A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of 'PhysioDirect' telephone assessment and advice services for physiotherapy

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Executive summary

Effectiveness of 'PhysioDirect' telephone assessment and advice services

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Executive summary

Background

Musculoskeletal (MSK) problems are very common and are an important cause of poor health owing to pain and functional impairment. These problems also have a major economic impact because of time lost from work. MSK problems are one of the most common reasons for consulting a general practitioner (GP). Many patients are referred to physiotherapy (1.23 million new GP referrals per annum in England). Providing timely access to physiotherapy has long been a problem in the NHS, with waiting times of several months for treatment in many areas. Several physiotherapy services have introduced 'PhysioDirect' services, in which the patient can telephone a physiotherapist for initial assessment and advice without waiting for a face-to-face appointment. They can be given advice about self-management and exercises, and the need and priority for seeing them face to face can be established. Services that have implemented PhysioDirect have claimed that it reduces waiting times for treatment, is popular with patients, and that about half of all patients can be managed by telephone alone. This type of service is increasingly being introduced in the NHS and in other countries but there is no evidence about health outcomes or costs, and little evidence about waiting times or patient satisfaction.

Objectives

- To assess whether or not PhysioDirect is equally as clinically effective as usual models of physiotherapy based on patients going on to a waiting list and eventually receiving face-to-face care.
- To investigate the cost-effectiveness of PhysioDirect compared with usual care.
- To explore the experiences and views of patients, physiotherapists and the physiotherapists' managers.
- To investigate the health outcomes and experiences of different groups of patients when referred to PhysioDirect rather than usual care.

Methods

Design

Pragmatic randomised controlled trial, incorporating economic evaluation and nested qualitative research, comparing PhysioDirect and usual care.

The study was designed to assess equivalence between the two arms of the trial in the primary clinical outcome. If equivalence in clinical outcome is established, differences in the costs of providing care and in the secondary outcomes (waiting times for treatment, time lost from work and usual activities, patient satisfaction) become particularly important and relevant to future provision of services.

Setting and participants

Four community physiotherapy services in different areas of England. They drew patients from 94 general practices covering a wide range of types of geographical area and population. Participants were adults (aged ≥18 years) who were referred by GPs or referred themselves for physiotherapy for a MSK problem. The inclusion criteria were deliberately broad to maximise generalisability. The main exclusion criteria were patients with non-MSK problems, those referred by hospital consultants, children, those unable to communicate in English by telephone and people with problems deemed on the basis of the referral form to be too urgent to be delayed by trial recruitment.

Randomisation

Consenting patients were randomised in a 2 : 1 ratio to PhysioDirect or usual care using a secure remote automated allocation system. Randomisation was conducted at the level of the individual, stratifying by physiotherapy site and minimising by sex, patient age group and site of MSK problem.

Interventions

Patients allocated to PhysioDirect were invited to telephone a senior physiotherapist for initial assessment and advice using a computerised template. Most patients were then sent written advice about self-management and exercises and invited to telephone back after 2–4 weeks to discuss progress. If the patient telephoned back then they were given further advice or offered face-to-face treatment as necessary. The PhysioDirect service also made it possible to identify patients who urgently needed face-to-face treatment and other patients who were unlikely to gain benefit from physiotherapy and could be discharged. The PhysioDirect services in each of the four sites were standardised as far as possible.

Patients allocated to usual care were put on to a waiting list for face-to-face assessment and treatment, followed by follow-up face-to-face treatment sessions as appropriate.

Outcome measures

The primary outcome was clinical outcome at 6 months after randomisation, assessed using the Physical Component Score (PCS) from the Short Form questionnaire-36 items, version 2 (SF-36v2) questionnaire. Secondary outcomes included other measures of health outcome: the Measure Yourself Medical Outcomes Profile; the European Quality of Life-5 Dimensions (EuroQol health utility measure, EQ-5D); a single question about overall improvement in the main problem for which the patient was referred to physiotherapy; and a composite measure of response to treatment. Other secondary outcomes included waiting times for treatment, time lost from work and usual activities, satisfaction with care provided and preference for PhysioDirect or usual care in future.

Measures of the process of care included the number, type and duration of consultations with physiotherapists, the time to first physiotherapy assessment (telephone or face to face) and rates of non-attended appointments with physiotherapists.

Data were collected from postal questionnaires at baseline, 6 weeks and 6 months after randomisation; electronic data downloaded from the PhysioDirect software; routine physiotherapy records; and patients' general practice records. When patients did not return questionnaires, attempts were made to collect primary outcome data by telephone. Data were self-reported in patient questionnaires, obtained by electronic download or collected from routine records by researchers who were blind to allocation.

Sample size and power

This study was powered to establish clinical equivalence in the PCS, with a difference of no greater than 2 points specified as demonstrating equivalence. Sample sizes for analysis of 976 and 488 in the PhysioDirect and usual-care groups, respectively, would provide 95% power to reject a null hypothesis of non-equivalence with an overall two-sided alpha of 0.05, assuming that the observed difference in means is zero. Assuming 20% non-collection of the primary outcomes, it was necessary to recruit 1875 patients to reach a target of 1500 patients for analysis. Following a protocol amendment we continued inviting patients to participate until 2000 patients had been recruited.

Analysis

Analyses of primary and secondary outcomes employed multivariable regression models to investigate between-group differences adjusted for stratification and minimisation variables and, where available, value of the outcome at baseline.

Economic analysis assessed cost consequences including NHS and patient costs, and the cost of lost production. A cost-effectiveness analysis was carried out from the perspective of the NHS. NHS costs

included the direct cost of physiotherapy consultations, costs of consultations in primary care, medication prescribed in primary care, and hospital care. The analysis was confined to costs related to the reason for which the patient was referred to the physiotherapy service.

Resources used were measured using the sources of data previously described, supplemented by time and motion studies. Resources were valued using standard methods and reference sources.

All costs were based on 2009 prices. Costs and outcomes were not discounted. The primary measure of cost-effectiveness was incremental cost per quality-adjusted life-year (QALY). Uncertainty in the cost-effectiveness ratios resulting from patient variation was captured by estimating confidence intervals (CIs) around the net benefit statistic and estimating cost-effectiveness acceptability curves. Uncertainty in the estimate of physiotherapist productivity was addressed using a sensitivity analysis based on data about the productivity of physiotherapists in a service that continued PhysioDirect in a slightly amended form after the trial ended. Uncertainty due to missing outcome and cost data was addressed using imputation by a chained equation procedure. In further sensitivity analysis, the use of the Short Form questionnaire-6 Dimensions (SF-6D) rather than EQ-5D measure was used to obtain QALYs.

Qualitative research

Qualitative research was conducted to explore the acceptability and implementation of PhysioDirect from the perspective of key stakeholders. Interviews were conducted with patients, physiotherapists providing PhysioDirect, and the physiotherapy manager responsible for the PhysioDirect service in each site. Patients were purposively selected to include individuals with different age and sex characteristics, presenting problems and experience of using or not using PhysioDirect. Data from the interviews were analysed qualitatively using a Framework approach.

Investigation of adverse events

General practitioners and physiotherapists were asked to report any suspected adverse event that may have been related to physiotherapy or to the trial procedures. In addition, the general practice notes of each patient were scrutinised by researchers at the end of the trial following a protocol designed to identify adverse events.

Results

Of all patients, 21% were ineligible for the trial and 50% of eligible patients declined to participate. A total of 2256 patients were recruited and randomised – 1513 to PhysioDirect and 743 to usual care. There were no important differences between groups at baseline. Primary outcome data were obtained from 88% of patients after 6 weeks' follow-up and 85% of patients after 6 months' follow-up.

Of all patients in the PhysioDirect arm, 1281 (85%) contacted the physiotherapy service at least once. Of the 1239 patients contacting PhysioDirect and being assessed initially by telephone, almost half (47%) were managed entirely by telephone. Patients in the PhysioDirect arm had fewer face-to-face appointments (mean 1.91) than those in the usual-care arm (mean 3.11) and fewer physiotherapy consultations of any type [mean 2.87 in PhysioDirect arm vs 3.25 in usual-care arm, incidence rate ratio (IRR) 0.87, 95% CI 0.80 to 0.94]. Patients allocated to PhysioDirect had a shorter wait for advice and treatment than those allocated to usual care [median 7 days vs 34 days; arm–time ratio 0.32 (95% CI 0.29 to 0.35)]. Patients in the PhysioDirect arm were also less likely to fail to attend face-to-face appointments [adjusted IRR 0.55 (95% CI 0.41 to 0.73)].

PhysioDirect and usual care were equivalent in terms of the primary outcome of PCS at 6 months' follow-up [43.50 vs 44.18, adjusted difference in means –0.01 (95 % CI –0.80 to 0.79)]. This finding was robust to adjustment for baseline imbalance, imputation of missing data, and adjustment for clustering by physiotherapy service and by general practice. All of the secondary measures relating to health outcomes

were also equivalent at 6 months' follow-up. The primary and secondary health outcomes were all suggestive of slightly greater improvement in favour of PhysioDirect at 6 weeks' follow-up.

Patients were equally satisfied with access to care in each arm of the trial but slightly less satisfied with their consultations and slightly less satisfied overall with PhysioDirect than with usual care.

No adverse events were detected in either arm of the trial.

The direct costs of physiotherapy were slightly greater in the PhysioDirect arm than in the usual-care arm, but sensitivity analyses based on evidence of more efficient operation of PhysioDirect after the trial ended suggested that it would be slightly less expensive than usual care. NHS costs in the PhysioDirect arm (including physiotherapy and other NHS services) were similar to those of usual care [mean £198.98 vs £179.68, difference in means £19.30 (95% CI –£37.60 to £76.19)], while the QALYs gained in the PhysioDirect arm were also similar [difference in means 0.007 (95% CI –0.003 to 0.016)].

The incremental cost per QALY gained was £2889, the net monetary benefit was £117 (95% CI –£86 to £310) based on a willingness to pay of £20,000 and there was an 88% probability that PhysioDirect was cost-effective at this willingness-to-pay threshold.

A scenario based on the more efficient operation of PhysioDirect after the trial ended increased the extent to which PhysioDirect was cost-effective, as did a sensitivity analysis after excluding hospital costs, whereas scenarios based on imputation of missing cost and outcome data, or using the SF-6D measure instead of the EQ-5D to generate QALYs, reduced the extent to which it was cost-effective. The costs and benefits were both very small under all scenarios, and there was wide variation in some elements of cost, such that the CIs for estimates of net mean benefit included zero. However, under all scenarios the probability that PhysioDirect was cost-effective at a willingness-to-pay threshold of £20,000 was $> 50\%$. Therefore, the overall conclusion that PhysioDirect is probably cost-effective was consistent and robust to these sensitivity analyses.

There was no evidence of difference between PhysioDirect and usual care in time lost from work or usual activities, the cost to patients or the value of lost production.

Findings from the qualitative research suggested that PhysioDirect is broadly acceptable to patients, although some saw it as a first step in accessing treatment rather than replacing a face-to-face consultation. Many patients valued the faster access to advice and care provided by PhysioDirect and found the physiotherapists to be helpful during telephone consultations. However, some patients found the service to be impersonal and remote. Physiotherapists and their managers felt that PhysioDirect provided an acceptable service, which was helpful in improving access and reducing waiting times. Some physiotherapists felt that the telephone nature of the service made it more difficult to establish rapport with patients. Most physiotherapists were happy to provide PhysioDirect sessions for a small part of their working week but would not be happy to spend most of their time on such work. Both physiotherapists and their managers felt that PhysioDirect would have a useful role as one (rather than the only) method for patients to access care in future.

Conclusions

Providing physiotherapy via PhysioDirect is equally as clinically effective as usual waiting list-based care, provides faster access to advice and treatment, appears to be safe, and is acceptable to patients.

The cost of providing physiotherapy is likely to be lower than usual care only if PhysioDirect is provided more efficiently than it was in this trial, although there is good reason to believe that this can be achieved.

PhysioDirect is probably cost-effective compared with usual care, given the threshold for willingness to pay that is usually used within the NHS.

In future, PhysioDirect services will probably increasingly be provided in conjunction with direct access for patients (rather than following referral from another health-care professional), and may be offered as a choice for patients wanting quicker advice rather than the only route to care.

Recommendations for research

As services evolve, further research should explore the costs and benefits of PhysioDirect services when they are provided to patients who have mainly referred themselves for treatment.

The PhysioDirect services in this study used experienced physiotherapists to provide telephone assessments, supported by computerised assessment templates. Some recently established PhysioDirect services use less experienced physiotherapists who are not supported by computerised templates. It is important to establish the costs, outcome and safety of care of PhysioDirect provided under these circumstances.

Further research should explore the potential of technological developments such as webcams and smartphones as a means of assessing and advising patients at a distance.

There are advantages and disadvantages to evaluating new services soon after they have been established. Further research should explore the extent to which the costs and outcomes of new services change over time and whether or not there is an optimum time at which to conduct evaluation of a new service.

Further research is needed to explore, in more depth, patients' expectations and preferences with regard to services based on initial assessment and advice by telephone.

Trial registration

This trial is registered as ISRCTN55666618.

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