



**Charité -  
Universitätsmedizin Berlin**

DISCHARGE

WP10

"Health-related Quality of Life"



# Contact Details WP10 Health-related Quality of Life"

➤ Prof. Dr. Jacqueline Müller-Nordhorn  
(jacqueline.mueller-nordhorn@charite.de)



➤ Coordinators:

Dr. Nina Rieckmann (nina.riECKmann@charite.de)

Dr. Christine Holmberg (christine.holmberg@charite.de)

Wiebke Stritter, MA (wiebke.stritter@charite.de)

Berlin School of Public Health  
Charité Universitätsmedizin  
Seestrasse 73  
13347 Berlin

# Overview

---

- Objectives of WP10 „Health-related Quality of Life“
- Measures
- Tasks and timeline for Pilot study
- Tasks and timeline for PRCT
- Errors to Avoid
  
- **Optional part of the Pilot Study:**  
Cognitive Interviews

# Objectives

---

- To compare health-related quality of life (QoL) in the intervention versus control group
- Additional:
  - » QoL across European regions at baseline and over time
  - » Assess factors associated with quality of life at follow-up
  - » Evaluate patient utilities using time trade-off methodology

# Pilot Phase

## February – July 2014

---

➤ Objective of the Pilot Phase:

To test patient understanding (content), and acceptability (length and content) of different QoL questionnaires in **60** patients (30 CT, 30 ICA)

.... as a basis to select the best Questionnaires for the intervention study

# QoL Measures Tested in the Pilot Study

	Generic	Disease-Specific	
1	SF-12 v2 (4 week)	MacNew	?
	EQ 5D-3L (EuroQol)		
	(HADS) Hospitals Anxiety and Depression Scale		
1	WHO-5		


Time-trade off question:

*"How many years of lifetime would you trade for years without chest pain?"*

# What do the Sites Need to do for the Pilot Study?









Own  
Contribution

## Clinical Sites –Tasks

February	<ul style="list-style-type: none"><li>• Translate time-trade off questions and send to <a href="mailto:nina.riekmann@charite.de">nina.riekmann@charite.de</a></li></ul>
March 1-15	<ul style="list-style-type: none"><li>• Review QoL questionnaire package for appropriateness of language</li><li>• Get familiar with Excel data entry document sent by WP10-team</li><li>• Feedback to <a href="mailto:nina.riekmann@charite.de">nina.riekmann@charite.de</a></li></ul>
March 15-May	<ul style="list-style-type: none"><li>• Make paper copies  and distribute QoL Questionnaire package to 60 patients with stable chest pain (30 ICA und 30 CT) who fulfil eligibility criteria for intervention study</li></ul>
May 30	<ul style="list-style-type: none"><li>• Send Excel document with entered data to <a href="mailto:nina.riekmann@charite.de">nina.riekmann@charite.de</a></li></ul>

# What do the Sites Need to do for the DISCHARGE PRCT?

Own  
Contribution

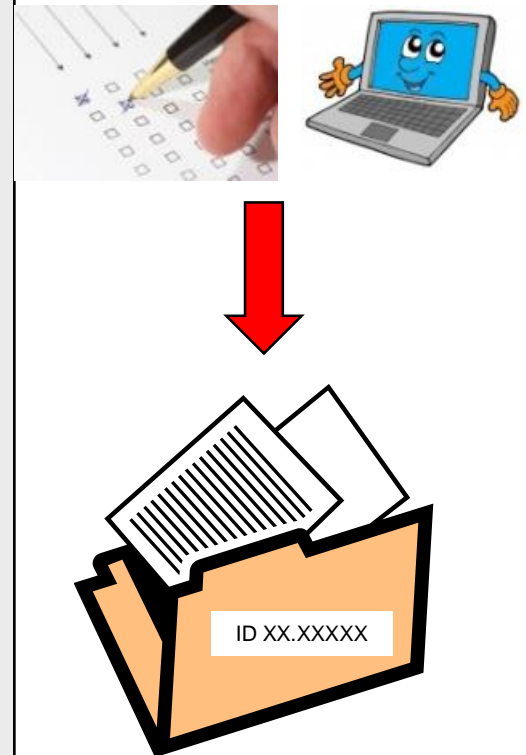
	Clinical Sites -Tasks
Aug 2014 – July 2016	<ul style="list-style-type: none"><li>• Distribute <b>FINAL</b> QoL Questionnaire package to ALL participants <b>PRIOR</b> to randomization</li><li>• QoL Questionnaire package can be completed on paper copies  or laptop </li></ul>
Aug 2015 – July 2017	<ul style="list-style-type: none"><li>• Send Year 1-year Follow-up QoL questionnaire package to participants (follow-up if not returned)</li></ul> <p>Either by email (together with eCRF) </p> <p>Or</p> <p>As paper copies via mail  </p>
Sept 2017- Oct 2018	<ul style="list-style-type: none"><li>• Send final Follow-up QoL questionnaire package to participants (follow-up if not returned)</li></ul> <p>Either by email (together with eCRF) </p> <p>Or</p> <p>As paper copies via mail  </p>



# Handling of QoL Data

Own  
Responsibility

- Enter ALL data into respective Excel data-entry documents and send to [nina.riECKmann@charite.de](mailto:nina.riECKmann@charite.de)
- Make copies of all completed QoL hard copy questionnaires and send them scans to [adriane.napp@charite.de](mailto:adriane.napp@charite.de) (or via mail to Charité, adress will be provided)
- Store the original hard copies at your site!
- Make print-outs of all data entered into laptops or online databases and **store them**



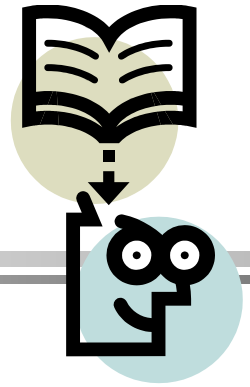
# Errors to Avoid

---

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



# Cognitive Interviews



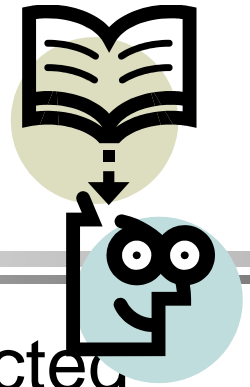
## What is it?

- General method to evaluate the transfer of information through questionnaires
- *How do participants understand the questions and the answer options given?*

## Why is it important?

- To get insight which questionnaire is accepted best by the patients
- To modify and improve the Time-trade off question and enhance clarity

# Cognitive Interviews



- Conducted primarily at Charité with selected participants of the pilot study
- Other sites: participation is desirable if psychologist or social scientist experienced in cognitive interviews (e.g. think aloud technique) is available

If interested, please contact:



[wiebke.stritter@charite.de](mailto:wiebke.stritter@charite.de)