Hernieuwd contact in de Klinische Genetica.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22897

Source
NTR

Health condition

recontact in clinical genetics
reclassification
actionable information
ehealth
webapplication
PHR

Sponsors and support

Primary sponsor: University Medical Center Groningen
Hanzeplein 1
9713 GZ Groningen
The Netherlands
Source(s) of monetary or material Support: self financing research (department of genetics UMCG and UMCG funding for salary researcher)

Intervention

Outcome measures

Primary outcome

experience with the personal health record compared to standard care:

- acceptability and usability ((adaptations of) the System Usability Scale, PWU, Webclic, VisAWI-s)

psychological impact of recontact via the online personal health record compared to standard care:

- anxiety (STAI: 6 items)

- worries (adaptation of the Cancer Worry Scale)

- affect (adaptation of the PANAS)

- trust in clinical genetics/ clinical geneticist Dutch version of the Wake Forest Physician Trust Scale

Secondary outcome

experience with the information message:

- content

- construction

- clarity

understanding of the new information:

- knowledge questions

- risk perception

pratical implications:

- opting out of new information

- requested follow-up with clinical genetics department

- informing of medical professionals/ familymembers about the new information by patients

Study description

Background summary

Genetic knowledge is expanding rapidly, due to technical advances, the increasingly broader scope of diagnostic testing in genetics and datasharing.

This leads to reclassifications of genetic test results and advancing insights about genetic conditions and recommendations for screening/ treatment with preventive options/health gains. Both clinicians and patients feel that it is important to recontact patients about clinically relevant new genetic information.

However, a systematic review by E. Otten has shown that there are many practical barriers hindering recontact.

E-health could be a possible solution to many of the practical difficulties. We have developed a personal health record that can be used for communication between patient and clinical geneticist (and other health care professionals/ caregivers etc).

In this trial we study if this personal health record is an acceptable, patient friendly and efficient method of recontacting. We compare recontact using this tool with our current standard of care, recontact by a personal letter.

Study objective

A personal health record (PHR)* is a practical, responsible and patient friendly tool to assist in the proces of recontacting in clinical genetics.

* PGO in Dutch. In English I've used the term PHR or the broader term webapplication.

Study design

T0: patient receives a letter stating that there is new information about their genetic condition/ past genetic testing . Patient is given the oportunity to opt-out from receiving new information and is asked to participate in the trial (before randomization). First questionnaire is enclosed.

T1: after receiving the new information via personal health record (intervention) or personal letter (control). Patients receive an invitation to an online questionnaire or a paper version of the questionnaire (if preferred by patient)

T2: 2-3 months after T0 or after follow up contact with the clinical genetics department UMCG. Patients have the option to request follow up contact with the clinical genetics department about the new information.

Intervention

The intervention studied is the receiving of new, layered actionable information about their genetic condition/ results of past genetic testing via a personal health record designed for this purpose, with the options of getting in contact with the former genetic counselor (or colleague) by email, telephone or in person if desired.

We compare this intervention to our standard care; receiving new information about a patients genetic condition/ results of past genetic testing via a personal letter, with the same options for follow up contacts.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- (former) patient of the clinical genetics department of the University Medical Center Groningen (or possibly another Dutch department for clinical genetics, in case the trial becomes multicenter)

- (former) patient falls under one of the specified groups eligible for recontact (e.g. NF1 patients, reclassification patients)

- (former) patient >16 years or parents of a (former) patient <16 years

- (former) patient wishes to receive new information about his/ her genetic condition/result of past genetic testing

- access to a PC or tablet/ ipad with internet

- an e-mailaddress

- mastery of the Dutch language

- written informed consent

Exclusion criteria

- (former) patient opts out of receiving new information about his/ her genetic condition/result of past genetic testing or doesn't answer first message about the possibility of receiving new information.

- no access to a PC or tablet/ ipad with internet (however if this is the case, patients are asked to fill in the questionnaires (seperate cohort))

- no e-mailaddress

(however if this is the case, patients are asked to fill in the questionnaires (seperate cohort))

- no mastery of the Dutch language

- no written informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2018
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-07-2018
Application type:	First submission

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	NL7124
NTR-old	NTR7470
Other	UMCG : 201400072

Study results

Summary results

Is there a duty to recontact in light of new genetic technologies?: A systematic review of the literature

Otten, E., Plantinga, M., Birnie, E., Verkerk, M. A., Lucassen, A. M., Ranchor, A. V. & Van Langen, I. M. Aug-2015 In : Genetics in Medicine. 17, 8, p. 668-678 11 p.
European Journal of Human Genetics
Recontacting patients in clinical genetics services: recommendations of the European Society of Human GeneticsManuscript:504-18-EJHG
European Journal of Human Genetics Title:Recontacting or not recontacting? A survey of current practices in clinical genetics centres in EuropeManuscript:798-17-EJHGR