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Evaluation of telehomecare Studies in Patients with Chronic Heart Failure: A health Technology Assessment Study

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Abstract

Background: Heart failure (HF) is a major complication resulting from a variety of heart diseases. HF is an increasingly important issue, whose prevalence has doubled in the last two decades. This is due to increased life expectancy, treatment and prevention of other heart diseases, and increased life expectancy. Promoting self-care through tele homecare is an emerging strategy for managing chronic diseases.

Objectives: The purpose of this study is to evaluate tele-care studies in patients with chronic heart failure (CHF). This is based evaluating the types of technologies used for patients in this method, effectiveness, cost-effectiveness and safety of these technologies based on the aspects of health technology assessment.

Methods: PubMed, Scopus, Web of Science, Cochrane databases, HTA (Health Technology Assessment), NHS EED (National Health System Economic Evaluation Database), DARE (Database of Abstract of Reviews of Effects), Embase, and (Society for Information Display) SID were searched using medical subject heading (Mesh) keywords. Then, studies were evaluated by two people and disputed by a third party. The quality of the extracted studies was evaluated based on the (Risk of Bias) RoB 2.0 checklist. The difference between the mean and its standard deviation was calculated (which was used as the effect size). To analyze the results, meta-analysis of random effects was performed. In addition, the subgroup and meta-regression analysis were performed to discover possible sources of heterogeneity. Finally, studies were evaluated in terms of Health Problem and Current Use of the Technology (CUR), Description and technical characteristics of technology (TEC), safety (SAF), Clinical effectiveness (EFF), Costs and economic evaluation (ECO) of 9 Aspects of Health Technology Assessment (HTA). Studies were evaluated with respect to the long-distance care in patients with CHF. We approach the method through systematic review and meta-analysis based on the principles of PRISMA-P. This systematic review examined the effectiveness of long-distance care interventions in patients with CHF, compared with conventional care methods. In general, evaluation of studies extracted in this systematic review will try to identify, evaluate and combine the effects of tele-care in patients with HF using meta-analytical methods in the evidence. Evaluating studies conducted in the field of tele-care in patients with CHF will help us to better understand how these methods work in the management of chronic heart disease [effectiveness, safety and cost reduction] and determine which care interventions Distance is more effective in patients with HF based on their characteristics according to clinical outcomes and resource use.

Conclusion: The results of this study can be used as a guide to provide valid evidence for the decision of senior managers of the Ministry of Health and large hospitals to use common technologies used in distance care for patients with CHF and other chronic diseases. This study will also provide a new understanding of the various studies that have been conducted to help patients with chronic failure by different types of remote care technologies in terms of effectiveness, safety, technology, and economic costs.

Keywords: Tele-homecare, Chronic Heart Failure, Systematic Review, Meta-analysis

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Introduction

Today, heart disease is the most common chronic disease and cause of death in adults around the world. Heart failure (HF) is recognized as the common endpoint of all heart disorders [1]. HF is a chronic disease with a high prevalence. It is an expensive and debilitating disorder with a poor prognosis and high mortality [2]. It is an increasingly important issue whose prevalence has doubled in the last two decades due to increased life expectancy, treatment and prevention of other heart diseases [3].1 to 2 percent of the world population suffers from HF. This has increased by 510 percent among people of 70 and above [4]. Congestive heart failure (CHF) is an important [5] public health [6] issue in many areas with significant mortality, high hospitalization rates, and poor quality of life [6]. In recent decades, population growth and improved treatment of further cardiovascular disease has led to the prevalence of CHF in most Western countries [7]. Readmission rate of 30 days and 6 months is estimated at about 25% and 50%, respectively. This costs more than $ 30 billion a year, and will double (by $ 69.7 billion by 2030) [7].

HF is a major healthcare problem with significant morbidity and mortality rates whose progression is characterized by frequent hospitalizations. This is because 30–50% of the patients hospitalized for HF die or experience readmission within the first 6 months after hospital discharge. Close monitoring of patients during their time of stay is mandatory. Telemonitoring (TM) is considered an adjunctive component of outpatient care. It is based on the online transmission of physiological data, signs, and symptoms that are either self-assessed by the patient or captured by supplementary equipment like mobile devices. Although current data on the benefit of TM in HF patients are heterogeneous, specific TM concepts have been shown to reduce hospital readmissions /admissions, and to improve further HF outcomes like all-cause mortality and health-related quality of life (QOL) [8].

In Iran, the most important risk factors for HF are type 2 diabetes, hypertension, stroke and age [9]. These patients spend millions of tomans annually on the country's medical systems [10]. This prevalence of HF in Iran is 8%, which is higher than Asian countries such as Japan, China and Malaysia. According to the previous studies, the prevalence of HF in Asia was reported to be from 1.26 to 6.7 percent, and the death rate was from 3.9 to 6.7 percent. This figure in Iran is about twice as high as the mentioned reports [11].

By 2030, annually, two-thirds of the cost of HF care would be related to the management of acute failure compensation courses in hospital [9]. So, about half of hospital readmission cases would be preventable [11]. Therefore, reducing the incidence of HF is the focus of health care centers, and is currently considered a major unmet clinical need .[12] The special focus of contemporary HF management is to reduce hospitalization and readmission rates [13].

According to Cochrane, telemedicine has the potential to improve health care and reduce health care costs for people with HF [14]. The main goals of home health care for HF patients are meeting self-care needs, detect early changes in symptoms, and less hospitalization [15]. Tele-homecare is a type of remote health care, a feasible and widespread technology which can monitor and enhance self-care in an efficient and effective manner. This is suitable for older adults who are dealing with a variety of health problems [13]. The present study is a study of health technology based on 5 aspects of Health Problem and Current Use of the Technology (CUR), Description and technical characteristics of technology (TEC), safety (SAF), Clinical effectiveness (EFF), and Costs and economic evaluation (ECO). [16] Furthermore, they are from 9 aspects of health technology assessment (HTA), which evaluate

studies conducted in the field of distance care in patients with CHF. The systematic method of face-to-face meta-analysis is based on the principles of PRISMA-P.

Materials and Methods

Study eligibility

Participants: The focus of this study is on evaluating studies on long-distance care for patients with CHF.

Intervention: Tele-care includes remote monitoring (tele-monitoring), tele-care services, use of reminder systems and decision support systems, long-distance education, remote consultation (visit), use of alarm systems.

Comparisons: It is about the usual care for patients with CHF

Outcomes: The following outcomes will be considered in primary studies:

The effect of remote care on controlling HF in patients is reducing costs, mortality, the number of hospitalizations, complications, and improving quality of life and returning to work and daily activities.

Types of studies

Eligible studies include randomized controlled trials (RCTs), cluster RCTs, controlled clinical trials (CCTs) or non-randomized cluster trials, and intermittent time series.

Search strategy

Primary studies were identified through searching PubMed, Google Scholar, Scopus, ISI Web of Science, CRD Cochrane databases, HTA, EED, DARE, EMBASE, and SID, using medical subject heading (Mesh) and non-Mesh keywords. The search strategy is presented in table 1. After finalizing the search, two independent reviewers selected the related studies according to the eligibility criteria. In the first step, the titles/abstracts were screened and all potential publications were selected. The researchers retrieved full-texts in the second step and selected the related studies. The final lists included studies selected by the two authors, combined with a clear reason for excluding non-eligible studies. A third reviewer was consulted in case of disagreement. The reference lists of related articles were also checked to find other potentially relevant articles. In addition, relevant journals were hand-searched, including the Journal of Telemedicine and Tele-care, Telemedicine and e-health.

Data collection and analysis

Selection of studies: A summary of the search, selection, and inclusion of studies was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.

Data extraction and management: Mean (M) and Significant Difference (SD) extracted data separately and were double-checked for final confirmation. A pre-designed form was used for data extraction. Three types of data were extracted including participants' characteristics, intervention details, and outcome measures.

Participants' characteristics: Published studies on CHF, if a study is performed on patients with chronic diseases in general but the results of people with CHF, HF in particular, is included in the study. The criteria used to diagnose CHF, were recorded on the data collection form. In addition, the mean age, duration of CHF, the presence of other comorbidities and complications at the time of admission, and management method (medication), if reported, were recorded in the data collection form.

Intervention details: Tele-care, including remote monitoring (tele-monitoring), tele-care services, use of reminder systems and decision support systems, long-distance learning, remote consultation (visit), use of warning systems.

Outcome measures

The effect of Tele care on controlling HF in patients leads to reducing costs, mortality, hospitalization, complications, and improving life

quality as well as returning to work and daily activities.

Dealing with missing data

In case of insufficient or missing data, the authors of the eligible articles were contacted at least twice, one week apart. If they were not contacted, the available data were analyzed. Then, the effects of missing data were reported in the results, and discussed by comparing the results with the results of the systematic reviews.

Assessment of risk of bias

RoB 2.0 tool was used to evaluate the articles, which is an updated tool of Risk-of-bias clinical trial in Cochrane [17]. RoB 2.0, a tool for risk-of-bias assessment Randomized Controlled Trials (RCTs), was first published in 2008, in the Cochrane intervention structured review reference book, and then, updated in 2011 [18].

Table 1: Search Strategy

Recent queries in PubMed		
Search	**Query**	**Items found**
#22	Search ("HOME HEALTH" AND TELE	19
#19	Search TELE MEDICINE	1775
#17	Search TELEHOME MONITORING	12
#15	Search HOME CARE	792684
#13	Search TELE HOME	368
#12	Search "Telemedicine"[Mesh]	26414
#9	Search tele medicine	1775
#7	Search telehealth	32764
#5	Search telemonitoring	1433
Recent queries in PubMed		
Search	**Query**	**Items found**
#2	(telemedicine [MeSH] OR telemedicine OR telehealth OR telecare OR telehomecare OR "tele-home care" OR "tele-homecare")	33,338
#3	#1 AND #2	2,105
#4	((telemedicine [MeSH] OR telemedicine OR telehealth OR telecare OR telehomecare OR "tele-home care" OR "tele-homecare") AND (("RCT") OR (trial*))	5630
Queries in SCOPUS		
Search	**Query**	**Items found**
#1	TITLE-ABS-KEY (“telemedicine") OR TITLE-ABS-KEY (“telehealth”) OR TITLE-ABS-KEY ("telecare") OR TITLE-ABS-KEY ("telehomecare") OR TITLE-ABS-KEY ("tele-home care") OR TITLE-ABS-KEY ("tele-homecare") AND ("clinical trials")	6,004
Queries in ISI		
Search	**Query**	**Items found**
#1	(TS= ("telemedicine") OR TS= ("telehealth") OR TS= ("telecare") OR TS= ("telehomecare") OR TS= ("tele-home care") OR TS= ("tele-homecare")) AND (TS=("RCT") OR TS=(trial*))	3712
Queries in DARE, NHS EED, HTA, Cochrane		
Search	**Query**	**Items found**
#1	Results for: ((telemedicine) OR (telehealth):TI OR (telecare):AU) and ((Systematic review:ZDT and Bibliographic:ZPS) OR (Systematic review:ZDT and Abstract:ZPS) OR (Cochrane review:ZDT) OR (Cochrane related review record:ZDT) OR (Economic evaluation:ZDT and Bibliographic:ZPS) OR (Economic evaluation:ZDT and Abstract:ZPS) OR Project record:ZDT OR Full publication record:ZDT) IN DARE, NHSEED, HTA	437

Based on the above search strategy, articles were extracted from databases and subjects related to remote care were evaluated and separated by four researchers in four sections of chronic heart failure, diabetes, COPD and old age through endnote software.

Data analysis

The mean changes in the quantitative outcomes of the study (such as odds ratio (OR) for complications) in the intervention and control groups were calculated to determine the difference as the effect size. In this study, a random effects model that considers the diversity between studies was applied. The Stata software version 12 was used to analyze the data. P-values less than 0.05 were considered significant.

Assessment of heterogeneity

Methods have been developed for quantifying inconsistency across studies that move the focus away from testing whether heterogeneity is present to assessing its impact on the meta-analysis. A useful statistic for quantifying inconsistency is:

$I2=((Q-\mathrm{df})/Q) \times 100\%$

In this equation, Q is the Chi2 statistic and df is its degrees of freedom. I2 describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance).

Thresholds for the interpretation of the I2 statistic can be misleading, since the importance of inconsistency depends on several factors. A rough guide to interpretation in the context of meta-analyses of randomized trials is as follows:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity*;
- 50% to 90%: may represent substantial heterogeneity*;
- 75% to 100%: considerable heterogeneity

The importance of the observed value of I2 depends on magnitude and direction of effects, and strength of evidence for heterogeneity (e.g., P value from the Chi2 test, or a confidence interval for I2: uncertainty in the value of I2 is substantial when the number of studies is small).

A low P value (or a large Chi2 statistic relative to its degree of freedom) provides evidence of heterogeneity of intervention effects (variation in effect estimates beyond chance). [19].

If high levels of heterogeneity exist among the trials (I2 >=50% or P <0.1), the study design and characteristics in the included studies would be analyzed to explain the source of heterogeneity by subgroup analysis or sensitivity analysis

Subgroup analysis and sensitivity analysis

Subgroup analysis was performed to evaluate whether the intervention(s), individuals' health status, and other trial characteristics explained the possible heterogeneity between studies. Additionally, sensitivity analysis was also be performed through excluding studies one by one from the meta-analysis.

Publication bias

In order to assess publication bias, the authors specified whether the RCT protocol was published before recruitment of patients. In the presence of a small sample bias, the random effects estimate of the intervention was more beneficial than the fixed effect estimate. Publication bias was assessed using Begg's funnel plots and Egger's and Begg's asymmetry tests.

Discussion

Today, heart disease is one of the most common chronic diseases and causes of death in adults worldwide. It is the common endpoint of all heart disorders [20]. HF is a chronic disease with a high prevalence. It is an expensive and debilitating disorder with a poor prognosis and high mortality [21]. CHF is a major cause of hospitalization for the elderly in developed countries [22]. CHF is a complex clinical syndrome that can result from a structural or functional heart or noncardiac disorder [23].

HF is a common disease that affects approximately 26 million patients worldwide [24]. In the United States, HF is the leading cause of hospitalization for people over the age of 65, and in 2010 alone, it cost $ 33 billion [25].

Furthermore, approximately 4.7 million people are diagnosed with HF (1.5 to 2% of the total population) and approximately 550,000 people are diagnosed with HF per year. In Europe, the prevalence is similar, namely at 4.0% to 2%. Little information is available on the prevalence of this disease in developing countries [22].

Challenges for HF patients include difficulty in changing lifestyles, nonobservance of complex medical regimens, financial constraints, lack of access to medical care, and adverse side effects. The cost of caring for these patients continues to rise. Despite advances in drug treatment with significant improvements in mortality, the 5-year survival of HF is still 61% [26]. The epidemiological significance, the burden of this health issue, and its high mortality highlight the need to improve management approaches [27].

The guidelines of the European Heart Association, the American Heart Association and the American Heart College recommend comprehensive management of patients with HF. These include appropriate medication and device therapy, cardiac rehabilitation (CR), Cardiovascular Implantable Electronic Devices (CIED) devices, and regular follow-up. Organizing outpatient care for patients can be ideal. It enables patients with HF to maintain the recovery they have achieved during hospitalization. For this reason, the new HF care model should focus on optimal outpatient care to reduce readmission and the prognosis of patients with HF. This leads to beneficial effects on patients' conditions and reducing the cost of health care [23].

Telemedicine has become one of the key areas of development and research in CHF management over the past decade [26]. Advances in modern telecommunications technologies have created new options for providing tele-care as a complementary method for medical management of HF patients [28]. Although the effect of telemedicine on CHF has been controversial, recently collected data suggested that an overall beneficial effect is greater in patients at higher risk of accidents [26].

Regarding the significant increase in health care costs in recent years, cost control has become increasingly important for health care planners and decision-makers. Also, interest in saving potential remote health costs has increased. Telehealth for the management of chronic diseases has been implemented in recent years to improve and maintain the health of patients with chronic diseases [29].

Telemedicine has made it possible to detect these types of diseases early. Providing timely intervention has prevented adverse consequences. Since this technology is based on the principle of "regular monitoring of physiological symptoms", any change in the clinical symptoms of heart patients can be a warning for the deterioration of one's condition. Therefore, remote medical technology is used to evaluate and monitor clinical symptoms. It can reduce the hospitalization rate and mortality of this group of patients [30].

Tele-care of patients with CHF is an emerging concept for detecting early warning signs of impending injury in order to prevent hospitalization [31]. The main goals of home health care for patients with HF are for the patient to be able to meet their self-care needs, detect early changes in symptoms, and reduce hospitalization [32]. Due to the emergence of various methods of tele-care in the world with the development of new technologies, we need to evaluate the use of the best method in terms of effectiveness, cost-effectiveness, safety and type of technology. Therefore, by evaluating studies that measure the impact of a variety of technologies available for tele-care in patients with CHF, we seek the best way to manage and treat CHF remotely.

This systematic review examines the effectiveness of distance care interventions in patients with CHF, compared to conventional care methods. In general, the evaluation of the

studies extracted in this systematic review aims to identify, evaluate and combine the effects of tele-care in patients with HF using meta-analytical methods as evidence. Evaluating studies conducted in the field of tele-care in patients with CHF can help to better understand how these methods work in the management of chronic heart disease [effectiveness, safety and cost reduction]. It also determines, according to clinical outcomes and resource use, which interventions for long-distance care are more effective in patients with HF, based on their characteristics.

This systematic review provides a more comprehensive overview of the management of CHF with tele-care interventions, by examining 5 out of the 9 aspects of HTA Core Model approach. We believe that the results will be essential for policy-making regarding the use of tele-care in CHF. This evidence can be useful for physicians, public health policy-makers, hospital managers, patients, and the general public.

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Authors' contribution

All authors contributed to the final version of the manuscript, equally.

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Conflict of Interest

Authors declared no conflict of interest.

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