



Charité - Universitätsmedizin Berlin

DISCHARGE

WP10

"Health-related Quality of Life"



Contact Details WP10

"Health-related Quality of Life"

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Health-related Quality of Life

- important outcome in clinical research complementing „hard“ outcomes
- broad concept, encompasses
 - physical health
 - mental health
 - level of independence (functional status)
 - social relationships

Health-related Quality of Life Measures in DISCHARGE

Generic

SF-12 v2 (4 week)

Health-related quality of life

EQ 5D-3L (EuroQol)

Health-related quality of life
Utilities for different QoL states

HADS (Hospital Anxiety and
Depression Scale)

Depression and anxiety symptoms

Disease-specific

Rose Angina questionnaire – short
form

Severe and not severe exertional
chest pain

Objectives of WP10

- To compare health-related quality of life in the intervention versus control group

- **Additional:**
 - » Compare quality of life across European regions at baseline and over time
 - » Assess factors associated with quality of life at follow-up:
 - Socio-economic status, lifestyle, clinical

Pre-randomisation forms

①

SES, QoL & Lifestyle (staff form)

(Print Document-No. 1381 - 1)

Revision 2015-08-11, KKS Charité

General comment for the following CRF document:

1) **The document has to be filled out BEFORE randomisation!** After the CRF is filled out completely the randomisation can be performed and the randomisation result can be communicated.

2) What is your general impression of the patient? Do you think that the patient could have a problem with reading and/or filling out the CRF alone? If Yes, please help the patient with filling out the CRF.

②



> Welcome > Patient 97-KKS-0016 > SES, QoL & Lifestyle - EN (1/2)

SES, QoL & Lifestyle (1/2)

③



> Welcome > Patient 97-KKS-0016 > SES, QoL & Lifestyle - EN (2/2)

SES, QoL & Lifestyle (2/2)

State of data entry of „pre-randomisation package“

DISCHARGE Date 12.02.2016 - 16:51 (MEZ) Centre DISCHARGE (P05; Copenhagen)
DISCHARGE (CCM Monitor) Melanie Estrella Country Denmark
Project DISCHARGE (v1.17) Patient Add-ID 05-COP-0006 Rand-Gr CT

> Welcome > Patient 05-COP-0006

Pre randomisation questionnaires



Staff Form
SES, QoL & Lifestyle Form

Randomisation



Medical history



Stress Tests



Physical examination



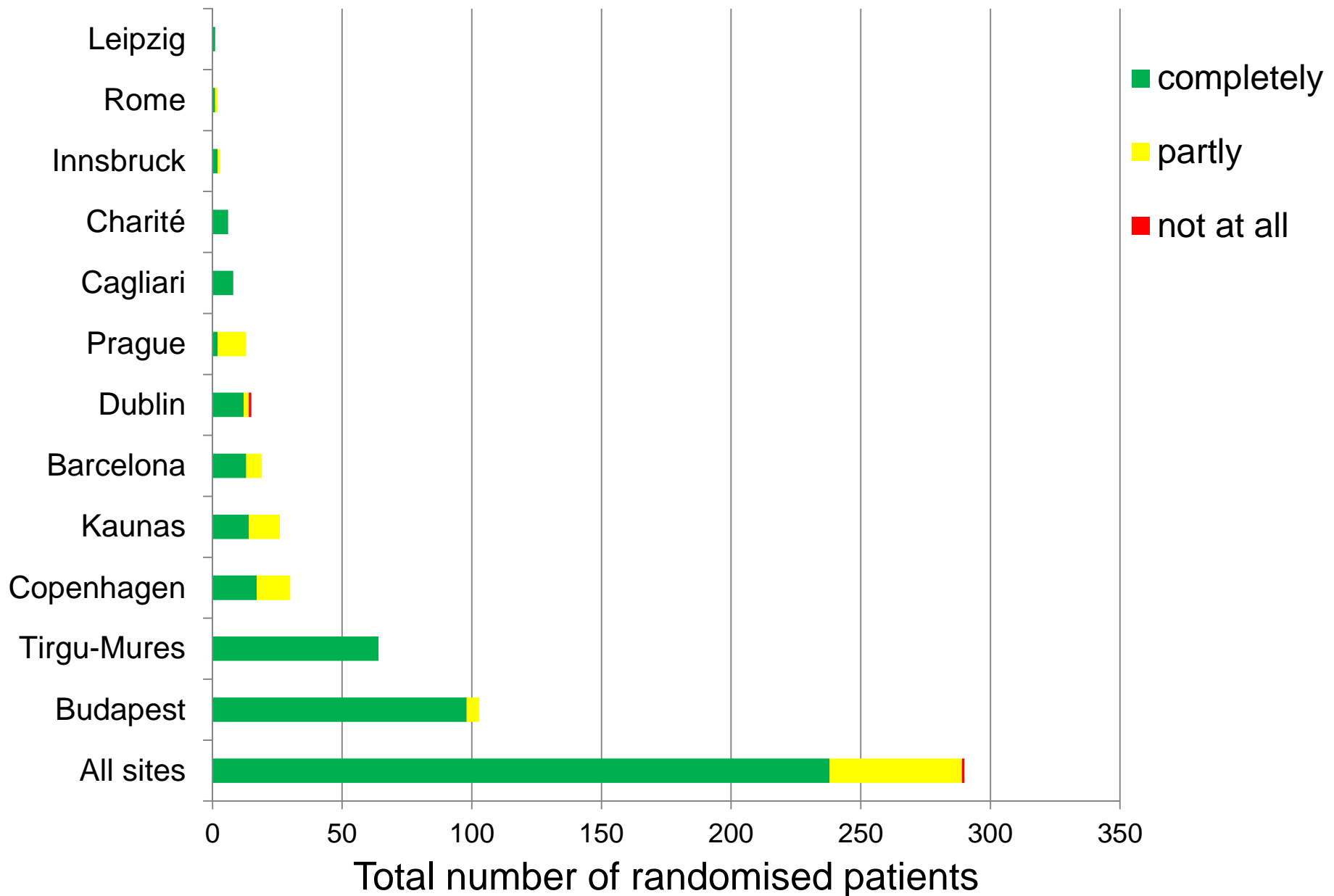
CT



ICA



Number of pre-randomisation packages entered ...



Data from KKS website as of Feb 12 2016

Errors to Avoid in PRCT

- Baseline QoL questionnaire package completed after randomisation
=> needs to be completed **BEFORE** randomisation
- Family member or friend completes questionnaires for participant
=> participants can be assisted but need to give own answers
- Questionnaires (paper form) distributed without ID or wrong version
=> useless!





Calcium imaging and selective computed tomography angiography in comparison to functional testing for suspected coronary artery disease: the multicentre, randomized **CRESCENT** trial

N=350 patients with stable angina
CT arm after 1.2 years:

- Higher-rates of event-free survival
- Diagnosis established sooner
- Lower cumulative diagnostic costs

Quality of Life in the CRESENT Trial

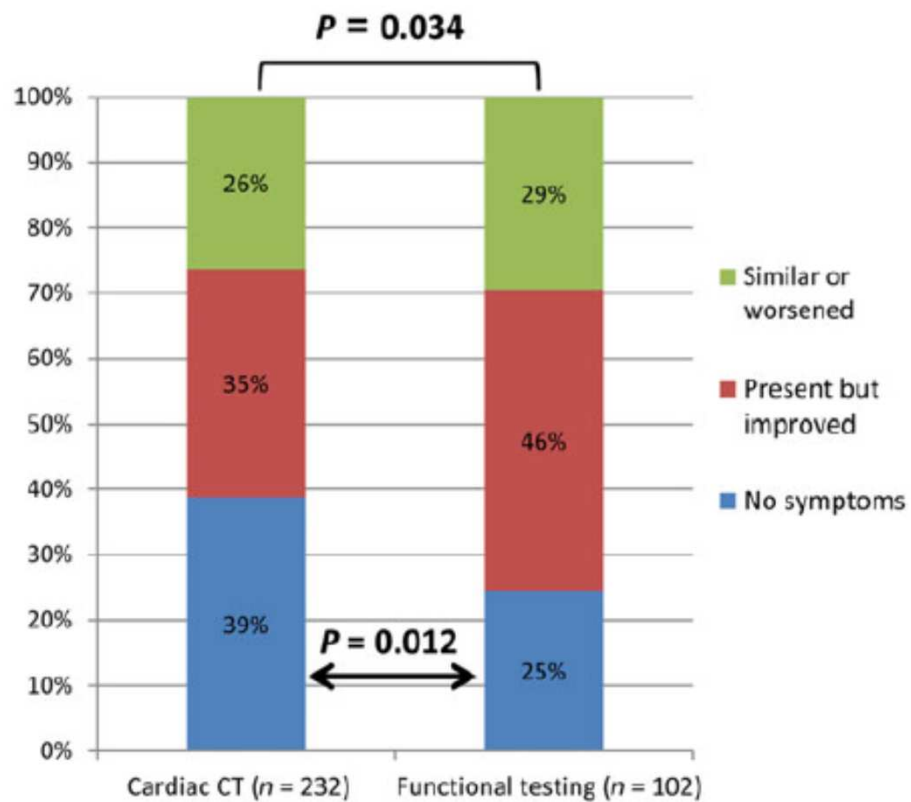


Figure 3 Angina status 1 year after randomization.

- More patients without Angina symptoms after 1 year in CT arm
- No group differences in QoL measures (SF-12, EQ5D, HADS)

Quality of Life in the DISCHARGE Trial

..... ???