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A systematic review of the mediating role of knowledge, self-efficacy and self-care behaviour in telehealth patients with heart failure

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### Summarv

We conducted a systematic review of controlled trials and pre-post studies to examine whether the putative benefits of telehealth, notably, improvements in clinical outcomes and quality of life, are mediated by increases in knowledge, self-efficacy and self-care behaviour in patients with heart failure. Telehealth was defined as any system of home-based self-monitoring of signs or symptoms of heart failure that transferred data for remote assessment by healthcare providers. Seven electronic databases were searched for studies that assessed any of six pathways in a proposed model. Data were independently extracted by two reviewers. Twelve studies met the inclusion criteria and provided evidence for or against one or more of the six pathways. Although all of the pathways in the model can be theoretically justified and three of the six relationships have been established in heart failure samples outside the context of telehealth, none of the pathways in the model were supported by the telehealth studies reviewed. Failure to replicate previously established relationships emphasizes the weakness of the telehealth literature, which impedes our ability to address questions such as how telehealth might achieve beneficial outcomes.

## Introduction

Patients with heart failure (HF) experience reduced health-related quality of life (HRQoL), an increased risk of depression and premature mortality. The high healthcare costs and poor quality of life associated with HF have prompted a search for more effective and more cost-effective disease management strategies. Telehealth (TH) has emerged as one promising approach. Some studies have suggested that TH has the potential to improve HRQoL and reduce hospital readmission and mortality rates for HF patients. The mechanisms by which TH achieves these apparent improvements are not well understood although two plausible pathways (increased monitoring by healthcare providers and improved self-care by patients) have been suggested. Increased surveillance by healthcare professionals offers opportunities for early intervention that may delay or preclude the need for more expensive treatment. Disease-specific educational messages, regular feedback to patients from peripheral monitoring devices, and more frequent interventions from healthcare providers responding to clinical readings may encourage improved patient self-care behaviour that can delay or reduce the likelihood of disease progression. The present review focuses on the evidence for the second putative pathway.

Increased use of self-care behaviours in HF have been found to improve symptoms, functional capacity, well-being, and prognosis and it has been suggested that up to 64% of HF hospital readmissions could be prevented by adherence to prescribed medication and diet plans. Unfortunately, up to 90% of HF patients do not fully adhere to their recommended regimen.

In the context of HF, lack of knowledge about disease-specific self-care behaviours is associated with non-adherence to recommended self-care practices. Other psychological constructs, which are themselves likely to be influenced by knowledge, may also influence self-care (e.g. risk perceptions; attitude towards the behaviour; intention to perform the behaviour; emotional responses to the potential health threat and the recommended

behavioural response; cognitive elaboration of action plans and coping plans) but few studies have examined these constructs in the context of TH for HF. Knowledge, however, is a theoretically plausible moderator and has been sufficiently studied in this context to be included in our model of self-care behaviour. Self-efficacy, defined as the confidence one has in performing a specific behaviour, is an important driver of sustained behavioural change. A substantial evidence base supports the general notion that self-efficacy influences the behavioural goals that people set for themselves (including health-related goals such as medication adherence or regular symptom monitoring), the effort with which these goals are pursued, and persistence in the face of barriers. More specifically weaker self-efficacy beliefs are associated with non-adherence to self-care recommendations for HF, while stronger self-efficacy beliefs are associated with greater adherence to medical regimens, dietary recommendations, exercise and practising stress reduction for patients with heart disease. Self-efficacy is both theoretically plausible and sufficiently studied in the context of TH and HF to merit inclusion in our model.

In the light of the theoretical and empirical work discussed, a model of self-care behaviour and two of its cognitive precursors (knowledge and self-efficacy) is proposed to describe potential pathways by which TH might lead to improved patient outcomes (Figure 1). The model is based on the assumption that the introduction of TH leads to changes in the frequency and type of interactions between patients and healthcare providers. Compared to conventional models of care that aim to manage HF in primary or secondary care, TH users are likely to experience more frequent but briefer interactions with providers that are focused on monitoring and maintaining optimum self-care.

TH is assumed to increase patients' knowledge of their disease and recommended self-care practices via educational components of TH (e.g. training, text messages, videos) and through increased follow-up interactions with healthcare providers (e.g. text messages, phone calls, videoconferencing) (shown as path a in Figure 1). In line with social cognitive theory TH may also support behaviour change by enhancing self-efficacy beliefs through modelling of good self-care practices, by providing opportunities for mastery experiences relating to self-care, by encouraging self-monitoring of self-care behaviour, and by providing regular feedback on markers of disease status

(e.g. bodyweight, blood pressure, heart rate) that can be associated with performance of self-care behaviours (path d). In turn, improved knowledge and stronger self-efficacy beliefs are expected to lead to more appropriate self-care practices (paths b and e). The direct path from TH to self-care (path c) posits no mediating construct(s) and is therefore theoretically implausible but was retained in the model for pragmatic reasons. Empirical evidence supporting path c would be useful in establishing a link between TH and beneficial changes in self-care even if potential mediating variables are not specified. Finally, improved self-care behaviour, whether achieved through improved knowledge (paths a þ b), stronger self-efficacy beliefs (paths d þ e) or some non-specified mechanism (path c), is expected to result in improved patient outcomes (path f).

The present systematic review uses the proposed model (Figure 1) to examine whether the introduction of TH leads to an increase in self-care behaviour or potential precursors of self-care behaviour (i.e. knowledge, self-efficacy) in HF patients. The objectives were:

- (1) to present a model of self-care behaviours in the context of TH for HF;
- (2) to provide a descriptive overview of quantitative studies reporting self-care behaviour or potential precursors of self-care behaviour in the context of TH for HF;
- (3) to evaluate the availability and quality of evidence for each a priori relationship specified in the model.

#### **Methods**

A search was performed on seven electronic databases (MEDLINE, EMBASE, CINAHL, Science Citation Index Expanded, Social Sciences Citation Index, Cochrane Controlled Trials Register, Database of Abstracts of Reviews of Effects) in August 2010 (see Table 1 available online only at http://www.itt.rsmjournals.com/cgi/content/full/jtt.

2012.111009/DC1). Quantitative studies were eligible if they a) examined the impact of a TH intervention on HF patients, b) reported primary data for community-dwelling HF patients independently of other clinical groups, c) reported measures of knowledge (of HF or related self-care), perceived self-efficacy or self-care behaviour, and d) reported appropriate comparison data from pre-post designs, controlled trials or randomized controlled trials (RCTs). The principal outcomes of interest were measures of association reflecting the relationships in Figure 1 or measures of difference reflecting the effect of TH in comparison to the pre-intervention period or to a control group. TH was defined as any system of home based self-monitoring of signs or symptoms of HF that transferred data for remote assessment by healthcare providers. Studies of patients with implantable devices and studies that did not require patients to actively monitor signs and symptoms were excluded. Non-English language articles were also excluded.

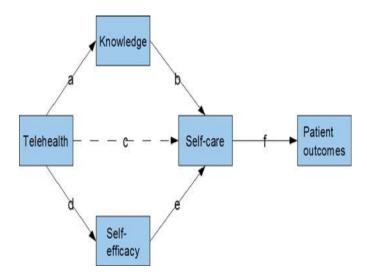


Figure1Proposed model of factors mediating the effects of telehealth. Path c posits that telehealth causes changes in self-care behaviour without any mediating variables. This relationship is implausible as there must be some intermediary mechanism (hence the dotted line), but the path was retained since we expected that some research would examine only this path

### Screening

Stage 1: the titles and abstracts of studies identified from the search (n ¼ 567) were independently reviewed by two researchers. Articles were excluded if they did not meet the review criteria (n ¼ 496). The inter-rater agreement (Cohen's kappa) for inclusion/exclusion of studies was very high at Stage 1 (kappa ¼ 0.82, P, 0.001).

Stage 2: the full text of the retained articles (n ¼ 71) were independently reviewed to identify studies that did meet the review criteria. Inter-rater agreement was high at Stage 2 (kappa ¼ 0.76, P, 0.001). At both Stages, disagreements about classification were resolved through discussion. Eleven papers were included from the database search. A backwards search of references and a forwards citation search identified one additional paper, giving a total of 12 papers (Figure 2).

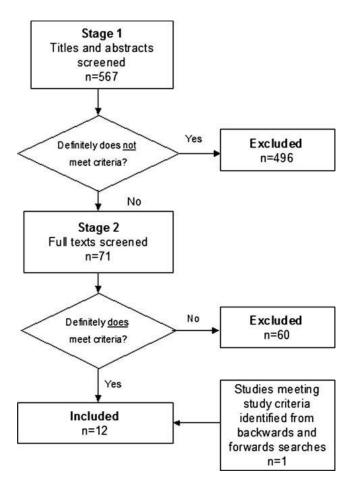


Figure2Study selection flow diagram

# Data extraction and quality assessment

Descriptive data were extracted by one reviewer using a standardised form and cross-checked by a second reviewer to ensure accuracy. Studies were independently quality assessed by the two reviewers using an adapted version of the Effective Public Health Practice Project's (EPHPP) Quality Assessment Tool for Quantitative Studies. <sup>24</sup> The adapted tool included a total of 26 items assessing seven of the EPHPP's eight domains plus three domains taken checklist, from Downs and Black's see Table 2 (available jtt.rsmjournals.com/cgi/confent/fill/jtt.2012.111009/DC1). The ratings from the ten domains were then used to generate a global rating (strong, moderate or weak) for each study. A procedure manual was produced beforehand to help reviewers interpret the individual quality assessment items, combine these into the domain ratings and combine the domain ratings into the global rating.

There were minor differences in ratings between reviewers at the item level but these were largely attributable to unclear or ambiguous descriptions of studies by authors. At the aggregated domain levels and at the global (study) level there was perfect agreement.

#### **Outcomes**

The outcomes of interest were measures of association directly or indirectly reflecting the six specific paths outlined above: TH and knowledge; knowledge and self-care; TH and self-efficacy; self-efficacy and self-care; TH and self-care; self-care and patient outcomes (i.e. quality of life or clinical markers of disease). Any measures of association were accepted, but most frequently they took the form of group differences (TH group vs. control group) or pre-post intervention differences on measures of knowledge, self-efficacy, self-care or patient outcomes.

### Presentation of findings

The heterogeneity of the studies made meta-analysis inappropriate, so the results were summarised as a narrative analysis of the evidence for each path in the model, supplemented by a descriptive vote count procedure which can, under certain circumstances, generate results that correlate closely with formal meta-analytic procedures.

#### Results

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# Study characteristics

The characteristics of the 12 studies are summarised in Table 3 (available online only at http://www.jtt.rsmjournals.com/cgi/content/full/jtt.2012.111009/DC1). The studies were published between 2003 and 2010 and -32,35,36 mostly conducted in the USA with one each in Canada, Italy and the Netherlands. Sample sizes ranged from 18 to 284 (median ¼ 74). Seven studies employed a controlled design comparing two groups (TH intervention vs. standard care). The remainder were RCTs comparing a control group with either two or three intervention groups, and one study employed a pre-post observational design.

#### **Patient characteristics**

All studies recruited community-dwelling adults with HF but three studies specifically focused on older HF patients and one examined HF patients who had received coronary artery bypass graft surgery. The mean age of participants ranged from 61–78 years and the proportion of males ranged from 37–99%, although gender was unreported in two studies. Seven studies reported baseline severity of HF; all used the NYHA functional classification. Overall participants were mostly classified as mild or moderately impaired, though some studies included HF patients with no impairment or severe impairment.

#### Intervention characteristics

The duration of the interventions ranged from 6 weeks to 12 months (median 3 months) and follow-up assessments took place between 2 and 12 months after the start of the trial. In five studies there was a break between the end of the intervention period and follow-up assessment for –29,35,36 some or all outcome measures. The technology used in the interventions to transfer clinical information included a home TH 27–30,32,34,35 system(four of which used the Health Buddy 27,30, 32,34 telephone, website videophone and a compliance monitoring device. In most studies patients were requested to use the equipment daily 4,5,27,28,30,32–35 although three studies did not specify the requested frequency of use. The intervention involved patient monitoring of signs and symptoms in all cases, and nine studies reported that education was part of –32,34,35 the intervention.

Six studies described the healthcare received by the comparison group as standard, usual or routine care. Three further studies stated that the comparison group received home nurse visits. The content of care received by comparison groups in these nine studies varied, but could include regular visits to outpatient clinics; hospital follow-up by nurse and cardiologist; counselling, training, education or information on disease-specific self-care behaviour; care as directed by their primary care provider; home visits from a nurse to assess vital signs and medication adherence. In the two remaining RCTs, the non-TH participants formed a control group, but no details were provided about any health care that they received during the study period.

# Table 4 Quality assessment of included studies

### **Quality assessment**

The overall quality of studies was poor (Table 4) with only a single study achieving a global rating of moderate. The most common weaknesses were in relation to reporting of statistical power and blinding of assessors. Approximately half the studies were also rated poor for reporting of potential selection bias, independence of data collection, attrition, intervention integrity and appropriateness of statistical analyses (e.g. controlling for relevant

covariates).

#### Bias

The small number and heterogeneous nature of the studies precluded formal assessment of publication bias (e.g. using a funnel plot). However, despite the generally ambiguous findings, nine of the 12 studies presented statements in their Abstracts suggesting that TH improves knowledge, self-efficacy or self-care. The contrast between the conclusions of the primary studies and the conclusions of the present review suggests that study authors have not sufficiently guarded against the influence of various forms of experimenter bias including confirmation bias (i.e. seeking or interpreting of evidence in line with existing beliefs, expectations or hypotheses) and outcome reporting bias (i.e. selective reporting of positive findings).

# Relationship between telehealth and knowledge

Two RCTs examined the effect of TH on knowledge of HF or knowledge of HF-related self-care behaviours. One study found that TH was associated with significantly higher HF knowledge scores at 3-months compared to a control group in two hospitals but there were no group differences in a third hospital. The other found non-significant differences in the proportion of correct answers to questions about medication in three groups (i.e. telephone, videophone, control) at 90-and 180-days.

Table 4 Quality assessment of included studies

Study ref <sup>‡</sup>	Author, year	Α	В	C	D	E	F	G	Н	1	J	K
4	Antonicelli, 2008	2	1	1	1	3	1	3	2	2	2	2
5	Artinian, 2003	3	1	1	3	3	1	1	2	1	2	3
27	Barnason, 2003	3	1	1	3	3	1	1	2	2	2	3
28	Benatar, 2003	1	1	1	3	3	3	3	2	2	2	3
29	Dansky 2008	2	1	1	3	1	1	3	3	3	2	3
30	Dansky, 2009	2	2	1	3	3	3	3	3	3	3	3
31	Jerant 2003	2	2	1	3	3	3	1	3	2	2	3
32	LaFramboise, 2003	2	1	1	3	3	1	2	2	2	2	3
33	Maric, 2010	3	2	2	3	n/a	3	1	2	1	2	3
34	Ramaekers, 2009	3	1	1	3	3	3	3	2	3	2	3
35	Seibert, 2008	3	2	1	3	3	1	1	3	3	2	3
36	Wakefield, 2009	3	3	1	3	3	3	2	3	3	2	3

A = Selection Bias; B = Study objective; C = Study design; D = Power; E = Blinding; F = Independent data collection; G = Attrition; H = Intervention integrity; I = Statistical analyses; J = Reporting of findings; K = Global rating (1 = high quality, 2 = moderate quality, 3 = poor quality) \*Numbers refer to the study number in the reference list.

## Relationship between knowledge and self-care behaviour

None of the studies examined the relationship between knowledge and self-care behaviour.

# Relationship between telehealth and self-care behaviour

4 27 30 33 Nine studies reported the effect of TH on (self-reported) self-care behaviour. presented evidence suggesting that TH improves self-care behaviour over timeframes from 4 weeks to 12 months. They assessed behaviours such as adherence to prescribed medication; fluid, alcohol or sodium restriction; daily weighing and adherence to exercise recommendations. At least four of these studies had substantial methodological limitations, such as failing to specify which care behaviours were assessed or how these were assessed, misclassifying physician behaviour as patient self-care behaviour, finding contradictory (i.e. non-significant) results on sub-scales of the measure used to assess self-care and failing to report significance tests for some or all findings. Three further studies failed to find any significant improvements in self-care behaviour for TH relative to alternative treatment or control groups. These studies tested various forms of TH (i.e. web-based exchange of clinical readings, nurse-led telephone-based TH, nurse-led video-based TH, a combined group of telephone and videophone TH 36 over timeframes of 60–180 days.

# Relationship between telehealth and self-efficacy

Six studies assessed the effect of TH on self-efficacy or confidence relating to the performance of self-care

behaviours. Three studies reported no change in self-efficacy over time for intervention or control groups , while three found improvements in self-efficacy across both intervention and control groups . Five of the six studies were RCTs and presented analyses of group differences in self-efficacy at follow-up. Of these, one found that TH improved self-efficacy relative to the control group , two found no group differences and two studies comparing multiple intervention arms found some group differences but no evidence of differences between standard

TH (i.e. store and forward monitoring of signs and symptoms) and the nominated control group <sup>29,32</sup> (see Table 5 for further details).

## Relationship between self-efficacy and self-care behaviour

Two RCTs examined the relationship between self-efficacy and self-care behaviours. One study examined associations between self-efficacy and seven self-care behaviours separately for a TH and a control group at 6 weeks and 3 months. Only two of 28 associations tested were significant but the direction of one of these associations (salt in eating) is unclear due to poor description of the measure and no associations were significant at the later 3-month assessment. A second study assessed the relationship between confidence to perform self-care behaviours and (self-reported) performance of nine self-care behaviours in a pooled sample drawn from the intervention and control groups. Associations involving five self-care behaviours were significant at 120 days but associations for the remaining four behaviours were not-significant.

## Relationship between self-care behaviour and clinical/HRQoL outcomes

None of the studies examined the relationship between self-care behaviour and HRQoL or clinical outcomes.

# Summary of the evidence

The evidence described above is summarised in Table 6. Individual studies were considered to have contributed confirmatory evidence if they reported findings that were statistically significant, internally consistent and in the direction hypothesised in our model. Non-confirmatory findings were either non-significant, internally ambiguous (i.e. different findings from within a single study provided conflicting evidence) or were not in the expected direction. None of the relationships in the proposed model were robustly supported by the evidence.

## **Discussion**

We reviewed evidence for a mediating role of knowledge, self-efficacy or self-care in the relationship between TH and patient outcomes such as HRQoL in the HF population. Twelve studies met our inclusion criteria. Overall evidence for pathways a, c and e was too ambiguous to draw clear conclusions, evidence relating to path d suggests that TH has no effect on self-efficacy in either direction, while no studies provided evidence for pathways b and f (Table 6). Taking into account the limited number of studies available, the poor methodological quality of those studies (Table 4) and the ambiguous or conflicting findings reported, we conclude that studies of TH for HF provide insufficient evidence to robustly support or disprove any of the hypothesised relationships in our proposed model (Figure 1).

Although the review does not provide clear answers to the research questions, there are useful lessons for future research. Outside the context of TH and HF, three of the six relationships specified in the model have received theoretical and empirical support. Research on beliefs about illness (e.g. cognitive representations of illness) demonstrates that subjective knowledge or understanding of symptoms and disease, in combination with an action plan, are directly associated with behavioural responses to illness including self-care. Self-efficacy is associated with a range of Study Outcomes.

#### Study ref # Outcomes

#### Path a: Telehealth improves knowledge

Tele health was associated with significantly greater increases in HF knowledge at 3-months compared to a control group in two hospitals (P < 0.001 and P = 0.040). No significant differences were found for a third hospital.

The proportion of patients correctly stating the purpose and side effects of their medications was 97% for the control group, compared to 69% for both the videophone (II) and telephone group (I2) at baseline (P < 0.01). At 90 and 180 days, the proportion of correct responses increased in the telephone group (96% and 88%) and the videophone group (94% and 88%) and were no longer significantly different from the control group (94% and 85%). Note: The magnitude of knowledge differences at baseline suggests a failure of the randomisation process and as these differences were not controlled in the follow-up a nalyses it is undear whether the apparent impact of the telephone and videophone interventions on knowledge was significant. Furthermore, as the proportion of correctly stated medications in the control group was already 97% at baseline, a ceiling effect could impair the ability to assess the impact of the control condition on knowledge of medications.

#### Path b: Knowledge improves self-care

n/a n/a

27

#### Path c: Telehealth improves self-care

Ninety-one percent (91%) of patients in the telehealth group reported compliance with prescribed treatment at 12-months, compared to 46% of patients in the control group (P < 0.03). Note: 'Compliance with prescribed treatment' was not further specified.

Significant improvements on a self-care behaviour scale were found at 3-months for both the intervention and control group (F(1, 16) = 6.81, P = 0.019). A non-significant time by group interaction effect suggested no significant impact of the telehealth intervention on self-care behaviour. Daily monitoring logs indicated no significant differences between groups for compliance with weight and BP monitoring.

Significant differences were found between the intervention and control group for the number of subjects reporting use of salt in cooking at 4 weeks (X<sup>2</sup> = 6.92, P < 0.01), exercise adherence (t = 3.09, P < 0.01) and stress reduction adherence (t = 3.77, P < 0.01) at 3 months post-operatively with the telehealth group showing improved outcomes. No significant differences were found for use of salt in eating, diet adherence, medication use and tobacco cessation.

Significant differences were found between the intervention and control group after 180 days for five of eight self-care items: increase in diuretic following an episode of shortness of breath (P < 0.05), increase in diuretic following an episode of arkle swelling (P < 0.001), increase in diuretic following an episode of sudden weight increase (P < 0.001), performance of daily weights (P < 0.001), and weight measurement on the actual day of questioning (P = NR). Note: the items regarding increase of diuretics refer to professional behaviour not patient behaviour.

No significant differences for medication adherence between a video-based Telecare group (11), telephone care group (12) and control group were noted at baseline and 60 days, suggesting no changes in medication adherence. Furthermore, no significant between group differences were found for any of 5 self-care indicators (weight, number of smokers, sodium intake, number of drinkers, exercise status) at both baseline and 60 days.

A significant increase in self-care maintenance behaviours was found from baseline to 6-months (P = 0.039). Self-care management behaviours did not increase significantly over time.

Receiving the telehealth intervention was significantly associated with increased compliance to fluid restrictions (P = 0.012), daily weighing (P < 0.001), physical exercising (P = 0.034) and alcohol restrictions (P = 0.040). No impact of the intervention was found on appointment keeping, taking prescribed medication, sodium restrictions and smoking cessation.</p>

Patients in the intervention group reported to weigh themselves 3.81 (SD = 3.69) times per week, versus 4.94 (SD = 2.31) times per week in the control group. Note: statistical significance of this difference was not reported.

There were no significant differences between the control and intervention (videophone (I1) and telephone (I2)) groups at baseline, 90 or 180 days for the number of patients that answered positively to the question: 'Are you taking your medications as prescribed'? (p-values not reported). Note: as the proportion of 'positive' answers were 97% (C) and 95% (I1 and I2) at baseline, a ceiling effect could impair the ability to assess the impact of the control condition on medication taking.

#### Path d: Telehealth improves self-efficacy

Using baseline self-efficacy scores as a covariate, there were significant differences in the adjusted mean self-efficacy scores between intervention and control groups, with intervention participants showing higher mean self-efficacy scores than controls (F(1,29), = 6.40, P < 0.02). There was no significant effect of time on self-efficacy scores.

Significant increases in self-efficacy were measured at 3 months in both the intervention and control group (P< 0.01) on a HF self-efficacy questionnaire.</p>
There were no significant differences found between the intervention and control group.

All groups (videomonitoring (I1), telemonitoring (I2) and standard home services (C)) reported improved confidence in performing self-care at 120 days (F = 8.90, P = 0.004). Also, significant differences in confidence were found between groups (F = 3.488, P = 0.035) at 120 days, although the telemonitoring condition did not differ significantly from the control group. Group differences are attributable to a greater increase in self-efficacy for the videomonitoring (synchronous) group relative to TH (asynchronous) group and the control group but the reported means suggest this represents regression to the mean rather than a true effect. There was no significant time by intervention interaction effect.

The 3 intervention groups and the control group showed significantly different patterns of change in self-efficacy from baseline to 2 months, as indicated by a significant group by time interaction, (P = 0.027). The telephonic case management (II) group showed significant decreases in self-efficacy (P < 0.05) compared to increased self-efficacy in the telehealth (I2), telehealth + home visits (I3) and home visits only (C) groups.

No significant change in confidence in performing self-care was measured from baseline to 6 months.

No significant differences were found between a videophone intervention (II), telephone intervention (I2) and usual care (C) for 'Self Efficacy to Manage Disease in General' and 'Self Efficacy to Manage Symptoms'. Furthermore, no significant changes were found from baseline to 90 or 180 days.

#### Path e: Self-efficacy improves self-care

Self-efficacy was significantly correlated (P < 0.05) with 'use of salt in eating' in the intervention group and 'stress reduction adherence' in the control group at 6-weeks. There were no other significant correlations, for either the intervention or control group, between self-efficacy and five other risk factor adherence variables (salt in cooking; exercise adherence, diet adherence, medication adherence and smoking cessation adherence) at 6 weeks, or between self-efficacy and any of the seven adherence variables at 3 months.

Confidence in performing self-care was a significant positive predictor of 'following a low salt diet' (P = 0.014), 'engaging in regular physical activity' (P < 0.001) and 'reducing salt in diet' (P < 0.001), taking an extra diuretic (P = 0.006) or 'calling a doctor or nurse' (P = 0.002) when symptomatic at 120 days. Confidence was not a significant predictor of 'weighing daily', 'maintaining desired weight', 'receiving an annual influenza vaccine' or 'reducing fluid intake'.

#### Path f: Self-care improves Quality of life/Clinical Outcomes

n/a n/a

Table 6 Summary of the evidence for each pathway

	Studies examining specific paths in the model <sup>‡</sup>												Confirmatory evidence <sup>†</sup>	Non-confirmatory	Balance of evidence
Hypothesised relationship		5	27	28	29	30	31	32	33	34	35	36	cvidence	cvidence	cvidence
Path a: Telehealth improves Knowledge										Х		Х	n/a	2 (249)34,36	Inconclusive
Path b: Knowledge improves Self-care													n/a	n/a	No evidence
Path c: Telehealth improves Self-care	X	Х	X			X	X		X	X	X	X	6 (341) <sup>4,27,30,33,34,35</sup>	3 (203) <sup>5,31,36</sup>	Inconclusive
Path d: Telehealth improves Self-efficacy			X	X	X			X	X			X		5 (567) <sup>28,29,32,33,36</sup>	Null hypothesis is supported
Path e: Self-efficacy improves Self-care			X		X								1 (93) <sup>29</sup>	1 (35) <sup>27</sup>	Inconclusive
Path f: Self-care improves QoL/ Clinical outcomes													n/a	n/a	No evidence

<sup>&</sup>lt;sup>†</sup>Number of studies (combined sample size);

prevention, protection and detection behaviours in healthy and disease-specific samples. These general relationships between knowledge, self-efficacy and self-care have been replicated in some HF samples where self-care behaviour is associated with improvements in HRQoL and clinical outcomes. These well established relationships are represented in Figure 1 by path b (knowledge is associated with self-care), path e (self-efficacy is associated with self-care) and path f (self-care is associated with HRQoL and clinical outcomes). Failure to replicate these relationships in the literature reviewed is attributable to poor methodological quality and a lack of guiding theoretical frameworks. The first criticism is borne out by our assessment of methodological quality where 11 studies were categorised as poor, and the remaining study as moderate, using a standardised quality assessment tool (Table 4). The methodological weaknesses included selection bias, inadequate statistical power, lack (of assessment) of intervention integrity and inadequate statistical analyses. Some of these apparent weaknesses may be artefacts of poor reporting, rather than poor design or implementation. Authors should adhere to reporting guidelines appropriate for their study design such as CONSORT for RCTs, TREND and STROBE for observational studies, and WIDER recommendations for the reporting of behavioural interventions.

The second criticism is supported by consideration of the contribution of theory to the reviewed studies. Studies were selected because they had assessed constructs such as knowledge, self-efficacy or self-care behaviour, which suggests that authors were using implicit models and hypothesising factors that might mediate the relationship between TH and key outcomes. However, reference to any guiding conceptual model in the design of the studies, clear justification for the specific constructs assessed and interpretation of findings within explicit theoretical frameworks was limited and in most cases absent. This observation is further borne out by Table 6 which shows the number of studies assessing each path in Figure 1. Certain combinations of paths, such as a-b-f, c-f or d-e-f, represent plausible mediated pathways that might account for the putative associations between TH and patient outcomes. Investigation of these combinations of paths suggests that researchers have employed logical theoretical models, even if these were not made explicit, yet only two of the 12 studies investigated any two logically adjacent paths (Table 6). Path c was the most frequently examined path, with nine studies investigating this relationship. This can also be taken as evidence of the lack of theoretical frameworks, since path c suggests that TH improves self-care behaviour without any mediating variables. That researchers choose to investigate this path over other more plausible causal pathways (a-b; d-e) supports our assertion that mechanisms of behavioural change in the context of TH are poorly theorised and rarely investigated. Failure to draw on explicit theoretical frameworks may explain why two of the three previously established relationships in our model (paths b and f) were not investigated in any of the studies currently reviewed.

Explicit reference to, or use of, theory in the broader TH literature is rare though not altogether absent. Theories that may be relevant to understanding responses of patients, carers, clinicians and organisations to the introduction of TH are abundant but use of theory to develop and evaluate behavioural interventions is less common. The present review provides an example of how theory can be used to guide research.

We employed extensive search strategies to identify the relevant literature but we may have missed some studies due to a lack of consensus on the terminology used to describe TH interventions. The exclusion of non-English language studies may have reduced the representativeness of our findings.

<sup>&</sup>lt;sup>‡</sup>Numbers refer to the study number in the reference list.

Use of TH for HF is increasing based on the belief that it can help reduce the growing burden of this disease. Widespread integration of TH into healthcare services will only be realised if the effectiveness and cost-effectiveness can be improved in carefully selected clinical groups. This requires better understanding of the causal pathways between TH and key outcomes. Our review has demonstrated that research on HF patients has failed to adequately examine cognitive and behavioural mediators that may account for the reported effects of TH.

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