To assess the impact of access to feedback and access to an internet-based self-management intervention after primary treatment of lymphoma by increasing self-management and decreasing distress. We hypothesise that patients who have access to feedback and/or the self-management website will report higher self-management and lower levels of distress, whereby we expect the effect to be larger for the patients who have access to both the feedback and internet-based self-management intervention.

## **Study design**

Randomized controlled trial (RCT). The impact of access to feedback on PROs (study arm 2), and the impact of access to feedback plus access to a self-management intervention (study arm 3) will be compared to usual care (study arm 1).

## **Intervention**

Feedback will be provided on quality of life, fatigue, emotional, physical, cognitive and social functioning, physical complaints, anxiety and depressive symptoms, coping and self-management. If patients prefer, they will also have access to a mean score of other people with lymphoma and to a mean score of a normative population of people without cancer.

The self-management website will focus on psychological problems (such as anxiety and depressive symptoms), emotional processing issues, social problems (such as work resumption and reactions to the environment), and physical problems (such as fatigue, pain and sexuality).

## **Study burden and risks**

There are no risks involved for the participating patients of this study. Participants are asked to complete a questionnaire at 4 different points in time: baseline (i.e. 6-12 months after diagnosis), 16 weeks, 1 and 2 years after baseline. This study aims to contribute to efforts to improve adjustment after primary treatment for patients with lymphoma.

## Contacts

### Public

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NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

All patients (men and women) that are newly diagnosed with Hodgkin or non-Hodgkin lymphoma in one of the participating hospitals and were 18 years or older at time of diagnosis.

### Exclusion criteria

Unable to complete a Dutch questionnaire.

Patients with severe psychopathology or dementia.

## Study design

### Design

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

**Primary purpose:** Treatment

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 25-04-2016          |
| Enrollment:               | 500                 |
| Type:                     | Actual              |

## Ethics review

|                    |                        |
|--------------------|------------------------|
| Approved WMO       |                        |
| Date:              | 28-10-2015             |
| Application type:  | First submission       |
| Review commission: | METC Brabant (Tilburg) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 27749

Source: Nationaal Trial Register

Title:

5 - LYMFOfcare: The impact of providing feedback on patients\* symptoms and health-rel ... 27-05-2025

## In other registers

| Register | ID             |
|----------|----------------|
| CCMO     | NL54096.028.15 |
| OMON     | NL-OMON27749   |