Digital interventions for hypertension and asthma to support patient self-management in primary care: the DIPSS research programme including two RCTs

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Scientific summary

DIPSS research programme including two RCTs

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Scientific summary

Background

Digital interventions (DIs) can promote patient self-management of long-term conditions, but evidence for how best to optimise their clinical effectiveness and cost-effectiveness remains inconclusive.

Objectives

This research programme sought to determine the most feasible, acceptable, clinically effective and cost-effective methods of integrating DIs into primary care to support patient self-management of long-term conditions. Two long-term conditions (i.e. hypertension and asthma) with different self-management approaches were selected as the focus of this research. Our specific objectives were as follows:

- To identify key features associated with maximising feasibility, acceptability (to patients and health professionals), clinical effectiveness and cost-effectiveness of DIs.
- To examine the range of delivery and support modes that can be used for DIs and assess their relative feasibility, acceptability (to health professionals and patients), clinical effectiveness and cost-effectiveness.
- To optimise interventions for hypertension and asthma and to carry out feasibility studies in preparation for full randomised controlled trials (RCTs).
- To undertake a RCT of a DI for hypertension to determine the clinical effectiveness and cost-effectiveness of integrating it into routine care.

Hypertension

Intervention planning and development

Objectives

- To review qualitative and quantitative evidence relating to self-management DIs in the context of hypertension.
- To identify behavioural barriers and facilitators from the evidence.
- To optimise a prototype DI using in-depth qualitative research with patients and health-care professionals (HCPs).
- To map intervention components to behaviour change theory.

Methods

The Intervention Development Team included patient and public involvement (PPI) contributors, clinicians, behaviour change experts and representatives of the charity Blood Pressure UK (London, UK).

The planning and development of the hypertension intervention provided one of the first examples of the widely used person-based approach, which emphasises understanding and addressing the population's needs and beliefs about the target behaviours, as well as drawing on evidence and theory.

A systematic review and meta-analysis of quantitative research on the effectiveness of DIs for hypertension was conducted to evaluate mean change in systolic and diastolic blood pressure (BP). A meta-ethnography of qualitative studies explored patients' and HCPs' experiences of using DIs for

self-management of long-term conditions. Facilitators of and barriers to each target behaviour were extracted from the evidence and tabulated. Intervention components were identified to promote facilitators and to overcome barriers. Intervention planning informed the development of a web-based intervention, incorporating patient training, an entry system for home BP readings and a HCP training module.

Think-aloud interviews with 12 hypertensive patients and focus groups with 55 HCPs explored perceptions of the prototype intervention. Eleven patients were interviewed after using the intervention to explore barriers in a real-life setting. Iterative analysis of the transcripts identified beliefs that could interfere with the target behaviours. Guiding principles were developed, which described the key behavioural challenges for this population and outlined key design features of the intervention to address these.

The intervention components were mapped on to the behaviour change wheel, and on to implementation mechanisms from normalisation process theory. A logic model was developed to propose how the intervention was theorised to change behaviour.

Results

The meta-analysis of eight studies found a weighted mean difference of −3.74 mmHg in systolic BP for patients using interactive DIs for hypertension. There were too few studies to understand why some interventions were more clinically effective than others. The meta-ethnography synthesised 30 qualitative studies and suggested that self-monitoring was a powerful mechanism for changing behaviour, but feedback messages needed to emphasise patients' responsibility to act rather than increase HCP burden. Behavioural analysis identified four target patient behaviours (i.e. engaging with the online intervention, self-monitoring BP, adhering to medication changes and healthy behaviour change) and three target HCP behaviours (i.e. engaging with the online intervention, changing medication when recommended and providing behavioural support to patients).

Qualitative research identified modifications to the intervention (e.g. a practice week to increase patients' and HCPs' confidence in home BP readings) to address barriers. Mapping the intervention components to theoretical constructs provided a description of the intervention. The logic model showed that the intervention components were theorised to increase self-efficacy and outcome expectancies in line with social cognitive theory.

Intervention evaluation

Objectives

- To conduct a RCT to assess clinical effectiveness and cost-effectiveness of the hypertension DI.
- To conduct process evaluation studies to explore patients' and HCPs' adherence to target behaviours and experiences of the hypertension DI.

Methods

Randomised controlled trial

An internal pilot trial was conducted, which ran directly into the main RCT, as no changes were required. Patients with uncontrolled hypertension (> 140/90 mmHg) and taking one, two or three antihypertensive medications were randomised ($n = 622$) from 76 general practices across Wessex and Thames Valley regions in Southern England. Patients in the intervention group completed two online motivational training sessions, took 7 days of BP readings once a month and entered these online. HCPs received e-mail prompts for when planned medication changes were needed, according to an algorithm based on national BP targets. Optional healthy behaviour change support was available via the DI. The primary outcome was difference in systolic BP at 12 months between the groups, controlling for baseline factors and using multiple imputation for missing values. Patients in the control group were provided with a Blood Pressure UK (London, UK) leaflet for hypertension and received

routine hypertension care. For the economic analysis, patients' medical records were reviewed to record changes in antihypertensive drug prescriptions and health-care appointments during the trial.

General linear modelling compared systolic BP between groups at 12 months, adjusting for baseline BP, practice, BP targets and sex.

Process analysis

Usage data were recorded automatically by the DI, and self-report questionnaires were completed by patients and HCPs. Semistructured telephone interviews were conducted with 28 intervention group patients, 7 usual-care patients and 27 HCPs. Thematic analysis explored how patients appraised the benefits or burdens of the DI, and regression analyses identified factors predicting patient engagement. A mixed-methods approach triangulated the HCP qualitative and quantitative findings.

Results

At 12 months, systolic BP was significantly lower in the intervention group than in the control group {−3.4 mmHg [95% confidence interval (CI) −6.1 to −0.8 mmHg]. The difference in diastolic BP was −0.5 mmHg (95% CI −1.9 to 0.9 mmHg)}. There were significantly more increases to antihypertensive medication in the intervention group than in the control group, both in terms of dose increases (relative risk 2.03, 95% CI 1.54 to 2.69) and new drugs added (relative risk 1.46, 95% CI 1.12 to 1.91). Cost-effectiveness analysis showed that the incremental cost per unit of systolic BP reduction was £11 (95% CI £5 to £29). Owing to a cost difference of £402 and a quality-adjusted life-year (QALY) difference of 0.044, long-term modelling puts the incremental cost per QALY at just over £9000. The probability of being cost-effective was 66% at willingness to pay £20,000 per QALY, and this was higher at higher thresholds.

The findings of the process evaluation included the following:

- Patients appraised the value of the DI in terms of perceived benefits (e.g. reassurance and improved health) and burdens (e.g. worry about health). Illness and treatment perceptions about hypertension appeared to influence perception of benefit or burden.
- Patient engagement was high, with 70% of patients continuing to enter BP readings in the final quarter of the 12-month trial. However, only 29% of patients registered online for healthy behaviour change support. Engagement with entering BP readings was predicted by self-reported medication adherence and perceived necessity and concerns at baseline.
- HCPs implemented 53% of recommended medication changes. HCPs were less likely to implement medication changes when systolic BP was closer to the threshold, and when the patient had already been recommended a medication change. The qualitative analysis indicated a more general reluctance among some HCPs to change medication, with concerns about a lack of context and a preference for recommending healthy behaviour change.

Asthma intervention

Intervention planning and development

Objectives

- To collate and synthesise quantitative and qualitative evidence relating to DIs for asthma self-management.
- To create an intervention plan, which involved developing guiding principles and carrying out behavioural analysis to identify barriers to key behaviours and specify how these will be addressed.
- To create an intervention prototype and use iterative qualitative interviews to optimise the intervention.
- To map the evidence onto behavioural barriers and intervention components onto theory.

Methods

The development process was guided throughout by a multidisciplinary Intervention Development Team that included PPI)contributors and representatives of Asthma UK (London, UK), a key stakeholder organisation. A systematic review of quantitative studies assessing the effects of interactive DIs (compared with usual care) to support self-management of asthma in adults was carried out. Two published primary mixed-methods studies of DIs for asthma helped identify effective intervention components to be included in My Breathing Matters. Thirty-four think-aloud interviews with 14 adults with asthma and 12 semistructured telephone interviews with adults with asthma who used the intervention for 2 weeks were carried out. The other methods are the same as those described for the development of HOME BP (see *Hypertension*, *Methods*).

Results

The systematic review provided some support for the potential efficacy of a DI for adults with asthma for improving asthma-related quality of life and asthma control. A DI was developed (i.e. My Breathing Matters) to improve functional quality of life in primary care patients with asthma by supporting illness self-management. Motivational content intended to facilitate use of pharmacological self-management strategies (e.g. medication adherence and appropriate health-care service use) and non-pharmacological self-management strategies (e.g. breathing retraining, stress reduction and healthy behaviour change). Guiding principles identified important considerations for the intervention design, including the need to engage people who do not view themselves as having active asthma (e.g. by demonstrating that impaired quality of life can be improved) and encouraging users to employ non-pharmacological methods of improving quality of life (e.g. by educating users on the benefits of breathing retraining). The behavioural analysis identified five target behaviours relating to the intervention's pharmacological (i.e. preventer medication adherence, engagement with a personal asthma action plan) and non-pharmacological (i.e. engagement with breathing retraining and cognitive behavioural stress management practice) components. Qualitative interviews showed that participants found the website acceptable and easy to navigate and understand. Several issues affecting acceptability of the intervention were identified, and the findings were used to optimise the intervention.

Intervention evaluation

Objectives

- To assess the feasibility of trial procedures and data analysis to inform a Phase III RCT.
- To explore the acceptability of My Breathing Matters, including how patients experienced and used the intervention.

Methods

Using a feasibility RCT design, adults in primary care with impaired asthma-specific quality of life were randomised to either usual care or the intervention group who accessed My Breathing Matters. The usual-care group received routine asthma care and a Asthma UK information booklet on asthma self-management. Participants completed outcome measures regarding asthma-specific quality of life (Mini Asthma Quality of Life Questionnaire) and asthma control (Asthma Control Questionnaire) at baseline and at 3 and 12 months. Health-care utilisation data (e.g. medication use) were collected via retrospective notes review. Intervention usage data were collected for intervention participants over the 12-month study period. A Satisfaction Questionnaire was administered to patients ($n = 36$) who used the intervention at 12-month follow-up. At 3 month follow-up, retrospective telephone interviews were carried out with 18 intervention participants to explore intervention participants' views and experiences of using the intervention. Qualitative data were analysed using inductive thematic analysis.

Results

Eighty-eight participants were recruited (target, $n = 80$) from seven general practices in Wessex, UK. Follow-up data were gathered from 91% of patients at 3 and 12 months. Four patients formally withdrew from the study and four patients did not complete the 12-month follow-up questionnaire. Notes reviews completed by the practice varied substantially in quality, and data quality were insufficient for a health economic analysis.

Eighty-two per cent ($n = 36$) of intervention participants logged in at least once (median logins 4; interquartile range 8). Eighty-six per cent ($n = 31$) of intervention participants indicated that they gained benefit from using the intervention and 78% ($n = 28$) reported that there were no, or very little, disadvantages to using it. Seventy-eight per cent ($n = 28$) of intervention participants rated that they would recommend My Breathing Matters to friends and family.

Overall, interview participants expressed positive views of the intervention. Participants found the content easy to understand and the website easy to use. Users reported several benefits from taking part in the intervention, including improvements in their asthma symptoms (e.g. reduced coughing and breathlessness), medication use (e.g. improved medication adherence, correct use of their inhalers, reduction in reliever inhaler use) and breathing awareness, technique and posture. Interviews highlighted minor improvements to the intervention design and factors that influenced users' engagement with the intervention (e.g. participants' perceptions of their asthma control and current self-management practices).

Conclusions

Implications for health care

The findings of the HOME BP trial suggest that the use of digital support to help patients self-manage their hypertension is not only clinically effective but also cost-effective (by NHS standards), as well as both feasible and acceptable for clinicians and patients. The hypertension DI could offer a feasible system for further implementation in primary care and could potentially make a worthwhile impact on the reduction of cardiovascular risk. The My Breathing Matters intervention appeared feasible, and the feasibility trial findings suggest that there is potential for a benefit in asthma patient-reported outcomes of an order of magnitude within the range of that seen from commonly used pharmacological treatments.

Recommendations for research

A fully powered RCT should be carried out to assess clinical effectiveness and cost-effectiveness of the My Breathing Matters intervention. For the HOME BP intervention, more comprehensive modelling of the long-term effects of BP reduction is recommended.

Limitations

Compared with the wider patient population, recruited participants were generally white (both conditions), older (asthma only), highly educated (asthma only) and there was a bias towards higher socioeconomic status (hypertension only). Issues with integrating DIs with existing clinical records systems could restrict the potential for wider implementation. Although our researchers and statisticians were blind to group allocation, participants in both RCTs were not blinded. The digital aspects of the HOME BP intervention were challenging to cost accurately.

This research programme has begun to influence future clinical research and practice through further implementation. The intervention development approach used in this programme of research involved a combination of theory-, evidence- and person-based approaches, and was found to be successful in facilitating the identification of important contextual barriers to and optimisation of the intervention. Dissemination of this process is under way.

Trial and study registration

The trials are registered as ISRCTN13790648 (hypertension) and ISRCTN15698435 (asthma).
The studies are registered as PROSPERO CRD42013004773 (hypertension review) and PROSPERO CRD42014013455 (asthma review).

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