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**Effectiveness of complex interventions
in palliative care.
The case of the LCP in Italy.**

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My plan for the next 20 minutes:

- using the MORECare statements on good practice in evaluating complex interventions in EoL care ...
 - ... to assess the process of assessment of the LCP in Italy, including the randomised cluster trial
- random reflections on some critical points of the LCP cluster trial
- some original data from a qualitative study nested within the LCP cluster trial

Liverpool Care Pathway for patients with cancer in hospital: a cluster randomised trial

Wallerstein M, et al. *BMC Medicine* 2013, 11:111

Evaluating complex interventions in End of Life Care: the MORECare Statement on good practice generated by a synthesis of transparent expert consultations and systematic reviews

Higginson IJ, et al. *BMC Medicine* 2013, 11:111

Checklist of components that require consideration when designing and conducting EoLC studies see Table 4

MORECare statement # 2: present objectives appropriate to the level of intervention developed

the assessment of the effectiveness is just an advanced step of the process of assessment of a complex intervention

Aim: Effectiveness
Costantini M, 2011
Costantini M, 2014
Di Leo S, submitted

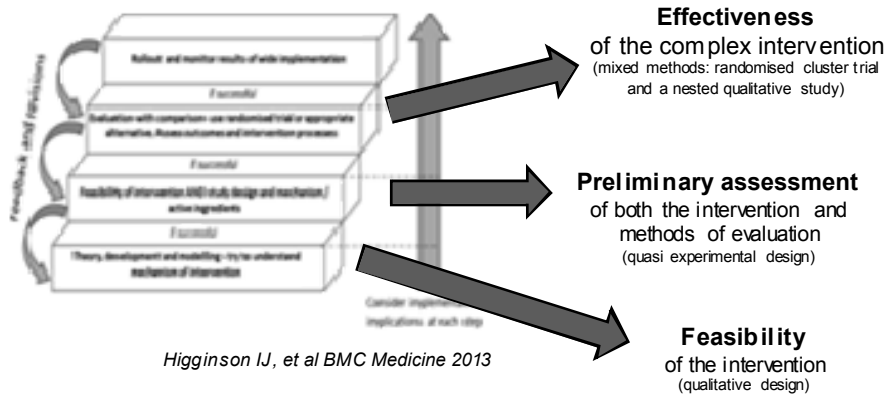
Aims: Standardization of the intervention and of the procedures of assessment. Preliminary assessment of the effectiveness of the LCP.
Costantini M, 2011
Raijmakers N, 2013
Costantini M, 2014

Aim: exploring expectations about and the impact on staff of the LCP-I implementation.
Di Leo S, 2011

Key steps in developing and evaluating EoLC interventions
Higginson IJ, et al *BMC Medicine* 2013

3 Indicate and justify stage ... for development and evaluation of complex interventions, for example feasibility, preliminary evaluation

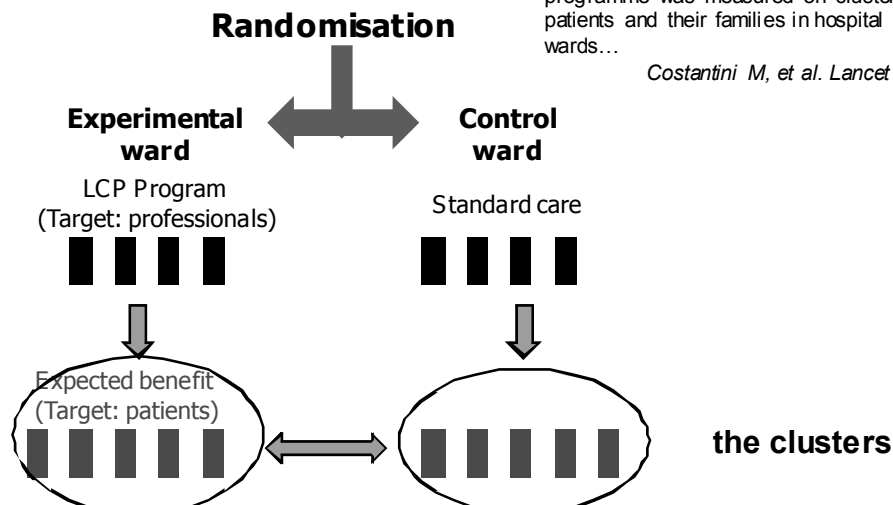
6: Justify methods of empirical studies, considering mixed methods, observational studies and randomised trials




6: Justify methods of empirical studies

... The objective of the LCP-I programme was to improve the quality of care for patients dying with cancer, but the targets of the intervention were the ward professionals. The effect of the LCP-I programme was measured on clusters of patients and their families in hospital wards...

Costantini M, et al. Lancet 2014



The lack of independence among individuals in the same cluster, creates special challenges in design, analysis and interpretation of the results:

- reduction in effective sample size  the cluster trial was underpowered

16 wards instead of 20, less cancer deaths than expected, a large ICC (0.10) but smaller than in the phase 2 (0.19)

- considering clustering in the analysis. In the LCP cluster trial:

P-value = 0.04 (not cluster adjusted)

P-value = 0.19 (cluster adjusted)

17: Choose outcome measures that meet the following criteria validity, and reliability, responsive to change, clinically relevance, applicable etc.)

❖ Interview with family members about the last week in ward

- ✓ the Toolkit after-death bereaved family member interview (Teno J 2001)

33 questions → seven 0-100 scales (0 the worst care)

- Overall quality of care
- Informing and making decisions
- Advance care planning (with a filter question)
- Respect, dignity, and kindness
- Family emotional support
- Coordination of care
- Family self-efficacy

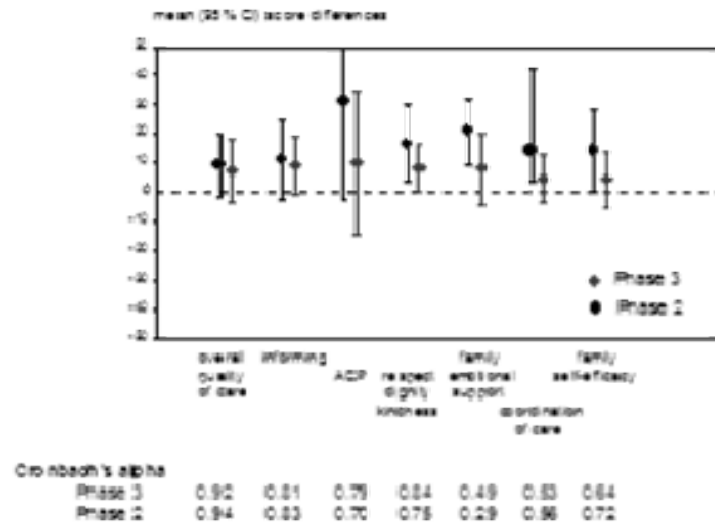
- ✓ the VOICES (Addington-Hall 1995; Costantini 2005)

12 questions → three symptoms: pain, breathlessness, vomiting

But also processes of care:

- ❖ Clinical documentation (drugs and procedures of the last two days)
- ❖ Telephonic interviews with GPs (communication with the ward)

17: Choose outcome measures that meet the following criteria validity, and reliability, responsive to change, clinically relevance, applicable etc.)



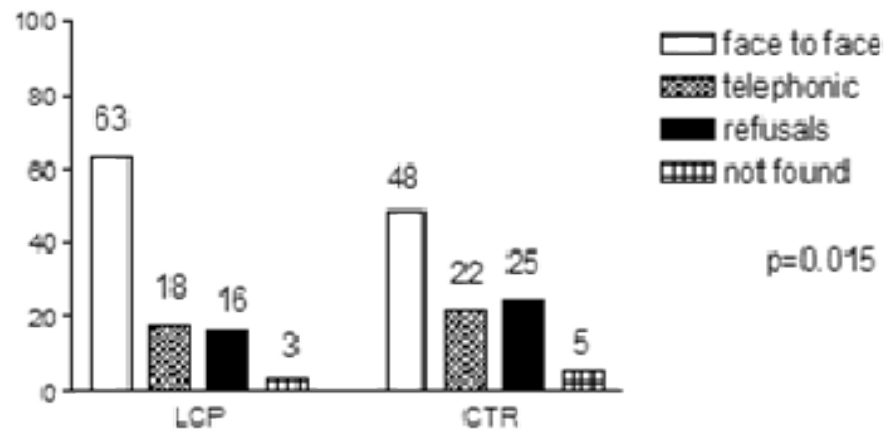
21-25: missing data

**Estimate in advance level of, and reasons for ...
done in the cluster trial with information
from phase 2, but we did not plan to
collect information about reasons for
missing data**



**in the randomised cluster trial
we could not interpret the missing data**

21-25: missing data ... (in the LCP cluster trial)



- ❖ **Plan in advance** (take time before to save your mental health after, during the analysis ...)
- ❖ **Complex interventions are usually implemented in complex systems** (where the Murphy's law works very well)
- ❖ **Start with a phase 3 trial only when you have collected all useful information from the previous steps** (yes, but please start ... we need studies aimed at assessing the effectiveness of complex interventions)

27: Mixed methods can be appropriate in all phases of development and evaluation

**“Less ticking the boxes, more providing support”:
a qualitative study on health professionals’
concerns towards the LCP**

Di Leo S, et al.

Aims

exploring the views of those physicians and nurses who, during the LCP-I implementation in hospital, showed and expressed negative opinions towards the LCP-I itself and its process of implementation

Methods

- ❖ qualitative study nested within the randomized LCP-I cluster trial
- ❖ semi-structured interviews on concerns and weaknesses of the LCP-I and its implementation
- ❖ sample of physicians and nurses from six hospital wards
- ❖ thematic analysis on the interview transcripts

Results

- ❖ **6 physicians and 5 nurses were interviewed**
- ❖ **12 categories were identified, referring to 4 major topics:**
 1. the implementation process
 2. the LCP-I clinical documentation
 3. the hospital environment
 4. the educational and professional background of healthcare staff

Selected categories from two topics

The implementation process

- ✓ Difficulties in attending the Education Programme
- ✓ Need for more support from the PCT during the LCP-I implementation
- ✓ Need for supplemental support from the PCT after the end of the LCP-I implementation

The LCP-I clinical documentation

- ✓ Weaknesses of the LCP-I clinical documentation



Thanks !