

# Home telemonitoring or structured telephone support programmes after recent discharge in patients with heart failure: systematic review and economic evaluation

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## Scientific summary

Support programmes after recent discharge in patients with heart failure

Health Technology Assessment 2013; Vol. 17: No. 32  
DOI: 10.3310/hta17320

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# Scientific summary

## Background

Heart failure (HF) is a complex clinical syndrome. It is associated with significant morbidity, mortality and reduced quality of life (QoL) and as such exerts a substantial burden on health-care systems, mainly because of repeated and lengthy admissions to hospital. The highest risk period for rehospitalisation is in the first few weeks after discharge from hospital, with 20–30% of patients being readmitted within a month, rising to 50% at 6 months. Early remote monitoring (RM) of patients (as a component of a care package) using structured telephone support (STS) or telemonitoring (TM) may be one way to meet the growing needs of HF patients.

## Objectives

The aim was to determine the clinical effectiveness and cost-effectiveness of home TM or STS strategies compared with usual care for adult patients who have been recently discharged (within 28 days) from an acute care setting after a recent exacerbation of HF. Specifically, the objectives were to (1) update two existing systematic reviews (published between 2009 and 2010) of TM or STS programmes for patients with HF within the scope of the current review; (2) evaluate the effectiveness and cost-effectiveness of home TM and/or STS packages compared with usual post-discharge care; and (3) identify key areas for primary research.

## Methods

Fourteen electronic databases (including MEDLINE, EMBASE, PsycINFO and The Cochrane Library) and research registers were searched to January 2012. Searches were supplemented by hand searching of relevant articles (including citation searching) and contacting experts in the field. The systematic review included randomised controlled trials (RCTs) or observational cohort studies with a contemporaneous control group that met the following criteria: remote home TM (using patient-initiated external electronic devices or cardiovascular implanted monitoring devices, with transfer of physiological data from patient to health-care provider using telecommunications technology) or STS programmes (including regular telephone contact between patients and health-care providers and reporting of symptoms and/or physiological data) in adults ( $\geq 18$  years of age) with a HF diagnosis and discharged from acute care (within 28 days) to home. The methodological quality of each included study was assessed according to established criteria. Where sufficient data existed, a random-effects network meta-analysis (NMA) was conducted using Markov chain Monte Carlo (MCMC) simulation.

A Markov model was developed to evaluate the cost-effectiveness of RM packages compared with usual care for recently discharged HF patients. RM interventions included (1) STS delivered via human-to-machine interface (HM), (2) STS delivered via human-to-human contact (HH) and (3) TM during office hours compared with (4) usual care. TM with medical support provided 24 hours a day, 7 days a week (24/7) or using cardiovascular monitoring devices was not considered in the economic model because of the lack of data and/or unsuitability for the UK setting. Given the heterogeneity among usual care and RM intervention components, cost-effectiveness analyses were performed using several costing scenarios. RM intervention costs included costs of the RM devices, monitoring costs in the RM centre and medical care costs to deal with alerts. Bottom-up costing methods were used to estimate the costs of these scenarios, designed to reflect usual care and different configurations of RM systems available in the UK. Base-case

costs and higher- and lower-cost scenarios were developed for each RM strategy whereas base-case and higher-cost scenarios were developed for usual care.

The costs and quality-adjusted life-years (QALYs) accrued by each strategy were estimated using monthly probabilities of death and of hospitalisations (HF-related complications or other causes), dependent on the type of RM intervention. Cost-effectiveness was assessed using both an incremental cost-effectiveness analysis and a net benefit approach at the £20,000 per QALY threshold. Probabilistic sensitivity analysis (PSA) and expected value of perfect information (EVPI) analysis were performed to capture uncertainty in the model parameters. A 30-year time horizon was taken and the economic perspective of the model was the NHS in England and Wales.

## Results

The literature searches identified 3060 citations. Six RCTs met the inclusion criteria and were added to the 15 trials identified from the previous systematic reviews. No trials of cardiovascular implanted monitoring devices or observational studies met the inclusion criteria. The methodological quality of the 21 included studies varied widely and reporting was generally poor on random sequence generation, allocation concealment, blinding of outcome assessment, definition and confirmation of HF diagnosis, and intention-to-treat analysis. Twenty studies contributed to the network comparing different pairs or triplets of treatment for TM or STS programmes with usual care, although not all studies provided information on each outcome. One study was excluded from the NMA because there were no events in either intervention group. For adults who have recently been discharged from an acute care setting after a recent HF exacerbation, the NMA found that, compared with usual care, RM was beneficial in reducing all-cause mortality by 23%, 24% and 51% for STS HH [hazard ratio (HR) 0.77, 95% credible interval (CrI) 0.55 to 1.08], TM with medical support during office hours (HR 0.76, 95% CrI 0.49 to 1.18) and TM 24/7 (HR 0.49, 95% CrI 0.20 to 1.18) respectively; however, the results for TM 24/7 should be treated with caution because of the poor methodological quality of the only study in this network. No beneficial effect on mortality was observed with STS HM. TM with medical support during office hours or 24/7 was associated with 25% (HR 0.75, 95% CrI 0.49 to 1.10) or 19% (HR 0.81, 95% CrI 0.33 to 2.00) reduction in all-cause hospitalisations, respectively, whereas there was no major effect of STS HM (HR 1.06, 95% CrI 0.44 to 2.53) or STS HH (HR 0.97, 95% CrI 0.70 to 1.31). Although there were no major effects on HF-related hospitalisation for STS HM (HR 1.03, 95% CrI 0.66 to 1.54) and TM with medical support during office hours (HR 0.95, 95% CrI 0.70 to 1.34), STS HH (HR 0.77, 95% CrI 0.62 to 0.96) was associated with a 23% reduction. The posterior predictive distributions for the HRs estimated from the NMA as predictive intervals (PrIs) also provided similar results as CrIs, albeit with more uncertainty. Whilst data were limited, care packages that included STS and TM generally improved QoL and were acceptable to HF patients.

A sensitivity analysis that excluded data from the Home Heart Failure Study (Home-HF) (as it provided better-than-usual support and optimal medical treatment to patients in the control group and appeared to be inconsistent with the data from the remaining studies, i.e. an outlier) found that TM with medical support during office hours was more effective than STS HH for all-cause mortality (HR 0.62, 95% CrI 0.42 to 0.89 and HR 0.75, 95% CrI 0.59 to 0.96 respectively) and all-cause hospitalisation (HR 0.67, 95% CrI 0.42 to 0.97 and HR 0.96, 95% CrI 0.72 to 1.27 respectively) but not HF-related hospitalisation (HR 0.86, 95% CrI 0.61 to 1.21 and HR 0.76, 95% CrI 0.61 to 0.94 respectively). By excluding this study from the NMA, larger reductions in effects were observed for all-cause mortality, all-cause hospitalisation and HF-related hospitalisation for TM during office hours.

In the cost-effectiveness analyses, base-case monthly costs per patient were estimated using bottom-up costing methods: £27 for usual care, £119 for STS HM, £179 for STS HH and £175 for TM during office hours. Five cost scenarios were also developed to calculate lower and higher estimates of costs of STS HH (£175 and £192 per month respectively) and TM during office hours (£133.50 and £215 per month respectively) along with a higher estimate of usual care costs (£92 per month).

The full incremental cost-effectiveness analysis using the base-case costs found that TM during office hours was likely to be the most cost-effective strategy at a £20,000 per QALY threshold. TM during office hours had an estimated incremental cost-effectiveness ratio (ICER) of £11,873 per QALY compared with usual care, whereas STS HH had an ICER of £228,035 per QALY compared with TM during office hours. STS HM was dominated by usual care. PSA showed substantial uncertainty in the most probable cost-effective strategy. TM during office hours was the most cost-effective strategy in 40% of the PSA runs whereas STS HH was most cost-effective in 35% of the PSA runs. STS HM and usual care were the most cost-effective in 19% and 6% of the runs respectively. Cost-effectiveness analysis performed using the HRs from the NMA that excluded the data from the Home-HF trial showed an improvement in the cost-effectiveness of TM during office hours. STS HM and STS HH were dominated and extendedly dominated, respectively, with the ICER of TM during office hours against usual care estimated as £6942 per QALY. The results from the uncertainty analyses suggest that TM during office hours was cost-effective in 73% of the runs, whereas STS HH and STS HM were cost-effective in 19% and 7% of the runs respectively.

Scenario analysis using higher costs of TM during office hours (£215 per month) increased uncertainty. TM during office hours and STS HH were both cost-effective in 37% of PSA runs, but TM during office hours was dominated by STS HH. The same scenario analysis (i.e. higher cost of TM during office hours of £215 per month) performed using the HRs from the NMA that excluded the data from the Home-HF trial suggested that TM during office hours would still be the most cost-effective strategy with an ICER of £8223 per QALY compared with usual care (STS HH is extendedly dominated by a combination of usual care and TM during office hours). Threshold analysis performed excluding the data from the Home-HF trial suggested that the monthly cost of TM during office hours has to be >£390 to have an ICER >£20,000 per QALY compared with STS HH. The ICER of TM during office hours compared with usual care, at a monthly cost of £390, is £13,357 per QALY. Scenario analyses performed using higher costs of usual care, higher costs of STS HH and lower costs of TM during office hours do not substantially change the conclusions. TM during office hours was estimated to be the most cost-effective strategy in all of these scenarios.

## Discussion

Although an extensive literature search was conducted, it is possible that some relevant studies may have been missed. However, such omissions are likely to have been minimal as the search included all identifiable publications in the grey literature (including contact with clinical experts in the field).

Data were analysed exactly by assuming a binomial likelihood function for the sample data. The statistical model acknowledged the fact that events accumulate over time by adjusting for the varying durations of each study using a complementary log-log link function. Parameter estimates, including between-study standard deviation, were estimated using MCMC simulation, which allows for uncertainty in estimates of between-study standard deviation; it also allowed estimation of the predictive distribution of the effect of each intervention in a new study.

The clinical effectiveness findings had several limitations. RM interventions were heterogeneous in terms of monitored parameters and HF selection criteria. Some trials were underpowered to detect the primary clinical outcome and did not report outcome assessor blinding. Furthermore, few trials reported results in such a way as to enable an assessment of intervention effect modifiers (i.e. meta-regression). Consequently, uncertainties remain around determinants of patient responsiveness, suitability of different systems and 'active ingredients' of RM interventions. A limitation of the statistical model (because of having only one observation from each study) was that hazards and relative intervention effects were assumed to be constant over time; nevertheless, this is better than assuming that duration of study has no impact on the data. Similarly, in the cost-effectiveness model, these constant effectiveness parameters were applied to the time-dependent baseline mortality hazard (which is greatest in the early period after discharge and subsequently declines over time) and constant risk of hospitalisation. If the studies reported

observations at different time points, time-dependent effectiveness parameters can be estimated and used in the cost-effectiveness model. Furthermore, optimal duration for each of the RM interventions can also be identified.

None of the reviewed studies provided estimates for patient utility and whether or not there was a difference between the RM and usual care groups; thus, in the economic model, similar utility values were used for HF patients undergoing both RM strategies and usual care. However, the validity of this assumption is unclear. Furthermore, the lack of detail provided in research studies concerning the components of RM packages and usual care (e.g. communication protocols, routine staff visits and resources used) made it difficult to estimate costs. Costing scenarios for different RM classifications were developed and costs were estimated using microcosting methods. Although users can decide which of these analyses is most representative of their setting, uncertainties remain about the assumptions made in the costing estimation. This uncertainty in costing was a limitation, especially given the small difference in QALYs between STS HH and TM during office hours. Hence, a small change in the difference between costs of TM during office hours and STS HH can lead to a marked change in the ICER. A further limitation was that the effectiveness remained the same for the different cost scenarios whereas in reality there might be some correlation between the costs and effectiveness of different RM strategies.

Hazard ratios of mortality and hospitalisation were the key drivers in the cost-effectiveness model, as mortality reductions lead to a gain in QALYs whereas reductions in hospitalisations lead to fewer costs and more QALYs. The intervention costs were only a small part of the overall costs (hospitalisation costs being the main contributor); thus, RM is likely to be cost-effective if it can save lives and reduce hospitalisations to a sufficient extent. However, some uncertainty persisted in the effectiveness parameters as suggested in the EVPI analysis.

## Conclusions

In general, although the effectiveness of the interventions varied widely according to the type of RM system used, STS HH and TM with medical support provided during office hours showed beneficial effects, particularly in reducing all-cause mortality for recently discharged patients with HF; however, these results were statistically inconclusive.

Given the variation in usual care and RM strategies, the cost-effectiveness analysis was performed using a set of costing scenarios. These scenarios were designed to reflect the different configurations of usual care and RM interventions present in the UK. The cost-effectiveness analyses suggest that TM during office hours was an optimal strategy in most scenarios.

Research recommendations include:

1. new research should seek to examine the 'active ingredients' of RM
2. qualitative research on patient experiences of RM may be useful to understand the processes by which RM works
3. RM studies should publish data in such a way as to identify which patient subgroups benefited most from the intervention
4. RM studies should include clear descriptions of the interventions and usual care to enable robust costing estimations
5. RM studies should report health outcomes at specific time intervals to identify temporal trends in effectiveness
6. future studies should provide greater detail on reconfiguration costs and link more clearly with the financial impact (e.g. cost variation with scale and over time) on provider organisations.

## Study registration

This study is registered as PROSPERO registration no. CRD42011001368.

## Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

## Publication

Pandor A, Thokala P, Gomersall T, Baalbaki H, Stevens JW, Wang J, *et al*. Home telemonitoring or structured telephone support programmes after recent discharge in patients with heart failure: systematic review and economic evaluation. *Health Technol Assess* 2013;**17**(32).

# Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Five-year impact factor: 5.804

*Health Technology Assessment* is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

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## This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/107/01. The contractual start date was in July 2010. The draft report began editorial review in May 2012 and was accepted for publication in August 2012. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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