ISRCTN00926323 https://doi.org/10.1186/ISRCTN00926323

The HeartCycle heart failure trials programme

Submission date 23/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/06/2011	**Overall study status** Completed	
Last Edited 12/06/2015	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://heartcycle.med.auth.gr/

Contact information

Type(s)
Scientific

Contact name
Prof John Cleland

Contact details
Department of Cardiology
Daisy Building
Castle Hill Hospital
Cottingham
Hull
United Kingdom
HU16 5JQ
+44 (0)148 246 1780
j.g.cleland@hull.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
An observational trial with randomised components investigating the ability of a third generation home telemonitoring system to enhance the management of patients with new-onset, recurrent or persistent severe heart failure

Acronym
HeartCycle 002

Study objectives
To assess the utility of home telemonitoring of patients with heart failure with an existing system (Philips MOTIVA), but which has upgraded software to incorporate care-plans and clinical algorithm functions into the device. These have been designed to inform both the patients and the health professionals caring for them about progress towards therapeutic targets and timing of appropriate investigations and changes in therapy changes. Existing home telemonitoring systems are based on the concept of early crisis detection. The new system provides the same crisis detection facilities but focusses on a concept of health maintenance, since identification of health crises will always be imperfect. It is hoped that such systems will prove to exert a much more profound reduction in morbidity and mortality than existing systems but proof of this awaits major outcome studies that will be based on the experience gained from studies such as this.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire and Humber REC, ref 11/YH/0118 approval pending as of 23/03/2011

Study design
Observational randomised cross over studies in four phases

Primary study design
Observational

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Heart failure

Interventions
1. The study is conducted in three phases and the overall study experience constitutes a fourth
2. Patients who have had a recent hospitalisation for heart failure or who have heart failure but who have not yet required hospitalisation will be invited to participate in a home telemonitoring (HTM) programme. HTM is provided by a set-top box and interactive television.
3. The patient is asked to measure heart rate, blood pressure and weight each morning and evening with user-friendly, wireless equipment
4. This information is relayed to a central computer, which provides feedback to the patient and the health professional and develops treatment recommendations
5. The patient receives heart rate, blood pressure and weight charts together with a 'healthy' range selected for that individual by the nurse or doctor
6. Lifestyle advice and small changes in diuretic (water-pill) dose go directly to both patient and health professional
7. More complex advice goes only to the nurse or doctor with the patient only alerted to expect to receive a telephone call about what to do
8. The first part of the protocol (A) is designed to introduce the patient to the monitoring system, sort out their treatment according to the individual management plan agreed with their doctor and make sure it is safely implemented and to assess stability
9. This observational period may last up to two months
10. The second part of the protocol (B) is designed either to minimise the use of diuretics (water pills) in patients who have few or no symptoms or optimise them in patients who remain symptomatic despite conventional diuretic doses
11. Minimising diuretic use is rarely done in routine clinical practice as there has been no reliable way of monitoring symptoms and fluid (weight) gain that indicate the need to restart diuretics
12. Many patients are probably needlessly treated with higher doses of diuretic than they need to control symptoms and there are concerns that this may adversely affect body systems including the kidney
13. On the other hand, many patients remain symptomatic despite diuretics and doses are often not increased to try to obtain optimal symptom relief
14. This will be conducted as a cross-over study with one month study periods, comparing usual care with the new strategy
15. The third part of the protocol (C) is designed to assess the effects of diet (eg:-coffee, salt, large meal) and environment (eg:- stressed, cool, warm, just after exercise or a shower) and timing of medication (single missed doses)
16. This will be conducted without the HTM nurse or doctor knowing what the intervention is until after they have 'guessed'
17. This is designed to see if these interventions have a substantial effect on HTM measurements and whether HTM staff can spot them
18. Protocol D lasts until 6 months after the last patient has been enrolled
19. This will enable assessment of what proportion of time patients remain in the 'health-maintenance' range with respect to heart rate, blood pressure and other vital signs and to obtain greater experience in the early detection of events leading to hospitalisation or death

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Protocol A: Observational Study of Therapy Optimisation.
1.1. Success will be measured as the proportion of patients reaching the target doses of each medication in their Care-Plan unless a specific contra-indication develops (such as bradycardia, hypotension, hyperkalaemia or renal dysfunction) to reaching target doses
1.2. The main aim of this part of the protocol is to provide a user-friendly tool that encourages and supports the health professional to optimise treatments that are known to alter prognosis
2. Protocol B Randomised, Open-label Diuretic Dose Minimisation and Optimisation:
2.1. Diuretic Minimisation Protocol: the primary outcome of this will be patient preference (see 7-point Likert scale which will be the evaluation tool in appendix) for down-titration or usual maintenance dose of diuretic.
2.2. Diuretic Optimisation Protocol: the primary outcome of this will be patient preference for up-titration rather than usual maintenance dose of diuretic.
3. Protocol C - Clinical Calibration Protocol:
A Single (Investigator) -Blind Assessment Trial of Everyday Patient Events:
Although interventions occur at random, this study will be analysed principally as an observational study designed to assess the impact of the challenges of everyday life on monitored vital signs.
4. Protocol D Long-term Evaluation:
This portion of the study focuses on the technical ability of the system to maintain the patients' vital monitoring signs within individually-tailored 'ideal' ranges and to gather information on medical events that were or were not predicted by the system

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2011

Completion date
01/03/2013

Eligibility

Key inclusion criteria
1. A clinical diagnosis of heart failure:
1.1. Cause of heart failure may be for any reason other than those that are rapidly reversible (see exclusion criteria)
1.2. May include patients with and without a low left ventricular ejection fraction or with valve disease
2. Requiring treatment with at least 40mg/day of furosemide or equivalent (1mg of bumetanide or 10mg of torasemide)
3. Evidence of advanced or unstable disease
4. Admission to hospital for or complicated by heart failure currently or within the previous 60 days. It is expected that most patients will be recruited by this criterion.
5.. Out-patients with persistent New York Heart Association (NYHA) III/IV symptoms
6. An elevated N-terminal pro-hormone of brain natriuretic peptide (NT-proBNP):
6.1. >1,000pg/ml if in sinus rhythm, including atrio-biventricular pacing
6.2. >2,000pg/ml if not in sinus rhythm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Unwilling to comply with the protocol
2. Patients should be willing and able to make daily measurements at home throughout Protocol B
3. Rapidly reversible causes of heart failure such as severe anaemia (defined as the need for a blood transfusion), thyrotoxicosis, admission with rapid (>120bpm), atrial fibrillation with good ventricular function
4. Inability, in the investigators opinion, to operate or comply with the home telemonitoring system (HTM) system, even with available support from carers and health volunteers if available
5. Patients who are unable to communicate directly or indirectly in the local language (English in the UK, German in Germany and Spanish in Barcelona) cannot participate
6. People aged <18 years and vulnerable patient groups such as those with dementia, psychotic illness or educationally severely subnormal will be excluded

Date of first enrolment
01/06/2011

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
England

Germany

Spain

United Kingdom

Study participating centre
Castle Hill Hospital
Hull
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Philips Research Laboratories (Germany)

Sponsor details
c/o Cristina Bescos
Philips Research Laboratories
Medical Signal Processing
Weisshausstr. 2
Aachen
Germany
D-52066
+ 49 (0)241 6003 687
Cristina.Bescos@philips.com

Sponsor type
Research organisation

ROR
https://ror.org/05san5604

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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?
Results article	results	11/12/2014		Yes	No