

# The effects of a multi-faceted health literacy intervention for patients with chronic kidney disease and their healthcare professionals: a quasi-experimental study

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aanpak</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON23167

### Bron

NTR

### Verkorte titel

TBA

### Aandoening

Chronic kidney disease

### Ondersteuning

**Primaire sponsor:** University Medical Centre Groningen, Nierstichting

**Overige ondersteuning:** Nierstichting

### Onderzoeksproduct en/of interventie

# Uitkomstmaten

## Primaire uitkomstmaten

Patients: activation, health behaviors

Professionals: use of health-literacy-tailored strategies

Cost-effectiveness: quality of life

## Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:

Health literacy, the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions, is an important asset to improve health outcomes<sup>1</sup>. Individuals with low health literacy (LHL) lack basic skills for preventing and managing chronic diseases, such as chronic kidney disease (CKD). Approximately 25% of CKD patients have LHL, and LHL-patients are known to have faster disease progression, higher prevalence of co-morbidities, and psychological problems<sup>2</sup>. To improve health outcomes for patients with LHL, interventions that empower both patients and professionals are needed<sup>3</sup>. Evidence-based health literacy interventions, which integrate the patients' and the professionals' needs, don't exist.

In this study, an intervention targeted at both patients and health professionals will be tested to:

- 1) Support patients with LHL to understand CKD, participate actively in consultations, participate in shared decision making and manage their disease and
- 2) Build the capacities of professionals to recognize HL problems and communicate effectively with patients with LHL.

The content and strategies of these interventions were based on in-depth interviews with CKD-patients with LHL and focus group discussions with nephrology professionals (UMCG research register: 201800346) and pilot tested in a co-creation study (UMCG research register: 201900259).

Aim

This project aims to test the (cost) effectiveness of a multi-faceted intervention for patients and health care professionals, compared to care as usual on patients' health outcomes, patients' and professionals' competencies, quality of consultations, and consequences for the costs in a quasi-experimental design.

The specific research questions related to this aim are:

1. Is the intervention effective in activating CKD-patients with LHL?
2. Is the intervention effective in improving health outcomes?
3. Is the intervention effective to improve health care professionals' HL knowledge and

application of HL tailored communication strategies?

4. Is the intervention cost-effective?

5. Are there any barriers or facilitators related to the process of implementing the intervention in the care system?

## **Doel van het onderzoek**

For the intervention group, patients will be more activated and have better health behaviors, professionals will have better use of health-literacy-tailored communication strategies, and the intervention will be cost-effective.

## **Onderzoeksopzet**

Measurements for patients and professionals in both the intervention and the control groups are done after recruitment (baseline), and 4 and 9 months after the intervention (T1 and T2).

## **Onderzoeksproduct en/of interventie**

For the intervention group, this study uses a multi-faceted intervention, focusing on both patients and healthcare professionals. All intervention strategies were based on in-depth interviews with both CKD-professionals and patients with CKD and LHL and co-created and pilot-tested in previous projects carried out by the same research group.

For patients, the intervention has a four-step approach:

The interventions are incorporated into the existing care of each patient group. We do not ask from participating healthcare organizations to plan extra care activities. The expectation is that the intervention steps cost patients additional two hours of time, in a period of three months (questionnaires not included). Patients are also encouraged to choose a significant other that joins each step of the intervention to provide additional support. The four steps consist of:

1. An attractive and easy to use awareness training with video's, graphics, and short explanations which aim to improve:
  - a. Insight/ knowledge of the importance of adhering to treatment (medications and lifestyle) by understanding (the long term risks of) CKD,
  - b. Active participation in consultation by informing and teaching important strategies (preparing a consultation, sharing CKD-related problems, asking questions, and participating in decision making).
2. The front side of a consultation card aims to put this knowledge and skills into action by:
  - a. Supporting patients to reflect on important CKD-related symptoms, problems in lifestyle and medication adherence, and preparing questions for the upcoming consultation.
3. The backside of the consultation card aims to support patients and professionals during the consultation by:
  - a. Discussing difficult information (such as lab values) and making shared decisions regarding important actions related to medication and lifestyle.
4. Reminders aim to help patients in the months after the consultation with:
  - a. Cards and emails that remind patients about actions that were discussed during the

consultation and asks if actions go according to the plans. If the patients have any problems, they are encouraged to contact the research team.

During the whole study, both patients and their significant others are offered a toolbox with information related to the topics in the awareness training and other intervention steps. This toolbox helps to look up information at any moment.

For professionals, we offer a 30-minutes online training and a 4-hour online workshop. The online training provides a brief overview of health literacy and kidney disease and the communication strategies as a preparation for the workshop. The workshop includes various activities, such as videos and oral presentations, role-play with visual recording, and case discussion. These activities will enable health professionals to:

- (1) recognize patients with LHL
- (2) gather and provide information
- (3) promote shared decision-making
- (4) promote self-management
- (5) enhance patients' positive attitudes, self-efficacy, and motivation to strengthen intentions and support behavior change.

## Contactpersonen

### Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years or older,
- CKD stages 1-4 for more than 3 months

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- high health literacy (checklist/screener),
- major cognitive problems,
- too severely ill according the physician,
- life-threatening conditions (e.g. cancer)

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

### **Deelname**

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	204
Type:	Verwachte startdatum

## **Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)**

**Wordt de data na het onderzoek gedeeld:** Ja

### **Toelichting**

After an embargo period of 12 months after publication of the main results, the processed, pseudonymised data will be made available for re-use in the Department of Health Sciences of the UMCG. Requests for re-use of data by third parties will be evaluated by the Principal Investigators, Associate Professor and the Quality and Privacy Advisor, who will check whether the research question falls within the scope of the informed consent. Third party use of data is governed in part by IP rules and agreements, that will become available after

publication of the main results. Data are not send but made accessible. After an approved access request, a researcher will be given access using a secured connection to the dataset.

## Ethische beoordeling

Positief advies

Datum: 21-10-2020

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	NL8990
Ander register	METc UMCG : UMCG research register: 201900534

## Resultaten