

Care 4 Ourselves - person-centered support for people with chronic heart failure and / or obstructive pulmonary disease.

Submission date 14/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/06/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Person-centred care (PCC) is the name given to a partnership between patients/carers and professional care givers. The starting point is the patient's story, followed by physical examination and tests. Then a care plan is created, with goals and strategies. PCC is based on four 'pillars': personal health plan, educational package, coaching & counselling, symptoms & signs.

The aim of this study is to assess whether PCC can work for patients with chronic obstructive pulmonary disease (COPD) and chronic heart failure (CHF) and their informal care givers and whether this can help improve quality of life and cope more effectively with the diseases. The goal is to enable patients and their informal carers to understand COPD and/or CHF and the therapy better, to identify their own resources to help coping and living with their chronic illness thanks to a dialogue and partnership between health carer and patient. This will be an advice-only service.

Who can participate?

Adults over 50 admitted to hospital with worsening symptoms of COPD and/or CHF

What does the study involve?

Participants are randomly allocated to one of two groups. The 'intervention' group will receive usual care (regular care provided within the health system) plus a PCC nurse-led intervention. The 'control' group will receive usual care.

What are the possible benefits and risks of participating?

Nor provided at time of registration

Where is the study run from?

Gothenburg University Centre for Person-Centred Care (Sweden)

When is the study starting and how long is it expected to run for?

From October 2013 to December 2015

Who is funding the study?
Gothenburg University Centre for Person-Centred Care

Who is the main contact?
Professor Karl Swedberg

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
154881

Study information

Scientific Title
Care 4 Ourselves - Person-centered information and communication technology (ICT) support interventions in persons suffering from chronic heart failure and / or obstructive pulmonary disease.

Acronym

C4

Study objectives

The inclusion of the principles of PCC in a tele-partnership system for patients with CHF and COPD will reduce the need for medical care (primary care and hospital re-admission) amongst these patients by improving self-management, self-efficacy and collaboration in the process of care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Regional Ethical Review Board in Gothenburg, Box 401 405 30 Gothenburg, 17/12/2014, ref: DN 687

Study design

The overall study design is an experimental embedded research design carried out in two phases and guided by the new MRC framework. In phase I preparatory qualitative studies will be conducted, in phase II we will run a randomized controlled pilot study over a six months period.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet**Health condition(s) or problem(s) studied**

Patients suffering from chronic heart failure and/or chronic obstructive pulmonary disease.

Interventions

The intervention consists of a communication and on-going dialogues between patients, their informal carers and tele-support nurses. The communication with the patient will be based on the principles of person-centred communication (listening, open questions, reflective listening and summarising of narrative). The intervention group will thus receive usual care (regular care provided within the health system) plus a PCC nurse-led intervention. The control group will receive usual care.

Intervention Type

Other

Primary outcome measure

Primary outcome measure: Self-efficacy, measured at baseline, three and six months.
Improved: Increase in Self-efficacy > 5 units at 6 months and has not been re-admitted to hospital
Worsened: Death or re-admitted to hospital within 6 months or a decrease in self-efficacy > 5 units.
Measurement scales: General Self-Efficacy Scale, Cardiac Self-Efficacy Scale
Unchanged: Self-efficacy has neither improved or deteriorated

Secondary outcome measures

1. Number of re-admissions
2. Change in Self-Efficacy
3. Health care utilization, measured as the number of re-admissions, and unscheduled outpatient visits due to unplanned visits to hospital and/or vårdcentral due to symptoms of COPD and CHF

Overall study start date

01/10/2013

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. History of confirmed diagnosis of COPD and /or CHF
2. Admission to hospital for relapse /worsening symptoms of COPD and/or CHF
3. Age: ≥ 50
4. National registration within the Västra Götaland Region (VGR)
5. Owning a phone and current subscription to a telephone service provider

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

220

Total final enrolment

221

Key exclusion criteria

1. Severe hearing impairment that prevents patient from using a telephone or other communication device
2. Patient has no registered address
3. Any severe disease with an expected survival < 12 months
4. Cognitive impairment - Short Portable Mental Status Questionnaire SPMSQ score >6
5. Ongoing documented diagnosis of alcohol or drug abuse

6. Other disease that can interfere with follow-up (e.g. severe depression, other severe mental illness)

7. Patient participating in another randomized study

Date of first enrolment

17/12/2014

Date of final enrolment

30/06/2015

Locations

Countries of recruitment

Sweden

Study participating centre

Gothenburg University Centre for Person-Centred Care

Gothenburg

Sweden

405 30

Sponsor information

Organisation

Gothenburg Center for Person-Centred Care Research

Sponsor details

Box 457

Visiting address:

Arvid Wallgrens backe (Hus 1)

Gothenburg

Sweden

405 30

Sponsor type

University/education

Website

<http://gpcc.gu.se/english>

ROR

<https://ror.org/01tm6cn81>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Göteborg Center for Person-Centred Care Research

Results and Publications

Publication and dissemination plan

Research results will be published in international scientific journals and presented at international conferences after completion of data analysis.

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/08/2018		Yes	No
Results article	CHF subgroup analysis results	01/06/2020	02/12/2019	Yes	No
Other publications	subgroup analysis	01/03/2021	22/06/2021	Yes	No
Other publications	Qualitative analysis	02/03/2016	04/04/2023	Yes	No
Protocol (other)			04/04/2023	No	No
Results article	Self-efficacy and healthcare costs	08/11/2023	05/06/2024	Yes	No