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A personal electronic health record (PEPA)

Submission date 11/12/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/12/2015	**Overall study status** Completed	
Last Edited 17/08/2020	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The Federal Ministry of Education and Research (BMBF) has funded the development of a patient controlled “Personal Electronic Health Record” (PEPA) as part of their current INFOPAT project. PEPA allows for the exchange of medical data between all interested groups, including the patients thenselves. A PEPA contains medical reports and findings including, for example, x-rays, CT scans and MRIs. The patients can safeguard their information and access all content. The aim of this study is to test the PEPA-prototype for cancer patients being treated at the National Center for Tumor Diseases (NCT) in Heidelberg.

Who can participate?
Adult colorectal cancer patients being treated at the National Center for Tumor Diseases (NCT) in Heidelberg.

What does the study involve?
There are two part to this study. The first part involves focus groups, in which a group of people are asked their opinion and attitudes towards, for example, an idea, product or service. Here, focus groups are set up that involve the patients, doctors and other health professionals to discuss current problems with the coordination of care offered to cancer patients, as well as discuss what people want to get from using PEPA (i.e. user requirements). The PEPA-prototype is then developed taking into account the conclusions from the focus groups. In the second part of the study, patients are encouraged to use the PEPA-prototype to prepare and follow up meetings with their physicians.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
National Center for Tumor Diseases (NCT) in Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
December 2015 to December 2016

Who is funding the study?
Federal Ministry for Education and Research (BMBF) (Germany)

Who is the main contact?
Dr Dominik Ose

Contact information

Type(s)
Scientific

Contact name
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69115

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
S-462/2015

Study information

Scientific Title
A personal electronic health record (PEPA) – feasibility study on implementation in real health care setting

Study objectives
Use of of a personal electronic health record can improve self-efficacy in patients with colorectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Faculty of the University Heidelberg, 12/11/2015, ref: S-462/2015

Study design
Prospective 3-months open-label before and after trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
Within the study a number of patients will be asked to use the PEPA within their personal care setting. Furthermore, it is envisaged to involve not only the NCT but also selected general practitioners (GP's) who treat the participating patients.

All patients will be motivated to use the PEPA in order to prepare and follow-up meetings with their physicians. Patients who are treated because of recurrence for example have appointments for chemotherapy at the NCT approximately every two weeks. For those appointments they have to have their up-to-date blood test results ready.

Intervention Type
Device

Primary outcome measure
Current primary outcome measures as of 03/05/2016:
Patient self-efficacy, German version of the Cancer Behaviour Inventory – Brief Version (CBI-B-G) at Baseline and after 12 weeks

Previous primary outcome measures:
Patient self-efficacy, measured using the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer) at Baseline and after 12 weeks

Secondary outcome measures
Current secondary outcome measures as of 03/05/2016:
1. Control Preference, measured using the Control Preference Scale at Baseline and after 12 weeks
2. Psychosocial distress, measured using the Distress Thermometer at Baseline and after 12 weeks
3. Utilization of medical services, measured using the Mannheimer Modul Ressourcenverbrauch at Baseline and after 12 weeks
4. Involvement in care, measured using the Patients' perceived involvement in care (PICS) at Baseline and after 12 weeks

5. Usability of PEPA-prototype, measured using the System Usability Scale (SUS) at Baseline and after 12 weeks

Previous secondary outcome measures:
1. Control Preference, measured using the Control Preference Scale at Baseline and after 12 weeks
2. Psychosocial distress, measured using the Distress Thermometer at Baseline and after 12 weeks
3. Quality of life, measured using the EQ-5D index at Baseline and after 12 weeks
4. Hope, measured using the Herth Hope Index (HHI) at Baseline and after 12 weeks
5. Depression severity, measured using the Whooley Depression Scale at Baseline and after 12 weeks
6. Utilization of medical services, measured using the Mannheimer Modul Ressourcenverbrauch at Baseline and after 12 weeks
7. Involvement in care, measured using the Patients' perceived involvement in care (PICS) at Baseline and after 12 weeks
8. Usability of PEPA-prototype, measured using the System Usability Scale (SUS) at Baseline and after 12 weeks

Overall study start date
01/12/2015

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Inclusion criterial for patients:
1.1. Patients eligible for participation in the pre-implementation and implementation study have to be diagnosed with colorectal cancer (ICD-10: C18, C19, C20)
1.2. They either should be receiving chemotherapy with curative approach at the NCT after their primary surgery (at least for 2 months remains) or chemotherapy after relapse with symptom relieving approach at the NCT as well
1.3. The participants must be 18 years of age or older and their disease status has to be classified with UICC-stadium III-IV

If the recruitment of a sufficient number of colorectal cancer patients should not be possible, the inclusion of other cancer diagnoses such as gallbladder ICD-10: C23.9, C24.0, C 24.1) or stomach (ICD-10: C16) will be envisaged.

Within the pre-implementation study also patients with diabetes mellitus type 2 (ICD-10: E11) are possible participants for the usability test because of their chronic disease.

2. Inclusion criteria for health care professionals:
The group of health care professionals is sub-classified into:
2.1. Clinicians of the NCT,
2.2. Other HCP's like nursing staff, social worker, stoma-therapists, nutritionists that are connected to the NCT as well as
2.3. General practitioners (GP's) according to German regulations and their
2.4. Medical assistants.

To be eligible for participation in the study the clinicians and other HCP's of the NCT have to cooperate closely with the included patients with colorectal cancer during their treatment at the NCT. The GP's can be both, single and group practices. For the implementation study they have to be the attending physician of the included patients with colorectal cancer and they should have their practices in a distance of 20 to 30 km to the NCT. Additionally the GP's have to have an internet access in their practices and an option to scan documents.

3. Inclusion criteria for stakeholder:
To be eligible for participation in the study, the stakeholders have to be directly affected by or involved in the implementation process of a PEPA. The final selection of the stakeholder is based on:
3.1. Relevant organizations for the implementation process
3.2. The position/reputation of specific actors and
3.3. The potential influence and participation that actors have by relevant decision making and general acting concerning the implementation process of a PEPA

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
31

Key exclusion criteria
1. Patients, who do not fulfill the inclusion criteria will be excluded
2. Additional exclusion criteria are:
2.1. Severe acute psychiatric disorders (for example, schizophrenia, schizotypal and delusional disorders)
2.2. Dementia
2.3. Mental and behavioural disorders due to psychoactive substance use
2.4. Insurmountable language and communication problems and emergent cases

HCP's (health care professionals) and stakeholders, who do not fulfill the inclusion criteria will be excluded.

Date of first enrolment
01/12/2015

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Heidelberg
Voßstr. 2, Geb. 37
Heidelberg
Germany
69115

Study participating centre
National Center for Tumor Disease
German Cancer Research Center
Im Neuenheimer Feld 280
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital Heidelberg - Department of General Practice and Health Services Research

Sponsor details
Voßstr. 2, Geb. 37
Heidelberg
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69115

Sponsor type
University/education

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
1. Results of Baseline measurement: Summer 2016
2. Results of Intervention (primary outcome): December 2016
3. Results of Intervention (secondary outcomes): Spring to summer 2016

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/07/2020	17/08/2020	Yes	No