Implementation of the Symptom Navi© Program for cancer patients in ambulatory services: A cluster randomized pilot study (Symptom Navi© Pilot Study)

A Pilot study on the implementation of a program to support symptom self-management in outpatient patients with cancer: Study Information and Informed Consent Form

The study is led by the Institut universitaire de recherche et de formation (IUFRS) at the University of Lausanne (Unil) and the Centre hospitalier universitaire vaudois (CHUV) in Lausanne

Dear Madam, Dear Sir

My name is Prof. Dr. _____ and I am responsible for this pilot study, which evaluates the introduction of a symptom self-management program for outpatient patients with cancer at the _____. This program is called the Symptom Navi© Program.

Symptom self-management means that you receive sufficient and appropriate information from health care professionals about how to deal with symptoms at home. This includes knowing when it is important to contact the treatment team immediately.

Selection of study participants

People who are treated in an oncological outpatient clinic in the German-speaking part of Switzerland where the Symptom Navi© Program will be implemented can participate. The study is open to adult patients who have been diagnosed with cancer within the last 15 weeks and are now receiving anti-cancer treatment. Patients younger than 18 years of age, unable to understand and read German, or for whom the program is not in their best interest (based on care team's recommendation) cannot participate in the study. Furthermore, patients who are additionally cared for by a palliative team cannot participate, as they receive intensive support for symptom management.

Study aims

The pilot study intends to test how the Symptom Navi© program can be introduced into practice and what benefits it has for patients' self-management of symptoms in the outpatient settings in comparison to usual care.

General information on the study

The Symptom Navi© Program is a new nursing support and counselling program designed to teach patients the basics of symptom self-management and general measures that can be used at home.
This program consists of 16 symptom flyers (information leaflets), semi-structured consultations between nurses and patients, and a training program for nurses in which they learn how to deliver and explain the symptom flyers. The Symptom Navi© Program was developed at the Lindenhofspital in Bern in collaboration with various universities, organizations and hospitals and has been used there for several years. Initial tests have shown that patients and caregivers appreciate the program and rate the information they have received as valuable and supportive.
In this pilot study, we compare the Symptom Navi© Program to the usual practice that has been applied so far. We would also like to learn how this program can best be introduced in hospitals and how patients and hospitals can benefit from the program. We also examine whether patients with the Symptom Navi© Flyers may misinterpret symptoms or may delay asking for help from health care professionals. For this, we will consult nursing staff and treating oncologists.
Various outpatient clinics in the German-speaking part of Switzerland will participate in the pilot study: University hospitals, cantonal hospitals, regional hospitals and oncology practices. For the pilot study, we will recruit a total of approximately 20 patients at each participating outpatient clinic during four to six months.
We will conduct the study as required by Swiss law. We also comply with all international research best practice guidelines. The responsible cantonal ethics committees have reviewed and approved the study.
A description of this study can also be found on the website of the Federal Office of Public Health: www.kofam.ch.

Study procedures

For patients, the participation in the pilot study will last 16 weeks. During these 16 weeks you will be required to complete a questionnaire four times.
When you are in the outpatient clinic for your treatment, nurses will inform you about how to deal with common symptoms of your treatment. They will either do this according to their usual practice, or work with the Symptom Navi© Program. The outpatient clinic in which you are being treated is randomly assigned to either usual practice or the Symptom Navi© Program. This means that the information you receive depends on the group your clinic is assigned to.
You will be required to fill in the questionnaires at the following time points:
- Shortly before the first treatment application (first cycle)
- Between the second and third treatment application
- Between the third and fourth treatment application
- 16 weeks after first treatment application

Your allocation to either of the group (usual care or symptom Navi© Program) should not bring any disadvantage to you, because we do not know which type of care is more effective.

The completion of each questionnaire should not take longer than 20 minutes. There are no additional clinical appointments for you to attend.
It may happen that we have to exclude you prematurely from participating in the study because the treatment team feels that you should not be expected to participate in the pilot study any longer. In this case, your treatment will be continued as planned and you will no longer need to fill in the questionnaires.

Rights of the participants

You only take part in this study if you want to. No one may in any way push or persuade you to do so if you do not want to participate. Your ongoing nursing care and medical treatment will continue exactly the same if you do not participate. You do not have to justify why you do not want to participate. If you decide to participate, you can withdraw your decision at any time. You also do not have to give a reason if you want to withdraw from the study. You may ask any questions about the study at any time. Please contact the person named at the end of this study information.

Obligations of the participants

If you participate in the study, we ask you to complete the questionnaire four times. There are no further obligations for you.

Benefits for the participants

If you take part in this study, you may not personally benefit from it. The results of the pilot study may be important for others receiving cancer treatment in the outpatient setting.

Risks and burdens for participants

There may be risks we don't know about yet. We will record these in the pilot study. We assume that your participation should not expose you to any serious additional risks or burdens compared to usual care.

Results of the study

The study physician will inform you during the study about any new findings that may affect the implementation of the study or your safety and thus your consent to participate in the study. You will receive the information orally and in writing.

Confidentiality of data and samples

We will collect your personal and medical data for this study. We will encrypt this data. Encryption means that any information that could identify you (e.g. name, date of birth, etc.) is replaced by a code (unique identification number) so that people who do not know the code can no longer deduce who you are. Within the _____ *(insert name of treatment centre)*, the data and samples can be viewed by authorized and clearly identified persons even without encryption. The information to decipher the code always remains in the institution and is only used in exceptional circumstances.

It is possible that there will be a review of the study during the process. This can be done by the authorities who have previously reviewed and approved the study. The institution that has initiated the study can also review the process. These reviews ensure that the rules are followed and that your safety is not compromised. To do this, the study leader may need to disclose your personal and medical information. Similarly, in the event of a claim, a representative of the insurance company may need to have access to your data. However, this may only apply to the data that is absolutely necessary to settle the claim. All persons involved in the study in any way must maintain absolute confidentiality. We will not publish your name anywhere, in any report, publication, printed or on the Internet.

Prof. Dr. Manuela Eicher is responsible for the compliance with national and international data protection guidelines.

Further handling of data and samples

In case of premature withdrawal from the study:
You can withdraw from the study at any time if you wish. We will nevertheless evaluate the data we collect about you up to the time of your withdrawal. A member of the study team will contact you if you withdraw from the study early and ask you for the reason, however answering these questions is voluntary. After the analysis, your data will be made completely anonymous, i.e. your assigned code will be detached from any personal identifiable information and destroyed, so that no one can retrace your data.

Compensation for participants

If you participate in this study, you won't get any compensation. There will also be no additional costs for you as you can complete the questionnaires at home (pre-paid envelope will be provided).

Coverage of damages

If the study harms you in anyway, the institution that initiated and conducts the study is liable. The requirements and procedure are regulated by law. If you have suffered any harm, please contact the leader of the study.

Financing the study

The majority of the costs of the study are paid by the employers of the members of the research team. A submission for additional funding by a foundation is being sought.

Contact person(s)

If you have any doubts, concerns or emergencies that arise during or after the study, you can always contact one of the contacts listed below.

Principal investigator:
(insert information)

Co-investigator:
(insert information)

Glossary (terms in need of explanation)

What does "pilot study" mean?

A pilot study is conducted to test the planned method and its feasibility for a larger study.

Written declaration of consent to participate in a study
Please read this form carefully.
Please ask if you do not understand or want to know something.

Study number: (assigned by of the respective ethics committee)	
Study title:	Implementation of the Symptom Navi© Program for cancer patients in ambulatory services: A cluster-randomized pilot study (Symptom Navi© Pilot Study) A Pilot study on the implementation of a program to support symptom self-management in outpatient patients with cancer
Responsible institution (Sponsor):	Prof. Dr. Manuela Eicher Institut universitaire de formation et de recherche en soins IUFRS Biopôle 2, Rte de la Corniche 10 1010 Lausanne
Place of conduct:	*(insert information)*
Principal investigator at local institution Name and First name in printed letters:	*(insert information)*
Participant: Name and First name in printed letters: Date of birth:	*(insert information)* *(insert information)* *(insert information)* ☐ female ☐ male

I was informed verbally and in writing by the study physician about the purpose, the procedures of the study, the expected effects, possible advantages and disadvantages as well as possible risks.
My questions regarding the participation in this study have been answered satisfactorily.
I can keep the written study information (two parts) and have received a copy of my written informed consent.
I accept the content of the written study information provided for the above mentioned study.
I participate in this study on a voluntary basis.
I can withdraw my consent to participate at any time and without giving reasons, without experiencing any disadvantages in further medical and nursing care.
I had enough time to make my decision.
I have been informed that an insurance policy will cover damages that are attributable to the research project.
I know that my personal data can only be passed on in encrypted form for research purposes/for this research project.
I agree that the study investigators, the authorities and the ethics committee responsible for this study may inspect my original data for review and control purposes, but with strict observance of confidentiality.

I am aware that the obligations stated in the participant information must be complied with during the study. In the interest of my health, the principal investigator may exclude me from the study at any time.

Place, Date	Signature Study participant

Confirmation from the study physician: I hereby confirm that I have explained the nature, significance and scope of the study to this participant. I hereby certify that I have fulfilled all my obligations in connection with this study in accordance with the applicable law. If, at any time during the conduct of the study, I become aware of any aspects that may affect the participant's willingness to participate in the study, I will inform the participant immediately.

Place, Date	Name and first name of the informing study physician in block capitals. Signature of the study physician