Investigating the effect of the digital Patient Benefit Assessment Scale, a goals-based tool, on patient-centred outcomes in the healthcare process.

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To measure the effect of the digital picture based Patient Benefit Assessment Scale on patient-centred outcomes regarding their health care process, the first eight domains of the factor health care process of the PPPC-R questionnaire (appendix 2)…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON56868

Source
ToetsingOnline

Brief title
The effect of the P-BAS on patient outcomes in the healthcare process.

Condition

- Joint disorders
- Miscellaneous and site unspecified neoplasms benign
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
caused by an insufficient supply of blood, intermittent claudication, pain and cramp in the calf muscles

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Medisch Spectrum Twente

Intervention

Keyword: goals, outpatients, quality of life, Shared decision making

Outcome measures

Primary outcome

To measure the effect of the digital picture based Patient Benefit Assessment Scale on patient-centred outcomes regarding their health care process, the first eight domains of the factor health care process of the PPPC-R questionnaire (appendix 2) are asked after the outpatient consult, and at three and six months.

Secondary outcome

• To assess whether the use of the digital picture based Patient Benefit Assessment Scale improves the level of shared decision making. The I-Share questionnaire (appendix 3) is asked after the outpatient consult.

• To assess whether the use of the digital picture baseds Patient Benefit Assessment Scale improves the quality of life of patients, measured with the SF-36 (appendix 4) at baseline and after three and six months after the first outpatient consult. level of shared decision making during the consultation experienced by patients.

• To study the cost effectiveness of the digital picture based Patient Benefit Assessment Scale, measured with the EQ-5D-5L (appendix 5) at baseline and after three and six months after the first outpatient consult.

• To examine whether the chosen treatment options of the intervention group differ from those of the control group. Based on the (electronic patient record the chosen treatment options can be analysed. The final comparison between treatments of the intervention group and the treatments of the control group is made after six months.).

Study description

Background summary

The prevalence of multimorbidity and chronic health conditions is increasing in patients aged 65 years and older. Multimorbidity and the complexity of health conditions have an impact on the shared decision making (SDM) process between patients and healthcare professionals. The patient*s goals are an important factor in SDM. The SDM process and thereby setting health oriented goals, is especially complex in older patients, often dealing with physical and cognitive impairments or low health literacy. Goals of treatment are often multi-layered, implicit and can therefore conflict with each other or with different treatment options. However, there is currently little or limited focus on the goals that are important to patients* SDM. It thereby raises the question whether current care, where healthcare professionals suggest treatment options, fits the goals, aims, preferences and needs of older patients. With the increased focus on personalized care and SDM, the Patient Benefit Assessment Scale for Hospitalised Older Patients (P-BAS HOP) has been developed. The P-BAS HOP has been designed to better meet the needs and identify the goals of acutely hospitalised elderly patients with multimorbidity. As a follow-up, in order to support patients with low literacy and increase the acceptability, a picture based P-BAS (P-BAS-P) was developed. Although literature shows promising strategies leading to improving SDM, relatively little is known about the effect of better including patient goals in SDM in an outpatient setting on patient centred outcomes, quality of life, treatment choice and cost effectiveness.

Study objective

To measure the effect of the digital picture based Patient Benefit Assessment Scale on patient-centred outcomes regarding their health care process, the first eight domains of the factor health care process of the PPPC-R questionnaire (appendix 2) are asked after the outpatient consult, and at three

and six months.

Study design

A randomised control trial.

Intervention

Before patients have their first outpatient consult, patients randomised into a control group and an intervention group. Both groups are asked to fill in questionnaires regarding their quality of life and a question regarding their digital health literacy. The intervention group is also asked to fill in the P-BAS questionnaire. Healthcare professionals are trained in using the P-BAS and the outcomes of this questionnaire during the consult. In this way the outcomes of the P-BAS can serve directly as input in the outpatient consultation and treatment process. After the outpatient consult various additional questionnaires are presented, concerning overall satisfaction with the treatment process, quality of life and the level of shared decision making.

Study burden and risks

The burden and risks of participating in this study are negligible. Regarding time investment, all participating patients will be asked to complete various questionnaires over time, taking approximately a total of 60 minutes. In line with the experiences of two previous studies including the P-BAS, we do not expect any health risks to be associated with the use of the P-BAS. The intervention that patients will receive (P-BAS), is expected to have a positive effect on the level of patients* quality of life since the P-BAS implies to contribute to the best personalized care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

• Age >= 65 years
• Patients who can read, speak and understand the Dutch language
• Patients with an outpatient consult whereby the consultation is expected to contain a decision with regard to treatment options
• Capable to fill in digital questionnaires and having access to the Internet and DigiD

Exclusion criteria

- Cognitive limitations (e.g. delirium or dementia), as assessed by the health care provider
- Patients without an email account

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2024
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO

Date:	10-06-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL84861.100.24