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Asia Pacific Journal of Family Medicine Volume 5 Issue 2

ORIGINAL ARTICLE

The Chronic Heart-failure Assistance by Telephone (CHAT) Study: Assessment of telephone support for vulnerable patients with chronic disease

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Accepted for publication 19 July 2006.

Abstract

Aim: To determine whether telephone support using an evidence-based protocol for chronic heart failure (CHF) management will improve patient outcomes and will reduce hospital readmission rates in patients without access to hospital-based management programs.

Methods: The rationale and protocol for a cluster-design randomised controlled trial (RCT) of a semi-automated telephone intervention for the management of CHF, the Chronic Heart-failure Assistance by Telephone (CHAT) Study is described. Care is coordinated by trained cardiac nurses located in Heartline, the national call center of the National Heart Foundation of Australia in partnership with patients' general practitioners (GPs).

Conclusions: The CHAT Study model represents a potentially cost-effective and accessible model for the Australian health system in caring for CHF patients in rural and remote areas. The system of care could also be readily adapted for a range of chronic diseases and health systems.

Key words: chronic disease management; chronic heart failure; integrated health care systems; nursing care, rural health services; telemedicine; telenursing

Introduction

Chronic heart failure (CHF) is a major public health problem. It is associated with a worse prognosis than most cancers and requires frequent, prolonged, and costly admissions to hospital.^{1,2} The associated burden is

particularly high in the elderly ([Fig. 1](#)).³ Increasing prevalence of CHF as well as the associated personal and economic burden mandate consideration and evaluation of new and innovative care models.^{4–6} As demonstrated by the recent DIAL trial undertaken in Argentina, clinical management augmented by specialist CHF nurses providing telephone support is one important approach and is clearly a system of care accessible to rural and remote patients.^{7–9}

Materials and methods

Study design

The chronic heart-failure assistance by telephone (CHAT) Study is a randomised trial of 534 people diagnosed with CHF in which all participants will receive standard care (SC) but half will receive a nurse-coordinated telephone intervention package (SC + I). This will use interactive voice response (IVR) software known as the TeleWatch™ telemedicine system developed by the Johns Hopkins University, USA.¹⁰ The nurse-coordinated telephone intervention package will be provided by experienced cardiac-trained registered nurses located in the National Heart Foundation of Australia call center – Heartline. A major component of the intervention package is in the form of prerecorded telephone CHF management scripts based on the Australian national guidelines for both the pharmacological and non-pharmacological management of CHF.¹¹ The TeleWatch™ system is a telephone-based, semi-automated telemedicine system that enables a limited resource of health care providers, namely nurses, to monitor symptoms and support a larger than usual caseload of CHF patients.

Study aims and objectives

The primary aim of the CHAT study is to develop an effective preventative and supportive management strategy for Australians with CHF, particularly those residing in rural and remote communities. The study will test this aim by determining whether telephone support, involving outpatient education and monitoring using a multidisciplinary clinical protocol-based approach for the management of CHF will improve patients' health status as represented by an innovative clinical composite score. Secondary aims include comparing total hospitalized days, the proportion of patients on target doses of angiotensin converting enzyme (ACE) inhibitors and changes in brain natriuretic peptide (BNP) levels. The cost-effectiveness of the intervention will also be determined.¹²

Study population

The study is currently recruiting Australia-wide with a target sample size of 534 CHF patients who are being predominantly cared for in rural and remote general practices as defined by Rural, Remote, Metropolitan Areas (RRMA) classification 3–7 and/or patients from RRMA classification 1 and 2 where access to formal CHF management programs is limited or inaccessible.¹³

General practitioners were self-selected for enrolment. Initially, the study was widely publicised to the Australian general practice population through various general practice networks and journals. GPs listed on national databases were sent a one-page 'expression of interest' fax-back letter of invitation. A member of the research team then contacted interested GPs regarding enrolment.

GP randomization

The general practice will be the unit of randomization. A cluster randomization trial is the design of choice aimed to prevent contamination between patient study groups. Once the GP has been assigned randomly to either the intervention or standard care study group, all patients recruited from that GP's practice will automatically be assigned to the same study group. Participating practices will first be stratified by RRMA before being randomly allocated to the standard care or intervention group.

Patient recruitment

Appropriate to a cluster-design randomised controlled trial conducted in general practice, all patients from a single practice are assigned to the same study arm. The GP will act as guardian for their consenting patients in so far as their participating patients will consent without knowing to which study group their GP practice has already been allocated. Enrolling patients will only be given details of this assignment once informed consent has been provided and included only once the selection criteria have been met ([Table 1](#)). Randomised GPs will be asked to enrol between two and 10 CHF patients per practice.

Intervention vs. standard care

Intervention package for patients, their families and carers

Half of the patient population will be randomly assigned to the intervention group and will receive a nurse-coordinated, CHF-focused intervention package. Each participant in this group will receive initial training in telephone calling from the 'CHAT nurse' to ensure competence in the independent utilization of the TeleWatch™ system technology. Once demonstrated, they will be instructed to call in, using a free-call 1800 number at no less than monthly intervals for a 12-month period (Fig. 2).

Responses entered by the patient are individually assessed by preprogramming of the TeleWatch™ system according to the patient's overall health assessment and color-coded according to severity of signs and symptoms of worsening CHF (Fig. 3). The patient has the choice to leave a voice message for the nurse or to request a telephone follow-up call. The frequency of patient calls is monitored and recorded to allow for the exploration of a 'dose effect'. We hypothesize a positive correlation between the frequency of calls and the effect of the intervention. Patients are more likely to learn skills associated with increased self-care activity the more feedback and reinforcement they receive through interacting with both the TeleWatch™ system and the CHAT nurses.

Participants and their families will be provided with an action plan on how to detect clinical deterioration and when and how to access emergency medical care and a personal copy of a Heart Foundation publication Let's Talk about Heart Failure, prepared specifically for this study, and includes a lay-person's version of the CHF national guidelines.¹⁴ They will also receive regular newsletters with helpful hints and information relating to their involvement in the study and will be given a individualized CHAT study patient diary to record all relevant clinical information, including visits to health services.

Intervention package for GPs

Each physician randomised to the intervention group will receive copies of the national guidelines for CHF management,¹¹ and the 'Diuretic Treatment Regimen',¹⁵ a laminated double-sided desktop version of the CHF – Clinical Practice Guidelines for quick reference, ongoing targeted contemporary educational materials and regular study newsletters. The CHAT nurse will activate the GP fax-back feedback loop to report participants' changing signs and symptoms to their GP (Fig. 4),¹⁶ and will activate a study-specific diuretic algorithm designed to maintain patients when they are not able to access their GPs.¹⁵

Standard care package for patients, their families and carers

General practitioners assigned to the standard care group will receive copies of the national guidelines for CHF management and the 'Diuretic Treatment Regimen'.^{15,17} Their patients will receive an individualized CHAT Study patient diary but no other literature.

To assist with the development of the therapeutic relationship, reported as being more difficult where physical contact is precluded, personal and professional profiles including a photograph of the telephone support nurse and the independent evaluator working within the call center environment will be provided to all participants.

Patient follow-up

Participant contact will be at least monthly for a minimum of 12 months. The nurse-coordinated telephone intervention follow-up will be supported by specific CHF management training decision support software, the TeleWatch™ telemedicine system.¹⁰ Telephone surveys will be used to evaluate study clinical endpoints and will be administered at baseline, 6 months and 12 months by a trained independent interviewer who remains blinded with regard to patients' treatment allocations. The survey will include questions relating to quality of life, economic assessment and utilization of health services.

Endpoint evaluations

The primary outcome variable will be a clinical composite (Packer) score,¹⁸ which combines changes in New York Heart Association class and the patient's 'global' assessment. This latter measure asks the patient to judge

whether their overall health status has changed since the commencement of the study and if so, to define the direction and estimate the magnitude of the change. Also included within the Packer composite score is the occurrence of major clinical events such as hospital admissions for or with CHF, all-cause mortality and withdrawal from intervention due to worsening heart failure within the study period.

Key secondary evaluations include total hospitalized days and patient quality of life ([Table 2](#)). Physiological evaluation of the intervention will be determined by BNP analysis. Both primary and secondary outcomes will also be compared in urban (RRMA 1–2) and rural and remote (RRMA 3–7) patients.

Data analysis and statistical methods

The primary outcome or Packer composite score is comprised of the following values: improved, no change or worsened. For example, assuming patients in the standard care arm would respond as 25% improved, 50% no change, 25% worsened, an odds ratio of 1.65 in a proportional odds model would improve the scores in the intervention arm to 36% improved, 48% no change, and 16% worsened. With patients individually randomised, to detect this change with 80% power would require 222 patients per arm. With an average of three patients per practice in a cluster-randomised design, an intrapractice correlation of 0.10, and applying the design effect for interval-scaled measures, the approximate sample size inflation factor is 20%, leading to a total sample size of 267 patients per arm.

Cost-effectiveness analysis

Cost-effectiveness will be assessed in a marginal analysis from a health system perspective, that is, including all private and public health service costs. The costs of the intervention and the cost offsets from reduced hospital admissions will be assessed from detailed data prospectively collected on drug utilization, investigations, hospital admissions, attendances at emergency departments and general practitioners (scheduled and unscheduled). This data will be supplemented using the Health Insurance Commission (HIC) and Department of Veterans' Affairs (DVA).

The measure of health outcome will be derived from mortality outcomes and differences in quality of life (as measured by the Euroqol, a generic measure of health-related quality of life)¹⁹ and will be expressed in quality-adjusted life years (QALYs). The resultant cost-utility ratios (cost per QALY) can easily be redefined as a cost per disability adjusted life years (DALYs) because the disability weights used in the Australian Burden of Disease studies were derived for health states with a Euroqol description.²⁰ All analyses will be on an intention-to-treat basis.

Discussion

Many clinical trials in CHF, whether of non-pharmacological or pharmacological therapies, including the recently published DIAL trial exclude up to 40% of the patients screened for the intervention on the basis of factors such as comorbid conditions and lack of proximity to the study center.^{21–23} Traditional empiricism demands homogeneity, but the reality is that in the community, CHF patients are heterogeneous.^{24,25} On the basis of these observations and a fundamental premise of the study which relates to the accessibility of care, in contrast to the DIAL trial, inclusion criteria have been designed to recruit a population that truly reflects 'real world' community practice, including patients with diastolic dysfunction. General practitioners will be recruited from practices identified by the RRMA to ensure the representative nature of study participants and will continue to provide 'usual care' during the 1-year study period. Recruitment will occur predominantly from RRMA classification 3–7 (rural and remote) general practices where access to formal CHF management programs is currently largely unavailable.

The inclusion of BNP as an objective measure will provide an opportunity to undertake a physiological evaluation of the intervention, which has not previously been evaluated in this manner, and to assess the prognostic capability of BNP within a CHF community-based patient population.

This is also the first study of its type where the participants are instructed to telephone the nurse rather than receive nurse-initiated telephone calls, which potentially could translate to care being provided for those in greatest need.

The CHAT study will also test a novel integrated and semiautomated IT support platform that enables patients to

telephone as often as they choose, and at a time which suits them best. This automated service is aimed to help monitor patients' progress and reinforce CHF self-care skills and activities while requiring fewer nurses than a traditional telephone-based health service.⁹

Acknowledgments

The CHAT investigators gratefully acknowledge the following funding sources: National Health and Medical Research Council of Australia, National Heart Foundation of Australia, Medical Benefits Fund of Australia, a Pfizer CVL Grant and My Chemist.

The CHAT Study Team would also like to acknowledge Dr Edward Kasper and Dr Jeff Spaeder, Department of Cardiology and Mr James Palmer, Applied Physics Laboratory Johns Hopkins University, Baltimore, Maryland, USA for the use of the TeleWatch™ telemedicine system along with ongoing expert advice and support of its usage.

Summary of implications for GPs

Compounding the pressure of a shrinking general practice (GP) workforce, Australia's ageing population mandates the consideration and evaluation of new models of care. There is a growing expectation that GPs will play an increasing role in chronic disease management. The CHAT Study will test an innovative and affordable 'system-of-care' designed to support GPs and their patients with chronic heart failure (CHF). Many patients have limited access to formal CHF management programs, particularly in rural and remote areas. Through recruiting a population that truly reflects 'real world' community practice, this study will test the capacity of telenursing to support GPs, improve CHF patients' quality of life and reduce their need for hospital readmission.

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Table 1 - Patient selection criteria

Criteria for Inclusion

- Adult male and female patients = 18 years
 - A diagnosis of CHF within the past 5 years†
 - A New York Heart Association (NYHA) classification of II, III or IV
 - Access to and able to operate a touchtone telephone
-

†Primary hospital discharge diagnosis of CHF within last 5 years AND/OR

- (a) Echo evidence of systolic HF (LV Ejection Fraction < 40%) OR reported moderate to severe LV systolic dysfunction OR
- (b) Echo evidence of diastolic HF (or reported impaired ventricular relaxation) on echo AND no other diagnostic explanation for CHF type symptoms (e.g., COAD, asthma).

Table 2 - Outcome measures

Primary outcome measure

Clinical composite (Packer) score

Secondary outcome measures

1. Patients' quality of life
 2. Cost-effectiveness per quality adjusted life year
 3. Proportion of patients on target doses of ACE Inhibitors
 4. Total hospitalized days
 5. Changes in measurements of brain natriuretic peptide (BNP)
-

Both primary and secondary outcomes will also be analyzed as a comparison between urban (RRMA 1 & 2) and rural/remote (RRMA 3–7) patients.

Figure 1 Projected numbers of older patients with coronary heart disease, high blood pressure and heart failure in Australia²⁶ (With permission from Prof D. Kelly and *Circulation*)

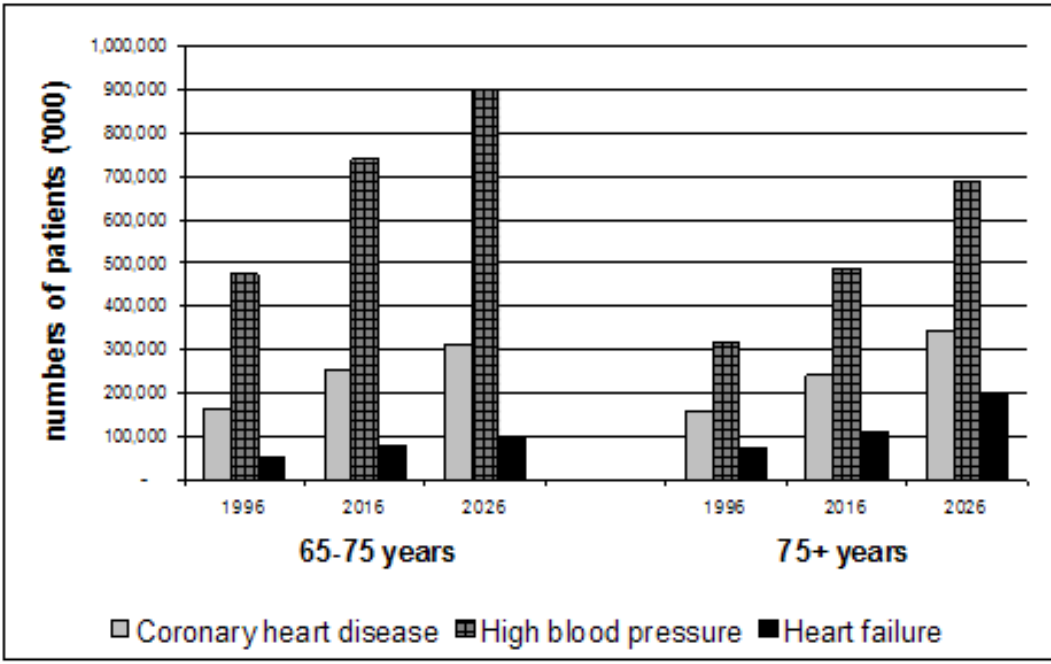


Figure 2 CHAT Study schema

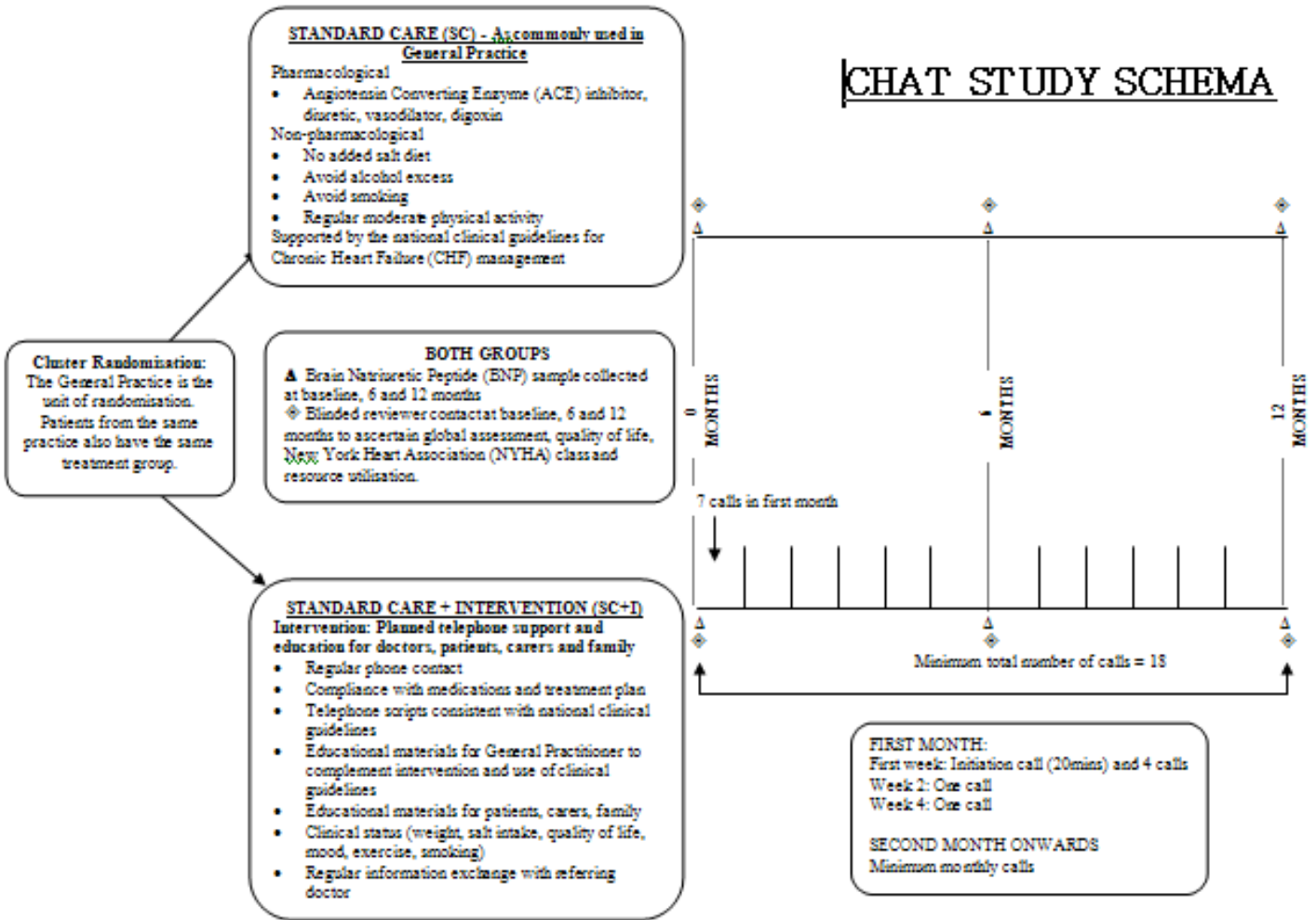


Figure 3 Operation of the TeleWatch™ system

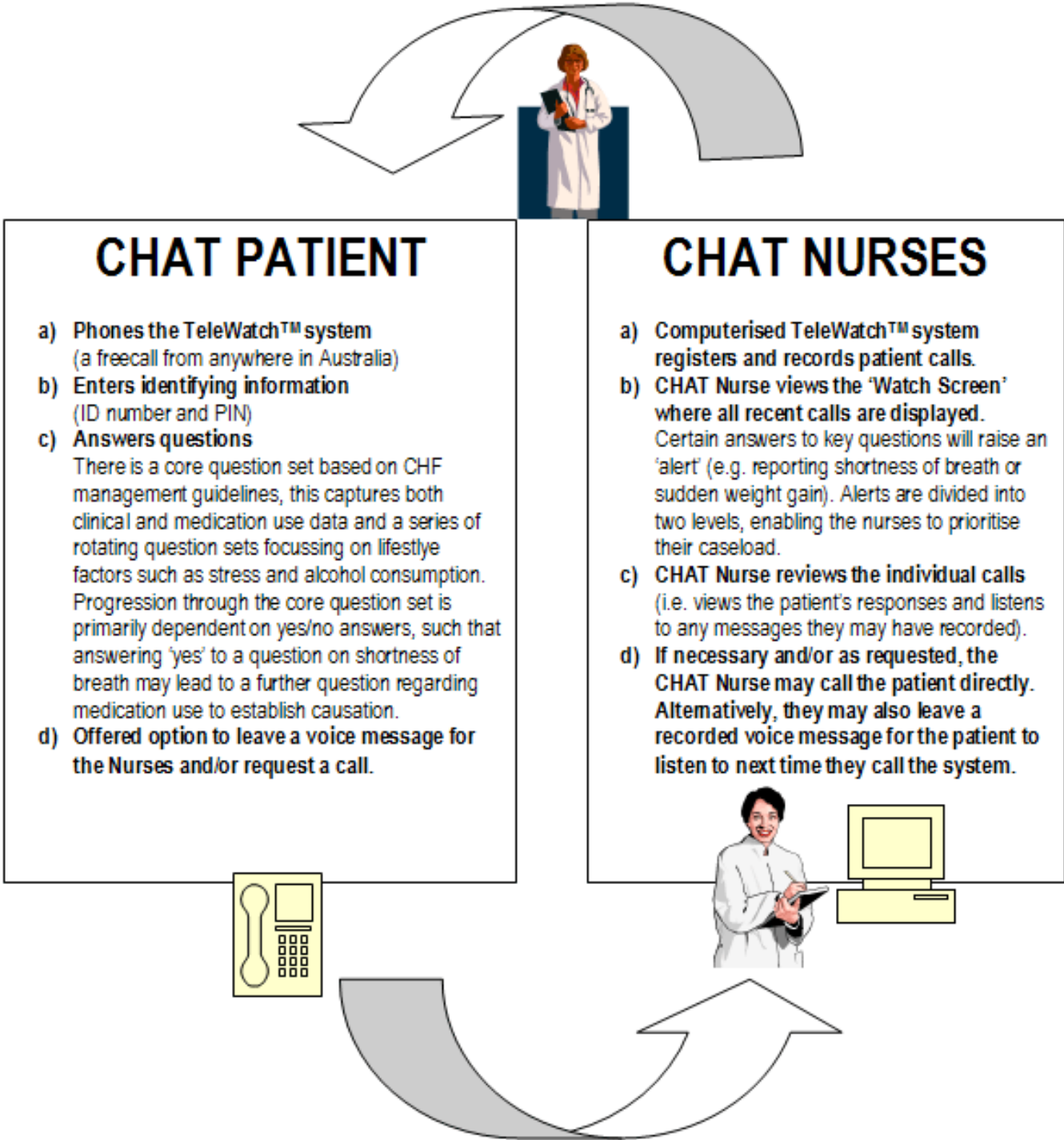


Figure 4 CHAT Study GP feedback loop

The CHAT Nurse GP Feedback Loop

In an emergency such as chest pain and increased SOB the CHAT Nurse will advise the patient to call an ambulance on 000

In a less urgent situation, the CHAT Nurses will activate the GP Feedback Loop.

The list below indicates the occasions when the CHAT nurse will advise the patient to see their GP as soon as possible and to notify the GP that this advice has been given.

The Process will include:

1. Advise the patient to see GP ASAP
2. Document into the CHAT data base clinical notes concerning the event and date, time and advice given.
3. Call the GP Surgery (Speak to GP or leave a detailed message and return phone number or email)
4. Document in the CHAT database that the was GP notified and GP response
5. Ask patient to call the CHAT Nurse after seeing GP to update database

The CHAT Nurse will enact the GP Feedback Loop when:

- The diuretic algorithm has been implemented and has not been effective
- The patient is reporting increasing shortness of breath over days
- The patients reports they are coughing a lot especially at night
- The patient report signs and symptoms of severe tachycardia
- The patient reports dizziness, passing out or falls
- The patient reports chest pain is getting worse or not responding to medication
- The patient reports temperature or shivering
- The patient appears confused or reports episodes of confusion
- The patient reports serious side effects from their medication regime
- The patient needs a prescription in < 48 hours
- The patient reports an issue not related to heart failure but the CHAT nurse feels should be followed up promptly

For less urgent matters the CHAT nurse will advise the patient to make a note in their diary to discuss the issue with their GP at their next scheduled visit.

NOTE: The CHAT Nurse GP Feedback loop has been adapted from 'Living with heart failure: A guide for patients, their families and carers', a patient resource developed by the *National Heart Foundation of Australia*.

R. Clark, J. Yallop and A. Nangle 10-11-04

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