The MuSt-PC: A Multidimensional Strategy to improve quality of life of patients with multiple symptoms and Palliative Care needs
Pilot study to assess the MuSt-PC tool

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53744

Source
ToetsingOnline

Brief title
The MuSt-PC: a pilot study

Condition

- Other condition

Synonym
All diseases: cancer, heart failure or COPD

Health condition

Patiënten met kanker, hartfalen, COPD.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: palliative care, quality of life, questionnaires, Utrecht Symptom Diary

Outcome measures

Primary outcome

The primary objective is to assess the ability and willingness of patients to complete follow-up assessments (i.e. the number of patients who completed all questionnaires during follow-up). After a baseline assessment, all patients will be asked to fill out the Utrecht Symptom Diary during two weeks. In the first week, twice daily (morning and evening), in the second week once daily (evening).

Secondary outcome

• Recruitment of patients; the number of patients that consented and those that declined participation (with the reason of decline), as well as number of eligible patients (with at least two items on USD-4D >= 4 at baseline) (% of patients);

• Adherence to advice by patients (medical (e.g., intake of medication) and non-medical (e.g.,relaxation exercises) provided based on the MuSt-PC CDSS (%);

• Patient impressions of the MuSt-PC CDSS (10 questions with a 4-point Likert scale);

• Time until symptom burden decreases after the use of the MuSt-PC CDSS based

on the filled out Utrecht Symptom Diaries (days);

• Feedback about the follow-up assessments within this pilot (open questions).

Study description

Background summary

In this pilot study, physicians and nurse practitioners working in different care settings will use MuSt-PC, for adult patients with any life-limiting illness, for whom the Surprise question is answered negatively: if the HCP answers *no* to the question *Would I be surprised if this patient died in the next 12 months?*. In total, at least 65eligible patients will be recruited and asked to perform all study assessments.

After a baseline screening assessment, all eligible patients with at least 2 simultaneously occurring symptoms with a numeric rating score >=4 on the 11 point scale on the Utrecht Symptom Diary, will be asked to fill out the Utrecht Symptom Diary during two weeks. In the first week twice daily (morning and evening), in the second week once daily (evening).

Study objective

The primary objective is to assess the ability and willingness of patients to complete follow-up assessments (i.e. the number of patients who completed all questionnaires during follow-up).
After a baseline assessment, all eligible patients (those with at least 2 simultaneously occurring symptoms with a numeric rating score >=4 on the 11 point scale on the Utrecht Symptom Diary) will be asked to fill out the Utrecht Symptom Diary during two weeks. In the first week, twice daily (morning and evening), in the second week once daily (evening).

Secondary objectives are:
• Recruitment of patients; the number of patients that consented and those that declined participation (with the reason of decline), as well as number of eligible patients (with at least two items on USD-4D >= 4 at baseline) (% of patients);
• Adherence to advice by patients (medical (e.g., intake of medication) and non-medical (e.g.,relaxation exercises) provided based on the MuSt-PC CDSS (%);
• Patient impressions of the MuSt-PC CDSS (10 questions with a 4-point Likert scale);
• Time until symptom burden decreases after the use of the MuSt-PC CDSS based on the filled out Utrecht Symptom Diaries (days);

• Feedback about the follow-up assessments within this pilot (open questions).

Study design

Patients in a palliative care trajectory with multiple simultaneously occurring symptoms will be asked to participate. Eligible patients will be identified by a selection of the GHCPs that participate in the feasibility study. After providing informed consent the patients will be given a treatment advice for their symptoms by their GHCP, based on the MuSt-PC clinical decision support system. Thereafter, patients will be followed and asked to fill out the Utrecht Symptom Diary during two weeks. In the first week, twice daily (morning and evening), in the second week once daily (evening). *

In this pilot study, we use the non-adoption, abandonment and challenges to scale-up, spread and sustainability of technology-supported change efforts in health care (NASSS) as the theoretical framework. This framework consist of seven domains: condition; technology; value proposition; adopters; organizations; wider system and embedding and adaptation over time (figure 1). The use and embedding within the health care system of the MuSt-PC CDSS is complex: most health care professionals do not recognize all symptoms and their interconnection in patients in a palliative care trajectory. The guidelines are directed at one symptom, and not yet multiple simultaneously occurring symptoms, the use of a CDSS in it-self might be difficult for some health care professionals.
Setting up this pilot study with the NASSS as theoretical framework will reveal the complexity of the various domains that have to be addressed so that, ultimately, development and implementation of the MuSt-PC CDSS over time can be ensured. Within this pilot study the emphasis will be on value proposition and adopters. Within the domain value proposition the efficacy and safety of the MuSt-PC CDSS will be studied. The following endpoints will be addressed: adherence to advices provided based on the MuSt-PC CDSS; number of occasions that patients and healthcare professionals had contact with regard to the symptoms; and time until symptom burden decreases. Within the domain adopter system the changes for the patients and the wider care network will be investigated. The following endpoints will be addressed: the completeness of the follow-up assessments; level of empowerment of patients by self-assessment of symptom burden; and the included patients will be asked to give feedback on the study with regard to follow-up assessments and felt support by the use of the MuSt-PC CDSS.

Study burden and risks

NA

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patients identified as in a palliative care trajectory (based on a negative answer to the surprise question *Would I be surprised if this patient died in the next 12 months?*)
• All diseases: cancer, heart failure or COPD
• Patients should have pain and at least one other symptom on the Utrecht Symptom Diary with a numeric rating score of 4 or higher
• Life expectancy of at least 4 weeks
• Able to fill out Dutch questionnaires
• Informed consent

Exclusion criteria

• Patients who are unable or unwilling to self-assess their symptoms at baseline.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-04-2024
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	12-05-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL81064.042.22
Other	will follow