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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21139

Source
NTR

Brief title
COMBO

Health condition

Thyroid cancer

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Choice and decision making role
Knowledge
Evaluation of the decision
Worries and trust
Patient evaluation of SDM process
Audio recording

Study description

Background summary

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.

Study objective

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.

Study design

Implementation
Evaluation

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2019
Enrollment:	128

Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable
Application type: Not applicable

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	NL8281
Other	METC radboudumc : METC2018-4521

Study results

Summary results
N/A