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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23824

Source
NTR

Brief title
SsA

Health condition

Communication
Disclosure
Amyloïd status
Mild Cognitive Impairment

Sponsors and support

Primary sponsor: Amsterdam UMC, location VU Medical Center (VUmc)
Source(s) of monetary or material Support: Amsterdam UMC
Health Holland
Alzheimer Nederland

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

In addition we will evaluate participants':

1) video engagement

2) behavioral intentions

3) experience of the disclosure of 'their' amyloid-PET results.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- Cognitively normal (no dementia or cognitive impairment)

- 50 years or older

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	576
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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

Study results