ABIDE Simulation-study: how to communicate a high risk for developing dementia to patients with mild cognitive impairment?

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23824

Bron
NTR

Verkorte titel
SsA

Aandoening

Communication
Disclosure
Amyloïd status
Mild Cognitive Impairment

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VU Medical Center (VUmc)
Overige ondersteuning: Amsterdam UMC
Health Holland
Alzheimer Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main outcome measures are participants' 1) understanding of the results and 2) emotional impact of receiving the results.

Toelichting onderzoek

Achtergrond van het onderzoek

Detection of Alzheimer's disease (AD) in an early stage, i.e. before the onset of dementia, is important for disease (self) management and scientific developments, such as medication trials. New diagnostic tests, such as recently FDA approved amyloid-PET tracers, can contribute to early and accurate diagnosis of Alzheimer's disease. This is especially relevant in patients with Mild Cognitive Impairment (MCI). These are individuals who suffer from cognitive impairments, without meeting the criteria for dementia. Roughly 50% of MCI patients develops dementia within 3 years. Amyloid-positivity on PET helps to better predict progression to dementia. Therefore, amyloid PET is increasingly used in clinical settings.

However, disclosure of amyloid-PET results to an MCI patient can be challenging. The predictive value is not perfect, and moreover, there is large variation between individual MCI patients in time of progression to the dementia stage. For this reason, clinicians using amyloid-PET scans report experiencing difficulty in providing MCI patients with these results. Clinicians are particularly concerned for the emotional impact the message may bring, as well as the patients' understanding of this complex message.

To this end a video-vignettes design will be used, allowing for conclusions about causality, to investigate how different communication strategies affect understanding, emotional state and behavioral intentions by randomly allocating 'analogue patients' to the conditions. Analogue patients are disease-naive ('healthy') individuals, instructed to imagine themselves in the position of the patient in the video while viewing the videotaped consultation.

In this experimental design, specific elements of a clinician's communication are varied across multiple, otherwise standardized, scripted videotaped consultations. Here, the neurologist's communication behavior is manipulated to create six conditions. First, a control condition, displaying a neurologist communicating results in a straightforward, basic manner.

This condition will be compared with five enhanced conditions, in which the neurologist: 1) provides explicit information about Alzheimer's disease, dementia and an amyloid-PET scan; 2) uses the PET-scan as visual aid in communicating the results; 3) uses best practice risk communication strategies from other fields; 4) uses an affective communication strategy in response to the patients' emotions, and; 5) uses the teach-back strategy. Data will be collected by means of embedding a combination of self-developed and existing validated questionnaires.

Doel van het onderzoek

The main objective of this study is to investigate which communicative strategies are most effective in increasing understanding and decreasing emotional impact in communicating increased risk for developing dementia status to persons with mild cognitive impairment as a result of a positive amyloid status. We hypothesize that the vignette versions containing one of the 5 enhanced communication strategies will result in 1) a better understanding of amyloid-status, and/or 2) result in a lower emotional impact, and/or 3) influence behavior intentions for relevant (disease self-management) behaviors, as compared to the standard practice vignette.

Onderzoeksopzet

The primary and secondary outcomes will be investigated by means of questionnaires. Questionnaires will be investigated at baseline (T0), right before viewing the assigned video vignette and at follow-up (T1), directly after viewing the video vignette.

Onderzoeksproduct en/of interventie

We will investigate the effect of communicative strategies by means of a video vignette study; a study where a consultation is acted out by professional actors and recorded on video. Participants are cognitively normal middle to old aged adults assuming the role of analogue patients; they will be asked to imagine themselves in the role of the patient.

Participants will be randomly assigned to either view 1) the standard practice video vignette or 2) one of the five best practice video vignettes in which a manipulation of a best practice communication strategy is used. In addition to viewing the vignette, participants will be asked to fill out an online questionnaire before (T0) and after viewing the video vignette (T1).

The five best practice video vignettes consist of the following manipulations:

1) Explicit information about the test and disease (amyloid-PET scan and Alzheimer's disease).

2) Use of visual aid: the amyloid-PET scan of the patient.

3) Risk communication best practice as known from other fields.

4) Affective communication strategy: responding to emotions.

5) The Teach-back strategy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Cognitively normal (no dementia or cognitive impairment)

- 50 years or older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Limited or lack of understanding Dutch (written and spoken)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	576
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL7222
NTR-old	NTR7421
Ander register	Central Reporting point Dataprocessing (VUmc) : VUmc_2018-3051

Resultaten