An evidence-based approach to the use of telehealth in long-term health conditions: development of an intervention and evaluation through pragmatic randomised controlled trials in patients with depression or raised cardiovascular risk

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Declared competing interests of authors: Chris Salisbury is a member of the National Institute for Health Research (NIHR) Health Services and Delivery Research Board and the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) West. He also had an honorary consultant contract with NHS Direct, the NHS trust that hosted this research, in order for him to act as principal investigator. Glyn Lewis is a member of the NIHR Efficacy and Mechanism Evaluation Board and Jon Nicholl is a member of the NIHR Clinical Trials Unit Standing Advisory Committee. Catherine Pope is a member of the NIHR CLAHRC Wessex, which is a partnership between Wessex NHS organisations and partners and the University of Southampton and is part of the NIHR.

Published January 2017
DOI: 10.3310/pgfar05010

Scientific summary

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Programme Grants for Applied Research 2017; Vol. 5: No. 1
DOI: 10.3310/pgfar05010

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

There is international interest in the potential of telehealth to support the management of patients with long-term conditions (LTCs). 'Telehealth' includes technologies to support health care at a distance, such as messaging, telephone support, the internet and remote monitoring.

The rising number of elderly people in the population, many with LTCs, means that new approaches are needed to better support people to manage their own health in order for health services to be sustainable in the face of rising demand and constrained resources.

Aim

The aim of this research was to develop, implement and evaluate new programmes of care for patients with LTCs based on telehealth and to provide evidence about the benefits and costs. Intended benefits were improved health outcomes, self-management, patient experience and cost-effectiveness of care provision.

The programme focused on two exemplar conditions: depression and high cardiovascular disease (CVD) risk. These are very common but different types of conditions. If new services based on a common approach proved effective, this would justify developing similar services for other LTCs.

Objectives, methods and results

Overview of the programme

This 5-year research programme consisted of five linked studies. The first three studies, conducted in parallel, used different research methods to understand which types of telehealth interventions for LTCs were most likely to be effective, for which patients and in what ways. We used this information to develop a conceptual model for the design and evaluation of a telehealth intervention – the Healthlines Service. The final phase of research consisted of two linked randomised controlled trials (RCTs), with nested process and economic evaluations, comparing the Healthlines Service in addition to usual care with usual care alone in the two exemplar conditions.

These five studies are summarised in the following sections in relation to their objectives.

Objective 1: to review evidence about telehealth interventions designed to improve health care for patients with long-term conditions in order to develop a theory about which types of interventions are most likely to be effective

We conducted a mixed-methods evidence synthesis consisting of six studies: (1) a meta-review of systematic reviews of home-based telehealth for LTCs; (2) a review of systematic reviews of telehealth for depression; (3) a synthesis of qualitative research on telehealth; (4) a realist synthesis based on the above three studies; (5) horizon scanning to ensure inclusion of up-to-date evidence; and (6) a systematic review of trials of effectiveness of telehealth interventions to reduce overall CVD risk.

Despite a large volume of literature on telehealth for LTCs, much research was of low quality. There was evidence that telehealth interventions sometimes effectively improved a range of outcomes, although effect sizes were generally small. It was difficult to reach clear conclusions about which types of telehealth

were most likely to be effective for different conditions or patient groups because the evidence was inconsistent. Furthermore, few studies assessed cost-effectiveness. Some telehealth interventions for depression and anxiety had moderate/large effect sizes [particularly computerised cognitive–behavioural therapy (CBT)]. Some studies suggested that effectiveness was enhanced with the inclusion of moderator support for internet-based interventions. The systematic review of telehealth interventions for CVD risk found no evidence of overall risk reduction. Studies demonstrated a small reduction in systolic blood pressure and weak evidence of a reduction in total cholesterol, but no evidence of a reduction in smoking. The review of qualitative literature suggested that patients appreciated telehealth because of perceptions of increased access to health care, but professionals were less positive. The realist synthesis proposed three mechanisms of action for effective telehealth for LTCs: relationships between health professionals and patients; fit with patients' needs and capabilities; and visibility through feedback. The evidence synthesis concluded that telehealth for LTCs is acceptable and could be effective, but rigorous evaluation, including of cost-effectiveness, is needed.

Objective 2: to explore patient and health-care access factors associated with unmet need and willingness to use telehealth services, specifically types of telehealth interventions most likely to be acceptable to different patient groups

We undertook a survey of patients with depression or raised CVD risk to explore key factors that influence interest in using telehealth. Randomly selected patients from 34 general practices were sent a postal questionnaire assessing sociodemographic characteristics, health needs, difficulties accessing health care, technology-related factors (availability, technology confidence, benefits/drawbacks of telehealth) and prior telehealth satisfaction. Multivariable regressions tested the relationships between these constructs and interest in telehealth via telephone, e-mail/internet or social media.

Of the 3329 patients who were sent a questionnaire, 44% completed it (depression: 606/1589, 38%; CVD risk: 872/1740, 50%). We found moderate interest in telephone-based and internet-based telehealth but little interest in social media-based telehealth. In regression analysis these findings were largely unaffected by patients' sociodemographic characteristics, health needs or difficulties accessing health care. The most important constructs related to interest in telehealth were confidence using technology and perceiving greater advantages and fewer disadvantages from telehealth.

Objective 3: using qualitative methods, to critically examine how telehealth resources could best be incorporated into the management of patients with long-term conditions and integrated with current primary care

We explored the views of patients and practitioners through semistructured interviews and focus groups with patients ($n = 38$), nurse care managers working for a telephone-based telehealth programme delivered partly by NHS Direct ($n = 16$) and practice staff in practices that did ($n = 11$) or did not ($n = 12$) refer into the telehealth programme. Observation was also undertaken at a telehealth call centre. Data were analysed thematically.

Patients were positive about telephone- and internet-based care for mental health problems, but less clear about advantages for CVD risk management. General practitioners (GPs) and practice nurses were ambivalent and sometimes sceptical about telehealth. Telehealth nurse managers characterised their roles in terms of traditional nursing ideals of developing caring relationships with patients, which patients also appreciated.

Introducing telehealth interventions involves adapting professional roles and developing new ways of working. Considering professionals' and patients' understanding of complex, multifaceted roles and modes of delivery is likely to facilitate telehealth service integration. The importance of relationships highlighted by patients and staff implied a necessity to ensure a personal rather than a 'call centre' approach.

Objective 4: to develop and optimise telehealth interventions that are likely to be acceptable, effective and efficient

Building on the evidence described above, we developed a theoretical framework for the development and evaluation of a telehealth intervention for patients with LTCs, the TElehealth in CHronic disease (TECH) model. This proposes that effective telehealth interventions are most likely to be effective and acceptable if they address four components: (1) engagement of patients and health professionals; (2) effective chronic disease management (including self-management, optimisation of treatment and care co-ordination); (3) partnership between providers; and (4) patient and health system context. The model proposes that the key intended benefits (and therefore outcomes for evaluation) of telehealth are improvements in health, access to care, patient experience and cost-effective care.

We used the TECH model to design telehealth interventions for two exemplar conditions: depression and raised CVD risk. The intervention (the Healthlines Service) was based on regular telephone calls over a 12-month period from a named health information advisor (HIA), who used motivational interviewing skills to encourage behaviour change and improved self-management. Participants were encouraged to identify goals and were offered links to information about quality-assessed resources on the internet. For participants with depression this included an interactive computerised CBT programme and for participants with hypertension and raised CVD risk it included blood pressure self-monitoring with automated feedback via a web portal. Participants' use of medication was reviewed by the HIAs using algorithms and, when they were not being treated in accordance with national guidelines, a treatment recommendation was e-mailed to their GP (including recent readings from monitoring of blood pressure, cholesterol or mental health, as appropriate, and a summary of the relevant guidelines) and copied to participants. Problems with medication adherence were addressed. The intervention was designed to work in tandem with general practice.

Objective 5: to determine the clinical effectiveness and cost-effectiveness of long-term condition management programmes based on telehealth in the two exemplar conditions

The Healthlines Service was tested in two pragmatic RCTs with nested process and economic evaluations. The trials were conducted among patients recruited from general practices ($n = 43$ for depression; $n = 42$ for CVD risk) in three areas of England. Patients were individually randomly allocated to receive the Healthlines Service plus usual care or usual care alone.

Depression

Eligible patients had a confirmed diagnosis of depression and a Patient Health Questionnaire-9 items (PHQ-9) score of ≥ 10. The primary outcome was the proportion of patients responding to treatment (defined as a PHQ-9 score reduction of ≥ 5 points and a PHQ-9 score of < 10) 4 months after randomisation, with continued follow-up for 12 months. Secondary outcomes included anxiety [Generalised Anxiety Disorder-7 items (GAD-7)], quality of life [EuroQol-5 Dimensions five-level version (EQ-5D-5L)], self-management skills and patient-reported access to and satisfaction with health care.

In total, 609 patients were recruited (intervention, $n = 307$; usual care, $n = 302$). Eighty-six per cent (525/609) of participants provided primary outcome data. Response to treatment at 4 months was higher in the intervention arm (27%, 68/255) than in the usual care arm (19%, 50/270) [odds ratio (OR) 1.7, 95% confidence interval (CI) 1.1 to 2.5; $p = 0.02$]. This difference was attenuated over the 12-month follow-up period. Improvements in anxiety associated with the intervention were sustained across all time points. Participants receiving the Healthlines Service depression intervention reported better access to support and advice, greater satisfaction with the support that they received and improvements in self-management and health literacy, although the effects were generally small. There was no evidence of optimised medication, nor were intervention participants more likely to report that their care was well co-ordinated. There was a high rate of patient dropout from the intervention, with participants receiving a median of five out of a possible 10 encounters. The intervention was more likely to be effective in those who received more encounters.

Cardiovascular disease risk

In the CVD risk trial, eligible patients were aged 40–74 years and had a 10-year risk of a CVD event of ≥ 20%, calculated using QRISK®2, and one or more modifiable risk factors (blood pressure ≥ 140 mmHg, body mass index ≥ 30 kg/m^2, smoking). The primary outcome was maintenance of or reduction in QRISK2 score after 12 months (as QRISK2 normally increases with age). Secondary outcomes were as for the depression trial, excluding anxiety, but also including individual CVD risk factors.

In total, 641 patients were recruited and randomised (intervention, $n = 325$; usual care, $n = 316$). Ninety-one per cent (586/641) of participants provided primary outcome data. More participants in the intervention group (50%, 148/295) than in the usual care group (43%, 124/291) maintained or reduced their QRISK2 score at 12 months, although this does not exclude a null effect (OR 1.3, 95% CI 1.0 to 1.9; $p = 0.08$). The intervention was associated with small improvements in body mass index (–0.4 kg/m^2, 95% CI –0.6 to –0.1 kg/m^2), systolic blood pressure (–2.7 mmHg, 95% CI –4.7 to –0.6 mmHg) and diastolic blood pressure (–2.8 mmHg, 95% CI –4.0 to –1.6 mmHg) but not smoking status (OR 0.4, 95% CI 0.2 to 1.0).

Participants in the intervention arm were slightly more likely to be adherent to their blood pressure medication, improve their diet and undertake more physical activity. There was no evidence that GPs of participants in the intervention arm more actively escalated drug treatment for either hypertension or raised cholesterol. Intervention participants reported better access to health care and better support and advice and were more satisfied with the treatment that they received than those in the usual care arm, but there was little evidence that they improved self-management. However, intervention participants were more likely to have discussed a care plan and to have a positive experience of the organisation and co-ordination of care than those in the usual care arm.

Cost-effectiveness

An economic evaluation estimated the cost–consequences and cost-effectiveness of the Healthlines Service interventions plus usual care compared with usual care alone based on cost and quality of life data from each trial. A cohort simulation model was developed for the CVD risk trial to estimate the long-term impact of the intervention.

The intervention was not likely to be cost-effective in the depression trial because of a very small mean quality-adjusted life-year (QALY) difference of 0.001 between arms in favour of the intervention, associated with an incremental cost of £192. In the CVD risk trial, the intervention was probably cost-effective in both the short term and the long term. A larger within-trial between-arms QALY difference (0.0132) was observed in this trial than in the depression trial and the incremental cost associated with the intervention was lower (£138).

Process evaluation

The process evaluation was based on interviews with eight NHS Direct staff members involved in developing and delivering the intervention, 13 health professionals in primary care whose patients used the intervention and 24 Healthlines Service intervention participants. Analysis of these interviews provided support for all components of the TECH model and showed that the Healthlines Service was largely delivered as planned, apart from problems delivering continuity of care from a HIA in the first few months, which may have detrimentally affected patient engagement. In the depression trial, some participants did not feel that the CBT approach was appropriate for their needs. In the CVD risk trial, some participants were more motivated by a desire to support research than by a wish to change their behaviour, reducing the potential for the intervention to deliver behaviour change.

Conclusion

A comprehensive telehealth service for patients with LTCs (the Healthlines Service) was developed based on an evidence-based conceptual model and evaluated through two RCTs. The Healthlines Service was associated with modest health benefits and small improvements in some aspects of self-management behaviours, access to health care, perceptions of support and patient satisfaction. These small benefits were associated with increased costs and so the Healthlines Service was unlikely to be cost-effective for depression but was likely to be cost-effective for CVD risk, especially in the long term. This programme was designed to explore the potential of telehealth to support the management of common LTCs. These conditions affect very large numbers of people and so even small improvements in health at an individual level can have important benefits at a population level.

These findings of small benefits and increased costs are consistent with previous pragmatic studies on the implementation of comprehensive telehealth programmes. Caution is needed before assuming that telehealth will have a transformative effect on making health care sustainable in the face of the rising prevalence of LTCs. However, telehealth encompasses many different technologies and the field is evolving. The TECH model provides a framework to focus development, as well as help our understanding of which approaches to telehealth work best, for whom and how. An evolutionary approach based on stepwise implementation of specific technologies, accompanied by careful independent evaluation, may be more appropriate than the ambitious comprehensive approach developed and evaluated in the Healthlines study.

Trial registration

This study is registered as ISRCTN14172341 (depression trial) and ISRCTN27508731 (CVD risk trial).

Funding

Funding for this study was provided by the Programme Grants for Applied Research programme of the National Institute for Health Research.

Programme Grants for Applied Research

ISSN 2050-4322 (Print)

ISSN 2050-4330 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-0108-10011. The contractual start date was in November 2009. The final report began editorial review in June 2015 and was accepted for publication in March 2016. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, NETSCC, PGfAR or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PGfAR programme or the Department of Health.

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