

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

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Aim: to develop, implement and evaluate COMBO to improve SDM during the treatment trajectory of TC patients in situations when clear cut recommendations cannot be made either because the benefits closely balance with risks, or because this balance...

Ethical review	Approved WMO
Status	Pending
Health condition type	Endocrine neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON55767

Source

ToetsingOnline

Brief title

Focus on values to stimulate shared decisions

Condition

- Endocrine neoplasms benign
- Endocrine gland therapeutic procedures

Synonym

Thyroid cancer

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: KWF

Intervention

Keyword: patient treatment preferences, quality of life, shared decision making, thyroid cancer

Outcome measures

Primary outcome

Primary outcome, SDM measure from the consultation

Our primary outcome measure is the quality of SDM, assessed from the audio-recording of the consultation. These recordings are transcribed and scored on the 5-item Observer OPTION scale assessing to what extent physicians involves patients in decision making. Atlas.ti is used to code the transcripts. Coders will be trained by an experienced coder using the training module from the OPTION instrument. Each consultation is assessed by two coders to enhance accuracy and test reliability. Coders are blinded to the randomisation arm. Prior to coding, in the intervention group only, utterances identifying the intervention group will be removed by an independent third coder. Discrepant ratings are iteratively discussed and resolved by consensus.

Secondary outcome

Secondary outcome measures

The outcomes below are measured to monitor the effectiveness of the decision aid/SDM-booster.

a) choice and decision making role

- b) knowledge
- c) evaluation of the decision
- d) worries and trust
- e) patient evaluation of SDM process
- f) audio-recording

Additional outcomes scored from the audio-recording are:

- duration of the consultation
- has a treatment choice been made
- is an additional consultation necessary

Physicians* understanding of patients* values

In the SDM-booster, three common values are incorporated that can be valued by patients as well as physicians. Physicians* understanding of patient values is assessed by the agreement between patient values and physicians* substitute values in relation to these three common values. For this purpose, importance weights are obtained for these three values, using a 4-points importance scale ranging from *hardly important * to *very important *

Patient values are measured pre-consultation at T1 and post consultation at T2. In the COMBO group, patient values will be measured at T1 after reading the decision aid.

Physicians* substitute values are asked at the end of the decision making consultation using a short questionnaire. The physician is invited to assume the patient perspective and asked: *How important does this patient find each of these three values?" Responses are on the 4-point importance Likert scale.

In addition, physician's own values are asked as follows: *And for yourself, which of these values do you find most important considering this patient", again using the importance Likert scale.

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

Aim: to develop, implement and evaluate COMBO to improve SDM during the treatment trajectory of TC patients in situations when clear cut recommendations cannot be made either because the benefits closely balance with risks, or because this balance cannot be determined based on existing evidence; to make physicians more aware of patients* values through SDM.

Research questions:

- 1) Does COMBO result in better SDM (primary outcome) and better decision outcomes in patients with TC?
- 2) Does COMBO improve physicians* understanding of what patients with TC find important?
- 3) What is the feasibility of COMBO regarding its uptake and what are experiences of patients with TC and their physicians?

Study design

Plan of investigation: In WP1, the decision aids, SDM-booster, and deliberation training will be developed together with patients, physicians, and experts in medical decision making and doctor-patient communication. Decision aids are developed for the care pathway: 1) extent of thyroid resection, 2) initiation of TKIs for high-risk patients. In WP2, patients with TC are randomised between COMBO and the training for physicians alone. The decision aid, the SDM-booster, and baseline questionnaire are sent to patients* home. The baseline measures contain demographic and clinical characteristics, patient pre-consultation values, and decision making and safety items. For both arms, the next decision consultation is audio-recorded and SDM as measured with the OPTION scale is scored. Physicians*own values and substitute values are also noted. Patients' post-consultation values and decision outcomes are assessed 1 week after the consultation by questionnaires sent at home. In WP3, the feasibility of the uptake of COMBO components is studied using interviews and questionnaires for patients and physicians. Power: a moderate effect size of 0.5 on OPTION can be detected with 128 complete patients with an alpha 5%, and a power of 80%. Seven academic hospitals will participate in the study, and 224 patients will be approached for participation.

Intervention

The intervention consists of a decision aid, a values clarification exercise (the booster), and the values communication training for physicians. The decision aid is randomised. We choose for this design because we aim to evaluate the combined tool, COMBO, against the best alternative care regarding shared decision making. As communication training is a prevalent strategy to implement SDM in Dutch health care, we consider communication training as a standard element of current care. Therefore the values deliberation training

for physicians is present in both arms.

Study burden and risks

Patients face difficulties to express their values in the patient-doctor communication. Listening to patient values is a prerequisite for honouring their treatment preferences, and for personalising their care. Audio-recordings in clinical practice show that behaviours such as "the physician invites patient to ask questions; the physician asks for expectations and fears; the physician asks whether information is understood" are not frequently observed. Clearly, more powerful tools should be created to improve SDM.

The aim of our study is to facilitate patients to express what matters to them in the treatment choice. The burden on patients in the intervention group is that they receive a decision aid: Decision aids have been shown to be safe, and are welcomed by patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

Patients with primary and advanced thyroid cancer

Exclusion criteria

Exclusion criteria are clinical exclusion criteria, lack of Dutch language proficiency, and mental incompetence hampering the process of shared decision making as judged by the physician.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2020
Enrollment:	128
Type:	Anticipated

Ethics review

Approved WMO	
Date:	14-01-2020

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-07-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL66538.091.18