

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28586

Bron

Nationaal Trial Register

Verkorte titel

STEC-2

Aandoening

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

Ondersteuning

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

VU University Medical Center, Amsterdam, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 ($d=0.5$).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	128
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	20-04-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A