

The Lumbar Puncture animation video: an effectivity study

No registrations found.

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

Summary

ID

NL-OMON22409

Source

Nationaal Trial Register

Brief title

VIEW

Health condition

Dementia

Sponsors and support

Primary sponsor: N.A.

Source(s) of monetary or material Support: N.A.

Intervention

Outcome measures

Primary outcome

- 1) understanding of information regarding the lumbar puncture procedure
- 2) level of anxiety for a lumbar puncture

Secondary outcome

- 1) general anxiety
- 2) specific anxiety for complications and/or the lumbar puncture procedure
- 3) knowledge about the lumbar puncture procedure
- 4) satisfaction with the lumbar puncture procedure
- 5) uncertainty regarding the lumbar puncture procedure

Study description

Background summary

Numerous studies have shown that liquor diagnostics have significant value in diagnosing Alzheimer's disease. As a consequence, the lumbar puncture is performed more often in academic and local clinics. Previous studies have shown that fear for a lumbar puncture and possible complications due to the procedure, can increase actual complications post-lumbar puncture. Patients can be fearful due to unrealistic expectations for the procedure or complications. Providing clear audiovisual information, in addition to the regular explanation the clinician provides, could contribute to realistic expectations, and thus lower fear for the lumbar puncture. We developed an animation to inform patients about the lumbar puncture procedure and possible complications. The aim of our study is to test the effect of the informative video on anxiety and understanding.

Study objective

Our hypothesis is that; 1) the information video contributes to an improved understanding of the lumbar puncture procedure, and 2) reduces anxiety for the procedure.

Study design

T0 - an online questionnaire to be filled out at home, one week prior to the visitation for the screening day at the memory clinic.

T1 - a questionnaire on paper during the screening day, prior to the start of the screening day (in the morning).

T2 - a questionnaire on paper during the screening day, at the end of the screening day (afternoon).

T3 - a brief interview by phone, one week after the memory clinic visit for the screening-day.

Intervention

Patients are shown an informative animation video

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- 1) everyone visiting the day-screening in the memory clinic (neurology), and who is eligible for a lumbar puncture
- 2) caregivers of patients eligible for a lumbar puncture

Exclusion criteria

- 1) audio-visual limitations
- 2) patients not eligible for a lumbar puncture

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): 14-04-2019
Enrollment: 120
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N.A.

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	NL7725
Other	METc VU medical center : 2018.660

Study results

Summary results

N.A.