

Focus on values to stimulate shared decisions in patients with thyroid cancer: A multifaceted COMmunication BOoster (COMBO)

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Psychological and communication theories predict that COMBO improves values deliberation, compared to a single tool. Alongside, patient decision outcomes such as being decisive, being knowledgeable, and being clear about values will improve. As...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21139

Bron

NTR

Verkorte titel

COMBO

Aandoening

Thyroid cancer

Ondersteuning

Primaire sponsor: Radboudumc

Overige ondersteuning: KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of SDM, assessed from the audio-recording of the consultation.

Toelichting onderzoek

Achtergrond van het onderzoek

Most patients with non-medullary thyroid carcinoma (TC) achieve remission after primary treatment. Nonetheless, 30% develop recurrent disease and/or distant metastases resulting in worse survival. Patients with low- and intermediate-risk, whilst having a good prognosis, generally undergo similar primary treatment as those with a high-risk disease and face the risk of complications and burden of treatment, without a proven benefit in long-term outcome. For these patients, current guidelines state that less aggressive treatment (e.g. hemi-thyroidectomy vs. total thyroidectomy, and selective use of radioiodine (RAI) therapy), and tailored follow-up can be equally acceptable leaving room for patients' preferences. For high-risk patients, important unanswered question regard the optimal timing of starting tyrosine kinase inhibitors (TKI). For those who are asymptomatic or only mildly symptomatic, starting the treatment too early may expose them to side effects and impair quality of life, without evidence of a survival benefit.

Different patients have different views on these decisions, and so do physicians. Therefore, care should honour preferences and values of individual patients, and care should involve patients through shared decision making (SDM). The principle of SDM is twofold: 1. physicians provide patients with information on the existing options, and 2. help patients identify their preferences considering their individual values and needs. This involves important life values, for instance the desire to do everything possible, or to minimise complaints.

Addressing patients' treatment-related values is arguably the most difficult part of SDM so patient values are less likely to be discussed and honoured in a consultation. Current tools improve values deliberation but their effects are clearly insufficient. Tools should be integrated and applied in consultations to increase effectiveness. To strengthen values deliberation with TC as an example, a multifaceted intervention, COMBO, is proposed including 1) a patient values clarification exercise, named SDM-booster, 2) a physician values deliberation training using the SDM-booster, and 3) a patient decision aid. The SDM-booster strengthens values deliberation by 1) strengthening and clarifying patients' values and preferences, 2) communicating patients' values in the consultation, 3) serving as a focus in the values deliberation training.

Doel van het onderzoek

Psychological and communication theories predict that COMBO improves values deliberation, compared to a single tool. Alongside, patient decision outcomes such as being decisive, being knowledgeable, and being clear about values will improve. As values are deliberated between

physicians and patients, physician's understanding of patient values will improve.

Onderzoeksopzet

Implementation

Evaluation

Onderzoeksproduct en/of interventie

This proposal improves values deliberation in treatment choices through development, implementation and evaluation of a multifaceted intervention (COMBO), that includes a decision aid, a values clarification exercise (SDM-booster), and a values deliberation training for physicians.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Total thyroidectomy vs hemithyroidectomy:

- patients with nodules >1 cm and <4 cm, with cytology result suspicious or malignant (Bethesda 5 or 6) with no clinical or radiological evidence of pathological lymph nodes and/or distant metastases before the primary (diagnostic) surgery
- patients with histologically (after diagnostic hemithyroidectomy) proven TC but are defined

as low-risk according to the ATA classification(97,98) -patients with multifocal TC
-patients with incomplete resection of the primary tumor
-patients with ATA defined intermediate risk or high risk

No treatment with RAI vs. treatment with RAI:

-patients with ATA defined low-risk (98) and patients with multifocal papillary TC in the absence of other adverse features.

Active surveillance vs. systemic treatment:

-patients with asymptomatic or mildly symptomatic RAI-refractory (slowly) progressive metastatic disease

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Total thyroidectomy vs hemithyroidectomy:

-patients with multifocal TC
-patients with incomplete resection of the primary tumor
-patients with ATA defined intermediate risk or high risk

No treatment with RAI vs. treatment with RAI:

-patients with ATA defined intermediate risk or high risk

Active surveillance vs. systemic treatment:

-patients with coexisting conditions that do not allow prescription of TKI's

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-03-2019
Aantal proefpersonen: 128
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

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	NL8281
Ander register	METC radboudumc : METC2018-4521

Resultaten

Samenvatting resultaten

N/A