

Distress and quality of life in autologous stem cell transplantation: stepped care.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28586

Source

Nationaal Trial Register

Brief title

STEC-2

Health condition

hematological malignancy; autologous stem cell transplantation; acute leukemia; multiple myeloma; (non-)Hodgkin; anxiety; depression

hematologische maligniteit; autologe stamceltransplantatie; acute leukemie; multipel myeloom; non-Hodgkin; angst; depressie

Sponsors and support

Primary sponsor: Inholland University, Research Group Mental Health Nursing, Amsterdam, the Netherlands

VU University Medical Center, Amsterdam, the Netherlands

Intervention

Outcome measures

Primary outcome

Psychological distress (measured with the HADS) and physical role function (subscale from the EORTC-QLQ-C30).

Secondary outcome

Other measures of psychological distress (PHQ-9, STAI-state), other aspects of quality of life (EORTC-QLQ-C30, SF-36), cognitions and coping (DGSS, SPSI-R).

Study description

Background summary

Background:

Psychological distress (i.e. depression and anxiety) is a strong predictor of functional status and other aspects of quality of life in autologous stem cell transplantation following high-dose chemotherapy (aSCT). Treatment of psychological distress is hypothesized to result in improvement in psychological distress, and thereby in improvement of functional status and other aspects of quality of life. Treatment for psychological distress will be delivered according to the stepped care approach: a less intensive intervention (i.e. internet based self-help program) is tried first, with more intensive and costly interventions (i.e. individual face-to-face counseling, medication, or planned referral to other services) reserved for those insufficiently helped by the initial intervention.

Aim:

To evaluate the outcome of stepped care for psychological distress on functional status and other aspects of quality of life in patients with hematological malignancy treated with autologous stem cell transplantation following high-dose chemotherapy.

Design:

Pragmatic randomized clinical trial with 2 treatment arms: stepped care and care as usual. Patients treated with aSCT are randomized immediately pre transplant (T0) to stepped care or care as usual. Stepped care and care as usual are initiated after a 3 weeks buffer period. Outcome is evaluated at 10 weeks (T10), 24 weeks (T24) and 36 weeks (T36) post transplant.

Stepped care:

The steps include (i) internet based self-help program (based on the principles of problem solving therapy). If psychological distress persists after the self-help intervention, a

diagnostic evaluation, standardized interview and problem analysis are performed. Based on this information, (ii) a contract is made with the patient on the next step and treatment is provided consisting of individual face-to-face counseling (based on the principles of problem solving therapy), medication, or planned referral to other services.

Care as usual:

Interview with patient, on ad hoc basis; emotional support and advise, on ad hoc basis; if urgent problems emerge, referral to other services.

Evaluation of outcome:

Primary outcome variables are psychological distress and functional status. Data are analyzed according to the intention to treat principle. The study is powered to detect a moderate effect size ($d=0.5$).

Study objective

Evaluation of the outcome of stepped care for psychological distress on functional status and other aspects of quality of life in patients with hematological malignancy treated with autologous stem cell transplantation following high-dose chemotherapy.

Study design

1. T0: pre-transplant;
2. T10: ten weeks post transplant;
3. T24: twenty-four weeks post transplant;
4. T36: thirty-six weeks post transplant.

Intervention

Protocol stepped care:

1. Step 1: Internet based self-help program ('Alles onder controle': a brief web based intervention for problem-solving which is based on self-examination therapy);
2. Step 2: The following treatment options are available in step 2: individual face-to-face counseling, medication, referral to other services.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with hematological malignancy (multiple myeloma, (relapsed) (non-)Hodgkin lymphoma, acute myeloid leukemia, or acute lymphoid leukemia) treated with autologous stem cell transplantation following high-dose chemotherapy;
2. Life expectation > 3 months.

Exclusion criteria

1. Age < 18 or > 65 years (65 is included);
2. Insufficient command of the Dutch language to complete questionnaires; or, if so: no support by family or professional interpreters;
3. Contra-indication for the stepped care approach;
4. No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	128
Type:	Actual

Ethics review

Positive opinion	
Date:	20-04-2009
Application type:	First submission

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
NTR-new	NL1669
NTR-old	NTR1770
Other	METC VU University Medical Center : 2008/289
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A