

Hernieuwd contact in de Klinische Genetica.

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A personal health record (PHR)* is a practical, responsible and patient friendly tool to assist in the process of recontacting in clinical genetics. * PGO in Dutch. In English I've used the term PHR or the broader term webapplication.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22897

Bron

Nationaal Trial Register

Aandoening

recontact in clinical genetics
reclassification
actionable information
ehealth
webapplication
PHR

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Hanzeplein 1
9713 GZ Groningen
The Netherlands

Overige ondersteuning: self financing research (department of genetics UMCG and UMCG funding for salary researcher)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T0: patient receives a letter stating that there is new information about their genetic condition/ past genetic testing . Patient is given the opportunity 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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- (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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- (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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	13-07-2018
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	26-07-2018
Soort:	Eerste indiening

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	NL7124
NTR-old	NTR7470
Ander register	UMCG : 201400072

Resultaten

Samenvatting resultaten

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