PRC

EPCCS
The European Palliative Care Cancer Symptom study

A prospective data collection

Main responsibility

- Marianne Jensen Hjermstad, PI
  - Stein Kaasa, PI
- Gunnhild Jakobsen in the trial office
  - Has the overview of everything!

Objectives

- **Objective A1**
  - to extend the knowledge about the palliative care cancer population at the participating sites
  - to gain new insight in the prevalence and development of the most frequent symptoms over time
- **Objective A2**
  - continue the work towards a standardized assessment system to improve symptom management
  - to evaluate the clinical usefulness of the newly agreed-upon classification and assessment system: CPACS
    - **BMJ Supportive & Palliative Care, 2011**

Objectives, cont'd

- **Objective B**
  - to collect data on the organization and delivery of PC, economic and academic resources at the participating sites
- **Objective C**
  - to further develop and consolidate the international collaboration in PC cancer research

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Design

- A prospective data collection
  - International
  - Multi-centre
- A modular approach
  - Opens for several side-studies
    - According to special interests, capacity etc.
    - Subject to specific protocol amendments
    - Designated PIs for each protocol amendment/side study

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A basic study in two parts, 1

- Objectives A1 and A2 - the assessment part
  - Health care providers
    - CRF on medical and treatment data
      - basic set: height, current weight, current medication and treatment, diagnosis (ICD-10), time of diagnosis, stage of disease, current anti-cancer treatment, site of treatment
      - MMSE, 4 item version
      - KPS - performance status
      - ECS-CP - pain classification

Fayers, Hjermstad JPSM 2006

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A basic study in two parts, 2

- Objectives A1 and A2 - the assessment part
  - Patients
    - Screening items
      - Pain intensity, neuropathic pain, breakthrough pain depression, cachexia/appetite
    - EORTC-PAL15, symptoms, QoL
    - ESAS-r – the revised version
      - ESAS (trad); probably the most widely used general symptom assessment tool
      - Difficulties in relation to terminology and numerical ratings
      - Too many, un-validated, adapted versions exist
      - Revised version

Watanabe, Nekolaichuk JPSM 2011
Carvajal, Centeno EJC 2011

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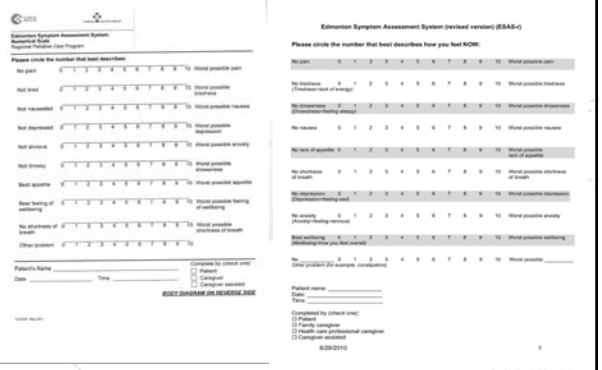
ESAS trad vs ESAS-r



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A basic study in two parts, 3

- Objective B, the centre survey
  - To be answered only once
  - To be completed on the internet, only
  - English language only
  - To assess provision and delivery of palliative care
    - Patient mix
    - Staff mix
    - Organization
    - Resources
    - Academic affiliation etc

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Why screening questions?

1. To assess the prevalence and fluctuation of these symptoms over time
2. To facilitate conduction of in-depth companion studies using the subgroups of the patient sample
   - clinical examinations
   - biomarkers etc., cachexia
   - qualitative and quantitative studies in those who screen positive for NP or BTP

What's meant by a basic study?

- That all other side-studies, in-depth studies etc. are subject to protocol amendments

WHY?

- Experience from our previous study; EPCRC-CSA
  - specific research questions need specific measures

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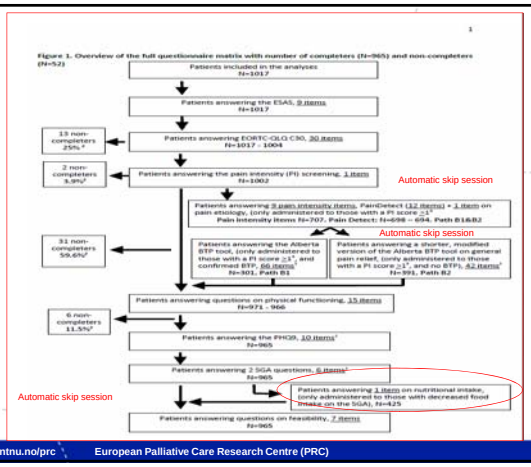

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Proposed side - studies

- The MGIO study Malignant GastroIntestinal Obstruction
- Main aim
  - to describe the clinical management of gastro-intestinal obstruction (diagnosis, treatment and symptomatology) in PC patients with advanced malignant abdominal disease
- EPCCS facilitates screening in a large no. of patients

• Upcoming?
- Neuropathic pain
- Breakthrough pain
- Biomarkers / clinical markers as predictors or classifiers of symptom development / treatment effects (!biobank!)

Methods; data collection

• Intended as a computer-based study (primarily)

• The centre data – no options
- to be entered directly on the web
- ENGLISH language only

• CRFs and patient data – optional
- Computer (= web) vs. paper forms
- Local language (of course!)

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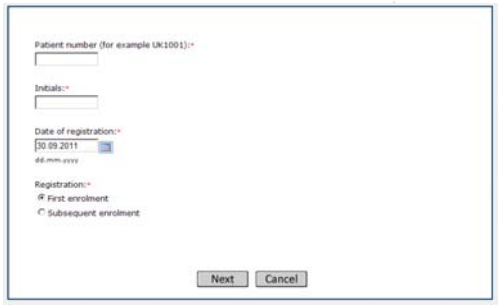
Example of the computerized tool, 1



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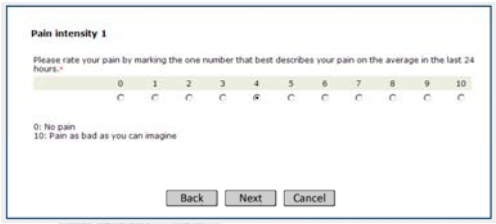
Example of the computerized tool, 2



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Methods; inclusion criteria

- Patient has a cancer diagnosis
  - radiological, histological, cytological or operative evidence
- Local, loco-regional or metastatic disease
- Defined as a palliative care patient; enrolled in a palliative care programme
- Age 18 years or older
- Able to provide written informed consent
- Able to complete the data collection tool, preferably without help
- Available for follow up registration, at least once

vs.

Patients receiving curative treatment

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Methods; patient inclusion

- 2 paths for patient inclusion:
  - **A.** All consecutive patients for a given time period
    - Aim: 50 evaluable patients after 6 months
  - **B.** A consecutive series of patients with a limited spectrum of diagnoses
    - Aim: 50 evaluable patients after 6 months
- Because (a high) attrition is expected, a high number of patients need to be included

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Methods; follow-up

- Included when coming to the participating centre
  - Patients will be at different stages in the disease trajectory
- Followed every 4 weeks for at least 6 mos, on site
  - Same set of questionnaires, almost…
  - Some items are skipped to reduce respondent burden
    - height, living situation, marital status etc.

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Is attrition a problem?

- No, not necessarily, because
  - This is an inherent part of research in palliative care
  - All (eligible) patients are asked to participate
  - All patients who decline, drop out etc. are registered
  - The case mix at each site is very different
  - This is reflected in
    - A. the centre survey
    - B. the final sample
- Yes, if patients are included as a convenience sample

Timeline

- Patient inclusion started
  - Norway and Spain May 2011
  - Several centers started in the fall 2011
- No exact deadline for closure has been set
  - 50 pts. with 6 mos. follow-up is demanding
  - Interim analyses in the early winter 2012

Practicalities

- The NTNU trial office is crucial
  - Gunnhild administers and answers everything
  - Short manuals are provided
  - Paper forms and supplemental material are provided
  - Paper forms will be scanned at the trial office
    - Returned by air-mail
    - Keep a copy in your own office!
  - Centres using computers – receive the internet link by e-mail
    - Answers are automatically stored at a safe server

Inspiring!

- The EPCCS has gained wide attention
  - 49 centres have expressed their interest
    - 15 different countries
  - 43 have confirmed actual participation
    - Italy (14) and Spain (9) in the lead!!!
  - appr. 12 have started patient inclusion
  - 12 languages, web or paper CRFs
    - Translations - a tremendous effort
      - Helpful assistance from local study coordinators
    - Finnish, Georgian and Bulgarian are challenging!

Interesting

- Pre-study survey
  - An overwhelming interest for computers (>80%)
- BUT
  - the vast majority of centres have chosen paper forms
  - seven centers will use computers only
    - UK 4, Canada 1, Bulgaria 1, Georgia 1
    - Some centers have started with paper, may switch

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FAQs

- Q1: What about life expectancy?
  - Involves a high degree of uncertainty
  - May result in a ”healthy bias” sample
  - May result in gate-keeping
- Q2: What if the patient cannot be followed for 6 months?
  - One follow-up is necessary
  - Reason for drop-out/non-completion must be registered
- Q3: Can we use telephone interviews for follow-up?
  - No not this time, objective registrations are wanted
- Q4: What’s in it for me?
  - Co-authorship, according to common procedures
  - Access to own data

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So,

- The study will provide
  - good insight in the prevalence and development of symptoms
  - good overview of PC delivery across Europe
  - ample opportunities for international collaboration

Yet

being feasible!