

The implications of discussing uncertainty in cancer genetic counseling about multigene panel testing for (analogue) patients* cognitive and affective outcomes.

Published: 18-02-2020

Last updated: 11-02-2024

This study aims to examine the effects of different manners in which counselors communicate uncertainty and respond to counselees* uncertainty, on analogue patients* affective and cognitive outcomes. In addition, the results of this study are used...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational non invasive

Summary

ID

NL-OMON49684

Source

ToetsingOnline

Brief title

Communication of and responses to uncertainty

Condition

- Chromosomal abnormalities, gene alterations and gene variants

Synonym

Hereditary cancer; oncological predisposition

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: KWF kankerbestrijding

Intervention

Keyword: Genetic counseling, Hereditary cancer, Uncertainty

Outcome measures

Primary outcome

Degree of uncertainty

Secondary outcome

Degree of anxiety, degree of control, satisfaction, hope, trust, trust in understanding, information recall and decision-making.

Study description

Background summary

Nowadays, multigene panel tests are increasingly used to determine whether someone has a predisposition for hereditary cancer. These tests involve sequencing multiple genes at once, including genes whose association with cancer and consequences are less known. Panel tests are mainly performed when multiple types of cancer run within family fitting multiple cancer syndromes, or when a targeted test did not identify a predisposition despite a strong suspicion. Unfortunately, sequencing increased amounts of (unknown) genes may increase the level of uncertainty. According to the framework of Han and colleagues, uncertainty may be scientific, i.e., relating to diagnosis and its implications, practical, i.e., related to the process of care, or personal, i.e., related to counselees* psychosocial issues. Informing counselees during genetic counseling about panel tests unavoidably involves communicating various forms of uncertainty as uncertainties are part of the information that is usually provided. With regard to decisions about panel testing, it is particularly important that counselees are fully informed to enable to make an informed decision. In addition, communicating uncertainties may also be beneficial for the relationship between counselor and counselee, and may enhance counselees* confidence in the counselor. However, previous studies have shown that the communication of uncertainty may not only be beneficial as it

may overwhelm counselees, cause them to worry, and can even impair their ability to make decisions. It is unknown what causes the differences in effects of the communication of uncertainty. One explanation might be that different manners in which uncertainty is communicated and counselors and counselees deal with uncertainty during genetic counseling, affect counselees variously.

In a previous study of this research project, we identified uncertainties expressed by counselors and counselors during oncogenetic counseling. This study showed that counselors and counselors differ in the uncertainties they express, and that counselors mainly expressed uncertainty about scientific topics, while counselees mainly expressed uncertainty about personal and practical topics (2). Subsequently, in a qualitative study, we investigated the experiences of counselors and counselees with discussing uncertainty in the context of panel tests. This study showed, among other things, that counselors feel uncertain about what they should communicate during pre-test counseling and that they differ in the degree of uncertainty they communicate to counselees (3). To gain insight in current practice, we subsequently conducted an observational study in which counselors conducted a consultation with a simulated patient (an actor) discussing a panel. Therefore, we gained insight into the manner and variation in which counselors communicate uncertainty and their responses to uncertainty expressed by patients. The results of this study showed that many scientific uncertainties are communicated by counselors and that they mainly respond to uncertainties expressed by the patient by using responses that limit the possibility to further discuss this uncertainty (4). In the current study we want to build upon these results by looking at the effects of different ways of communicating and responding to uncertainty on counselees outcomes, such as their level of uncertainty, fear and understanding. In addition, we want to investigate whether characteristics of counselees influence the effect of communicating and responding to uncertainty, on their outcomes.

(1) Han, P.K., Klein, W.M., & Arora, N.K. (2011). Varieties of uncertainty in health care: a conceptual taxonomy. *Medical Decision Making*, 31 (6), 828-838.

(2) Medendorp, N. M., Hillen, M.A., Murugesu, L., Aalfs, C.M., Stiggelbout, A.M., & Smets, E.M. (2018). Uncertainty in consultations about genetic testing for cancer: an explorative observational study. *Patient education and counseling*, 101 (12), 2083-2089.

(3) Medendorp, N. M., Hillen, M.A., Murugesu, L., Aalfs, C.M., Stiggelbout, A.M., & Smets, E.M. (2018). Uncertainty related to multigene panel testing for cancer: a qualitative study on counselors 'and counselees' views. *Journal of community genetics*, 1-10.

(4) Medendorp, N. M., et al. (2019). "We do not know for sure": The discussion of uncertainty regarding multigene panel testing during cancer genetic consultations. (submitted)

Study objective

This study aims to examine the effects of different manners in which counselors communicate uncertainty and respond to counselees* uncertainty, on analogue patients* affective and cognitive outcomes. In addition, the results of this study are used to make recommendations about how to communicate and respond to uncertainty in genetic counseling about multigene panel testing, and contribute to the development of a skills training in communicating and dealing with uncertainty for genetic counselors.

Research questions:

1. How are different manners of communicating uncertainties (current practice vs. outline) associated with (analogue) patients* affective and cognitive outcomes (i.e., level of uncertainty, anxiety, sense of control, satisfaction, hope, trust in the counselor, confidence in understanding, understanding, recall, empowerment and decisional conflict)?
2. How are different manners in which counselors respond to counselees* uncertainties (current practice vs. providing space vs. balancing uncertainty) associated with (analogue) patients* affective and cognitive outcomes (i.e., level of uncertainty, anxiety, sense of control, satisfaction, hope, trust in the counselor, confidence in understanding, understanding, recall, empowerment and decisional conflict)?
3. How are combinations of different manners in which counselors communicate and respond to counselees* uncertainties associated with (analogue) patients* affective and cognitive outcomes (i.e., level of uncertainty, anxiety, sense of control, satisfaction, hope, trust in the counselor, confidence in understanding, understanding, recall, empowerment and decisional conflict)?
4. Do (analogue) patients* sociodemographic characteristics (i.e. age, gender, educational level, health literacy, medical history and experience with genetic counseling) and personality characteristics (anxiety, uncertainty tolerance, optimism, preferences for information, desired role in decision making, expectation of degree of uncertainty and coping style) moderate the association between the manner in which uncertainty is communicated and counselors respond to counselees* uncertainties, and (analogue) patients* affective and cognitive (i.e., level of uncertainty, anxiety, sense of control, satisfaction, hope, trust in the counselor, confidence in understanding, understanding, recall, empowerment and decisional conflict)?

Study design

The study involves an experimental video vignettes design using analogue patients.

Video vignettes are short, scripted video-taped physician-patient consultations, played by actors. Manipulating oncologists* communicative behavior in actual clinical practice would not be ethical, because it might lead to suboptimal communication and adverse patient outcomes. Therefore, a randomized experimental video-vignettes design was used in this study. Six versions of a vignette in which a consultation is displayed showing a counselor and counselee discussing a multigene panel test. The six versions contain the same content but differ only in specific elements of the communication. This

approach allows us to determine the effect of different communication and response styles on (analogue) patients* outcomes. Moreover, it allows to investigate causal relationships between communication and outcomes, as the communication of counselors is standardized and only small variations are applied. In this study we will create manipulations regarding how uncertainty is communicated by counselors, and how they respond to counselees* uncertainties. One current practice video vignette is developed with the communication of uncertainty as similar as possible to current practice of communicating and responding to uncertainty by counselors. One vignette is developed in addition to the current practice vignette, which is called outline. The content of the uncertain information that is communicated will be similar to the current practice vignette, but uncertain information will be provided to a much lesser extent. With regard to counselors responding to counselees* uncertainty, two variations in addition to a current practice (i.e. information provision) vignette are developed. One variation contains responses by counselors that provide space for the patient to further express his uncertainties expressed by the patient (e.g. by inviting the patient for further disclosure) and the second variation contains responses that balance and emphasize the two sides than uncertainty contains (e.g. that uncertainty can generate both a negative and positive outcome). The video vignettes are viewed by so-called analogue patients who will watch the video while being instructed to imagine themselves being the video patient. Generally, former patients are used as analogue patients as they have a certain level of experience with the studied type of consultations.

Study burden and risks

Burden and risk are estimated as very low. Completing the questionnaire will only involve a one-off time burden of 45 minutes.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Adults who have visited one of the participating genetic centers and having received genetic counseling for hereditary cancer.

Exclusion criteria

Children, and adults having received genetic counseling for possible hereditary predisposition for other diseases than cancer. Being either cancer patient themselves or a relative of a cancer patient.

Study design

Design

Study type: Observational non invasive

Masking: Single blinded (masking used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-07-2019

Enrollment: 222

Type: Actual

Ethics review

Approved WMO	
Date:	29-05-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	12-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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

CCMO

ID

NL68644.018.18