PHARM-CHF
Pharmacy-based Interdisciplinary Program for Patients with Chronic Heart Failure
A Randomized Controlled Trial

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Aim of the study

The aim of the study is to investigate, whether a continuous interdisciplinary intervention leads to a reduction of hospitalizations and mortality in elderly patients with chronic heart failure.

The intervention, consisting of regular contacts with the local pharmacy and weekly dosing aids, aims to improve medication adherence and management.

Methods

Randomized controlled trial (RCT), prospective randomized open design blinded evaluation (PROBE design)

- Intervention group: continuous pharmacy-based intervention conducted in cooperation with the physician
- Control group (not known in the pharmacy): usual care

Inclusion criteria

- Age: 65 years and older
- Chronic heart failure (CHF)
- Stable CHF medication including a diuretic
- Hospitalization for decompensated heart failure within past 12 months
- Written informed consent

Exclusion criteria

- Use of a weekly dosing aid
- Unwillingness or inability to visit a participating pharmacy once a week
- Planned cardiac surgery
- Life-threatening condition with life-expectancy < 6 months
- Unwillingness or inability to comply with study protocol (including drug abuse or alcohol dependency)
- Participation in other studies (currently or in the last 3 months)

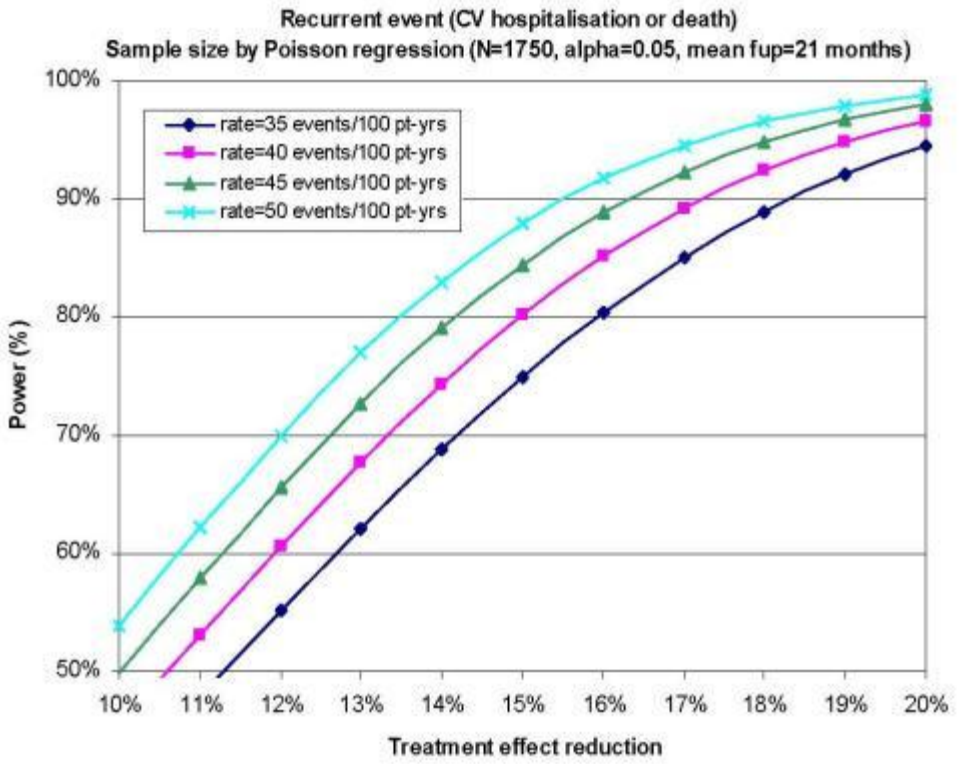
Primary and secondary endpoints

- Primary endpoint
  - Number of recurrent cardiovascular hospitalizations or all cause death

Sample size calculation

- Mean follow-up: 21 months
- Event rate (for CV hospitalization and all cause death) of 35 / 100 patient-years of follow-up in the control group
- 17 % reduction in the event rate between the intervention and usual care group
- 85 % power, α=0,05
- N=1,750 patients (875 patients/group)
- Plus ~ 15 %: drop-outs/ lost-to follow-up
- N=2060 patients have to be enrolled in the study

Figure 1: Mean follow-up of 21 months, N=1750 for varying treatment effects



Methods

Study size:

- 2.060 ambulant patients from different regions
- About 300 medical practices and 300 pharmacies

Follow-up:

- Average study participation of 21 months for each patient (minimum of 12 months), expected study duration 30 month

Primary and secondary endpoints

- Primary endpoint
  - Number of recurrent cardiovascular hospitalizations or all cause death
- Secondary endpoints
  - Cardiovascular hospitalizations (unplanned) (recurrent event, number)
  - All-cause mortality (time to event)
  - All-cause mortality or all-cause hospitalizations (unplanned)
  - All-cause hospitalizations (unplanned) (recurrent event, number)
  - Quality of life (Minnesota Living with Heart Failure Questionnaire) after 1 year

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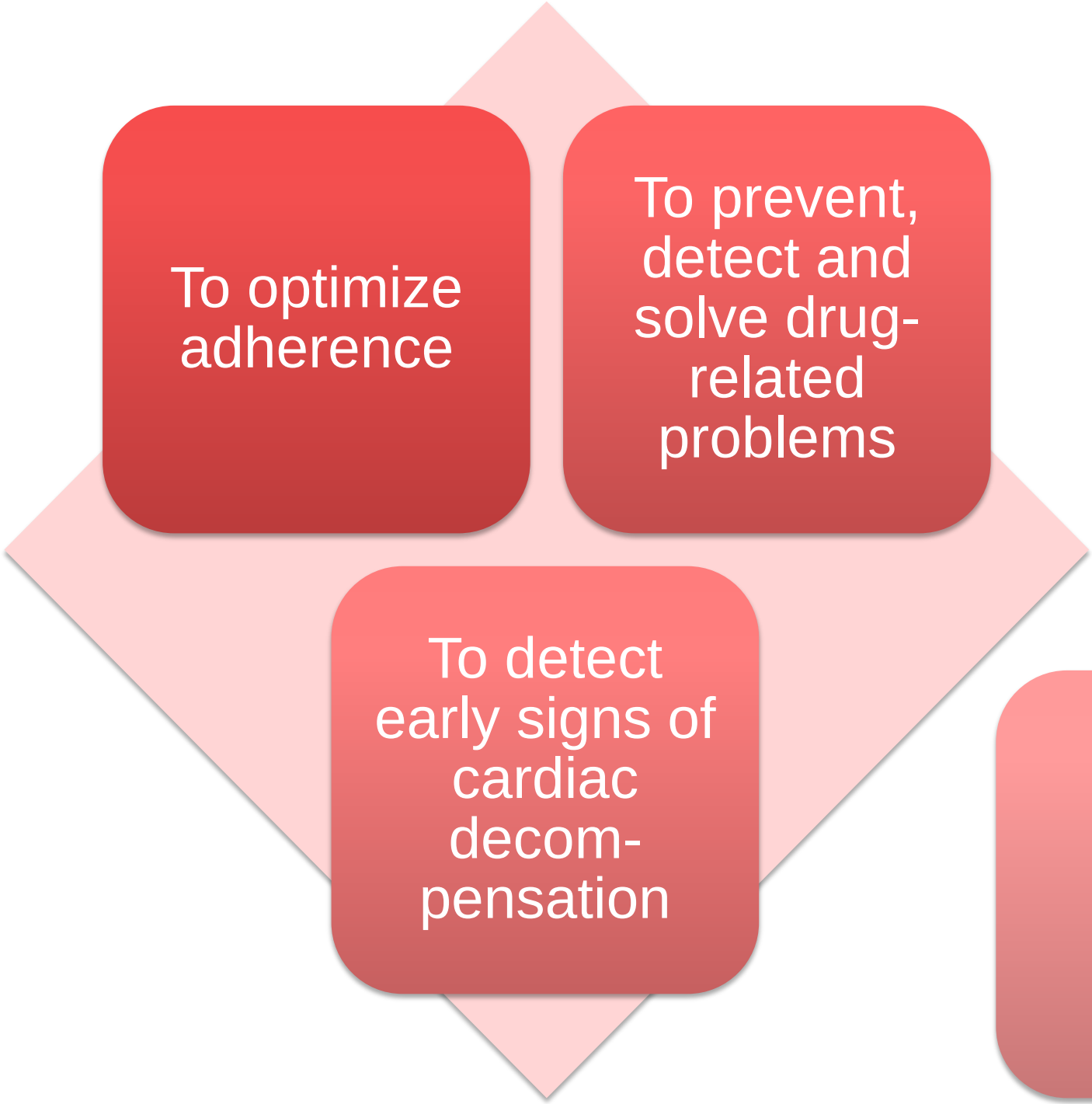
Medical practice - 1

- Screening and randomization (online randomization)
- Intervention group
  - Information of patients about participating pharmacies
  - Medical practice interacts closely with the pharmacy, e.g. for consolidation of the medication plan or discussion of potential DRP

Medical practice visits

Intervention and control group:

- Visits in the medical practice at baseline (V1), after 12 months (V3), and at the end of the study (V6), and, if applicable, after 24 month (V5)
- Telephone visits by the medical practice after 6 month (V2) and, if applicable, after 18 months (V4)


To optimize adherence
To prevent, detect and solve drug-related problems
To detect early signs of cardiac decom-pensation

Medication review: consolidation of the medication plan

Intervention group

At the beginning:

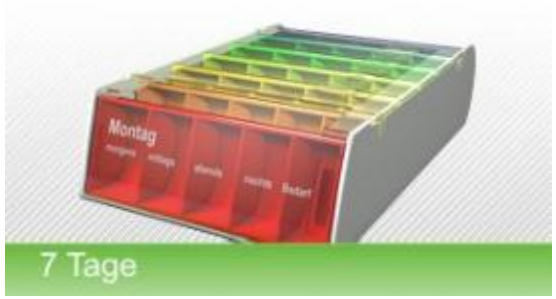
- Compilation of patient's medication (based on physician's medication list and patient interview)
- Check for drug-related problems (DRP) such as drug-interactions and double medications using a check-list
- Contact with physician to discuss problems and risks – if necessary.
- Consolidation of medication plan

Medication review: consolidation of the a medication plan

Continuous care within (bi-) weekly pharmacy visits

Intervention during weekly visits (1)

- Updating the medication plan if necessary
- Contact with physician in case of newly detected DRP
- Provision of medication in a weekly dosing aid



Intervention during (bi-) weekly visits (2)

- Discussion and counseling regarding
  - Medication
  - Adherence
  - Potential side effects
  - Signs and symptoms of cardiac decompensation
- Measurement of blood pressure and pulse
- In case of significant changes in vital signs contact with physician.
- Documentation.

Research is teamwork!

Scientific Heads of the Study:

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