The Lymphoma InterVEntion: personalized feedback and a self-management intervention to improve patient reported outcomes

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27749

Source
Nationaal Trial Register

Brief title
Lymphoma InterVEntion [LIVE]

Health condition

lymphoma; self-management; web-based intervention; personalized feedback; education; patient reported outcomes

Sponsors and support

Primary sponsor: Netherlands Comprehensive Cancer Organisation (IKNL)
Source(s) of monetary or material Support: Jonker-Driessen Stichting, Oestgeest, the Netherlands

Intervention

Outcome measures

Primary outcome

Self-management skills (heiQ; Osborne, 2007), Satisfaction with information provision (ISQ; Thomas, 2004) , and psychological distress (HADS; Zigmond, 1983).

1. Osborne RH, Elsworth GR, Whitfield K. The Health Education Impact Questionnaire (heiQ): an outcomes and evaluation measure for patient education and self-management interventions for people with chronic conditions. Patient education and counseling. 2007;66(2):192-201.

2. Thomas R, Kaminski E, Stanton E, Williams M. Measuring information strategies in oncology - developing an information satisfaction questionnaire. Eur J Cancer Care. 2004;13(1):65-70.

3. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta psychiatrica Scandinavica. 1983;67(6):361-70.

Secondary outcome

1. General health-related quality of life (EORTC QLQ-C30)

2. Disease-specific health-related quality of life (EORTC QLQ-HL27 for Hodgkin lymphoma, QLQ-NHL-HG29 for aggressive and QLQ-NHL-LG20 for indolent non-Hodgkin lymphomas, and QLQ-CLL17 for chronic lymphocytic leukaemia

3. Adjustment to cancer (MAC)

4. Self-effecacy (SE-28)

5. Illness perceptions (B-IPQ)

6. Fatigue (MFI)

7. Health care use

Medical disease-specific data are collected form the Netherlands Cancer Registry and for the experimental groups, technical data on the use of personalized feedback and the web-based intervention are collected, in addition to the standardized questionnaires.

Study description

Background summary

Patients with lymphoma are at risk of experiencing adverse problems, with up to a quarter reporting psychological distress. Greater resources for coping with the cancer experience can reduce the risk for poor psychological health. Personalized feedback and a web-based self-management intervention provide patients with knowledge and skills, which might improve empowerment and increase active participation to self-manage their symptoms, since time spent with a health care professional is limited.

Study objective

The purpose of this study is to develop an intervention for patients with lymphoma to reduce the impact of psychological problems that arise after diagnosis. The research question is whether personalized feedback and/or a self-management intervention compared with usual care is effective in reducing psychological distress and/or improving self-management skills and information provision.

Study design

Baseline (6 to 12 months after lymphoma diagnosis) and 16 weeks, 12 months and 24 months after baseline

Intervention

The Lymphoma InterVEntion [LIVE] trial consists of two components: (1) the provision of personalized feedback to patients about their self-reported symptoms and quality of life in comparison with other age and sex-matched lymphoma patients and/or a norm population, and (2) a web-based self-management intervention Living with lymphoma directed at improving self-management skills and information provision, while reducing psychological distress. The provision of personalized feedback on PROs facilitates monitoring one’s own symptoms and functioning. The second component, Living with lymphoma, is an adaptation from BREAst cancer e-healTH (BREATH) for patients with breast cancer survivors and is based on cognitive behavioural therapy (CBT) components, such as psychoeducation and cognitive reframing and is directed to lymphoma patients.

The control group receives usual care.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosed 6 to 12 months before inclusion with Hodgkin lymphoma or non-Hodgkin lymphoma, including chronic lymphocytic leukaemia as defined by the International Classification of diseases for Oncology-3 codes (ICD-O-3)

2. Diagnosed in one of the participating hospitals

3. Aged 18 years or older at time of diagnosis

Exclusion criteria

1. Problems with the Dutch language

2. Severe psychopathology or dementia

3. Patients in transition to terminal care

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	222
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42473
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5790
NTR-old	NTR5953
CCMO	NL54096.028.15
OMON	NL-OMON42473

Study results