ISRCTN18812755 https://doi.org/10.1186/ISRCTN18812755

Improvement of primary care for patients with chronic heart failure: comparing two strategies.

Submission date	Recruitment status	[_] Prospectively registered
09/07/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2020	Circulatory System	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hartfalen-iq-robuust.nl/

Contact information

Type(s)
Scientific

Contact name
Mr Jan van Lieshout

Contact details
P.O. Box 9101
114 IQ Healthcare
Nijmegen
Netherlands
6500 HB
+31 (0)24 36 66 264
j.vanlieshout@iq.umcn.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Improvement of primary care for patients with chronic heart failure: A cluster randomised controlled trial comparing two strategies

Study objectives
Our null hypothesis is that tailoring does not result in better implementation of the guidelines on chronic heart failure (CHF) compared to a standardised delivery of our implementation programme. In addition, we will also examine whether any of the two programmes is associated with improvements in healthcare delivery and patient outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The medical ethical committee (CMO Regio Arnhem - Nijmegen) assessed the study proposal and materials and concluded that approval was not required (ref: 2009 / 314)

Study design
Randomised controlled trial; practices are stratified according to practice size; randomisation is in blocks of 4 per stratum.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Patient information material may be found at http://nhg.artsennet.nl/kenniscentrum/k_voorlichting/NHGPatientenbrieven.htm#clusterK

Health condition(s) or problem(s) studied
Chronic heart failure in primary care

Interventions
We offer two implementation programmes: standardised and tailored.

1. Standardised delivery of the implementation programme
The implementation programme comprises of educational and organizational components, targeted at physicians, nurses and assistants, and patients. We included educational materials, a

proposal for task delegation and cooperation within the primary care practice, support by a visiting practice consultant, the possibility to contact a GP with extra knowledge of heart failure treatment, and a guiding registration form. A few adaptations were made regarding the specific recommendations, based on the revised practice guideline, and in several components, based on the lessons learned in a pilot study.
The information on non-pharmaceutical and pharmaceutical treatment was brought into line with the new interdisciplinary practice guidelines, which forms an adaptation of the European practice guideline. The paragraph on non-pharmaceutical treatment was enlarged and the pharmaceutical paragraph had some changes. Now, medication advice is different for patients with systolic heart failure compared to patients with a preserved systolic heart function, so called diastolic heart failure. Finally, new recommendations on the use of devices are formulated.
The guiding registration forms, both an instrument as part of the intervention and for data collection, were revised. For all patients there is one page with demographic data, information of the CHF (duration, severity, systolic or preserved systolic function, diagnosis echocardiography based, cause, co morbidity) and pharmaceutical treatment at the start of the project period. A second page poses questions about non pharmaceutical issues as advice about physical activity and influenza vaccination. Finely, we developed different forms for patients with systolic or diastolic heart failure, based on the recommendations on medication.
All practices will be offered three visits by a practice visitor, trained in supporting behaviour change in practices. In a pilot study all practices received at least one visit; we offered a selection of the practices three extra visits. The support needs were always satisfied after three visits in total. Practices visited just once reported a lack of support and some practices did not work with the materials offered at all.
An important lesson learned from the pilot phase was the finding that only a little interdisciplinary collaboration existed and we did not gain much improvement in this field. This was an important reason for using the multidisciplinary practice guideline as a starting point instead of the monodisciplinary GPs practice guideline. Furthermore, the regional advisors will determine the social network in the practice area, providing information on other primary care disciplines, for instance dieticians and physiotherapists, with extra expertise and interest in heart failure treatment. These workers in the other disciplines will be informed about the project and receive relevant information in line with the multidisciplinary guideline.
All materials are offered paper based in a binder. All materials will also be web based and we will examine the possibilities for designing the guiding patient registration forms on the study website.

2. Tailored delivery of the implementation intervention
General practices in the tailored group will receive the same materials as the GPs in the standard intervention group. They will receive up to three practice visits, depending on their needs. After inclusion of a practice in the tailor-made group, the GPs will receive an email with a list of barriers for improvement. The barriers listed are based on previous research and grouped in relation to the innovation, the health care professional, the patient, and the context. GPs are asked to indicate the relevance of each barrier in their practice situation on a five point scale, and whether or not they suppose the barrier can be solved. They are offered the possibility to add barriers perceived but not yet presented. In a second round they will receive feedback about their scoring in the first round and possibly additional barriers posed by other GPs. Depending on their relevance scores and perceived possibilities for change, a prioritising for the approach for the coming period is proposed. The GPs will agree on their own list and these prioritised issues will form the bases of the support from the practice visits.

First measurements will be taken at the start of the project, when a practice is included (June to October 2010). The duration of the intervention period will be one year. During this time, practices will keep track of the therapy they offer their patients and include this information on

the patient registration forms. After one year the GPs will send in these forms to the researchers, they will send out the patient questionnaires, and the interviews will be held.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Patient's experience of receiving structured primary care for CHF (Patient Assessment of Chronic Illness Care [PACIC])
PACIC is a questionnaire consisting of 27 items, which is related to the Chronic Care Model, which we translated and validated for use in general practice in The Netherlands.
2. Patients' health-related utilities (EQ-5D)
EQ-5D consists of 5 questions and a Visual Analogue Scale (VAS).

Secondary outcome measures
We will examine both changes within groups and differences at follow-up between groups with respect to:
1. Percentage of patients on the maximum tolerated dosage of ACE inhibitor or ARB and of beta blockage
2. Medication completed according to the guideline
3. Percentage of patients receiving of influenza vaccination in the winter season 2010-2011
4. Percentage of patients receiving professionally guided physical activity training
5. Number of non pharmaceutical issues addressed
If possible, subgroup analyses will comprise type of heart failure (systolic or diastolic) and diagnostic certainty (secondary care diagnosis, echocardiography diagnosis). Interviews will be used to assess the feasibility of the programme and goal attainment, organisational changes in CHF care, and formalised cooperation with other primary care disciplines and specialist care.

Overall study start date
01/06/2010

Completion date
01/11/2011

Eligibility

Key inclusion criteria
The study population will consist of 60 general practitioners (GPs) recruited in the south of the Netherlands. GPs will be contacted either direct or indirect via various regional organisations by advisors of the regional supportive structures for primary care.
GPs will include those chronic heart failure patients from their practices of whom the GPs consider themselves to be the physician taking care of the treatment of this condition in the patient, expecting 8 to 10 patients per practice.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 GPs and 60 times 8 to 10 chronic heart failure patients

Key exclusion criteria
1. GPs: None
2. Patients:
2.1. Those exclusively experiencing secondary care for their chronic heart failure
2.2. < 18 years of age

Date of first enrolment
01/06/2010

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 9101
Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
Stichting Robuust (Netherlands)

Sponsor details
Le Sage ten Broeklaan 11
Eindhoven
Netherlands
5615 CP
+31 (0)40 294 99 77
info@rosrobuust.nl

Sponsor type
Government

Website
http://www.rosrobuust.nl

ROR
https://ror.org/01nsg2f90

Funder(s)

Funder type
Government

Funder Name
Stichting Robuust (Netherlands) - bond of regional supportive structures for primary care in The Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/03/2011	18/12/2020	Yes	No