

A pragmatic randomised controlled trial of 'PhysioDirect' telephone assessment and advice services for patients with musculoskeletal problems: economic evaluation

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Key Words: economic evaluation; physiotherapy; telehealth; primary care; cost & cost analysis

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ABSTRACT

Objectives

To compare the cost-effectiveness of PhysioDirect with usual physiotherapy care for patients with musculoskeletal problems.

Design

(i) Cost-consequences comparing cost to the NHS, to patients, and the value of lost productivity with a range of outcomes. (ii) Cost-utility analysis comparing cost to the NHS with Quality Adjusted Life Years (QALYs)

Setting

Four physiotherapy services in England

Participants

Adults (18+) referred by their general practitioner or self-referred for physiotherapy.

Interventions

PhysioDirect involved telephone assessment and advice followed by face-to-face care if needed. Usual care patients were placed on a waiting list for face-to-face care.

Primary and secondary outcome measures

Primary clinical outcome: physical component summary measure from the SF-36v2 at six months. Secondary outcomes included: Measure Yourself Medical Outcomes Profile; a Global Improvement Score; response to treatment; patient satisfaction; waiting time. Outcome for the cost-utility analysis: QALYs

Results

2249 patients took part (1506 PhysioDirect; 743 usual care).

(i) Cost-consequences: there was no evidence of a difference between the two groups in the cost of physiotherapy, other NHS services, personal costs or value of time off work. Outcomes were also similar.

(ii) Cost-utility analysis based on complete cases (n=1,272). Total NHS costs, including the cost of physiotherapy were higher in the PhysioDirect group by £19.30 (95% CI: -£37.60 to £76.19) and there was a QALY gain of 0.007 (95% CI: -0.003 to 0.016). The incremental cost-effectiveness ratio was £2,889 and the net monetary benefit at λ =£20,000 was £117 (95% CI: -£86 to £310)

Conclusions

PhysioDirect may be a cost-effective alternative to usual physiotherapy care, though only with careful management of staff time. Physiotherapists providing the service must be more fully occupied than was possible under trial conditions: consideration should be given to the scale of operation, opening times of the service, and flexibility in the methods used to contact patients.

Article Summary

Article focus

- What is the cost of providing PhysioDirect telephone assessment and advice, followed by face-to-face care if needed, to adults with musculoskeletal pain problems, compared with usual physiotherapy care?
- What are the patient benefits of PhysioDirect compared with usual care?
- Is PhysioDirect a cost-effective alternative to usual care for primary care patients with musculoskeletal conditions?

Key messages

- There was very little difference between the two groups in terms of cost or outcomes
- PhysioDirect has potential to be a cost-effective alternative to usual care but requires careful management of staff resources

Strengths and limitations of this study

- Findings are based on a large sample of patients with a wide range of musculoskeletal problems based in diverse locations
- The study takes a broad perspective, including the health care provider, patients, and a valuation of lost productivity
- Physiotherapists were constrained by trial conditions and were underutilised

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1 INTRODUCTION

There is a trend to explore the use of new technology in the delivery of health care, particularly the use of telephone assessment and triage, as for example in NHS Direct.¹ These services aim to better manage patient demand, and research has shown that telephone based services can be safe, clinically accurate, cost-effective, acceptable to patients, and reduce the workload of clinicians,²⁻⁵ although there have been some concerns about using telephone triage in patients presenting with acute health problems.⁶

8

9 Musculoskeletal pain problems are one of the most common causes of disability. Over a quarter of 10 all patients registered in general practice will consult at least once for a musculoskeletal problem each year,^{7,8} with musculoskeletal pain accounting for around 15% of all GP consultations.⁹ This high 11 prevalence of musculoskeletal problems results in large direct and indirect healthcare costs,¹⁰ 12 estimated for low back pain alone at £10,668 million for the UK in 1998¹¹ and rising substantially 13 since then.¹² Most patients are managed with advice and analgesia but many are referred to 14 physiotherapists, with 1.23 million new referrals each year from GPs and 4.4 million in total.¹³ 15 16 Ensuring timely access to physiotherapy has long been an issue within the UK NHS, with waiting 17 times of more than four months in some areas. Patients may suffer unnecessary pain and disability, 18 and there are high productivity losses: for example, back pain accounts for some 120 million days of certified absence from work each year.¹¹ Delay may also cause NHS inefficiencies on the one hand as 19 20 some patients recover and do not attend their physiotherapy appointment when it finally arrives, 21 whilst on the other, some patients continue to access more expensive forms of treatment whilst 22 awaiting their appointment.

23

In response to these problems, physiotherapy services have drawn on the new service models and a
range of 'PhysioDirect' services have been developed. These vary in format though they commonly
involve a physiotherapist assessing a patient's musculoskeletal pain problem over the telephone,

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1	sometimes supported by computerised assessment templates, offering tailored, self-management
2	advice supplemented by written advice sent by post. Alternatively if the assessment findings
3	suggest that face-to-face care is needed this is arranged, and patients who are initially managed by
4	telephone advice can phone back for further advice and/or face-to-face treatment. ¹⁴ There is,
5	however, limited evidence about the costs and benefits of this approach within physiotherapy. Local
6	evaluations and non-randomised studies suggest that these services may be popular with patients ¹⁵⁻
7	¹⁷ and diagnoses made by physiotherapists over the telephone are comparable to diagnoses reached
8	in face-to-face assessments ¹⁸⁻²⁰ although there is some concern that the experience of the
9	physiotherapist providing the telephone assessment might be important. ^{18,21}
10	
11	In particular there is no information about the costs or cost-effectiveness of PhysioDirect services,
12	despite: (i) a major underlying rationale for their development being to generate greater efficiency
13	in the use of resources; and (ii) a ready presumption that telephone-based services result in lower
14	costs (by assuming that services better use physiotherapy time, use less costly telephone
15	consultations and reduce rates of appointment non-attendance). Without such evidence, preferably
16	generated alongside high quality primary evidence obtained using rigorous study designs, it remains
17	unclear whether such services should be more widely implemented. This paper reports the results of
18	an economic evaluation conducted alongside a randomised controlled trial powered to generate
19	evidence on whether PhysioDirect services for primary care patients with musculoskeletal problems
20	produce equivalent outcomes to usual face-to-face services.
21	
22	
23	METHOD
24	Study design

- 25 We conducted an economic evaluation alongside a randomised controlled trial to establish the cost-
- 26 effectiveness of PhysioDirect compared with usual care based only on face-to-face treatment over a

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1	period of 6 months. The trial and its clinical findings have been reported in full elsewhere. ^{14,22} The
2	primary perspective for the economic evaluation was the health and social care provider, as that is
3	of greatest interest to UK policy makers. ²³ However, the nature of the intervention suggests there
4	could be an impact on patients' costs, and as it is known that musculoskeletal conditions account for
5	a considerable amount of time off work ^{10,11} we included these perspectives in the analysis. We used
6	a cost-consequences approach to compare cost from all three perspectives (health care provider,
7	patients and carers, lost productivity) with a range of clinical outcomes and used a cost-utility
8	analysis to compare cost to the National Health Service (NHS) with Quality-Adjusted Life-Years
9	(QALYs).
10	
11	Setting and participants
12	We recruited adults aged 18 and over from four community physiotherapy services in England –
13	Bristol, Somerset, Stoke-on-Trent, and Cheshire – which provided diversity in terms of socio-
14	economic status and a mix of urban and rural communities. All patients referred by their general
15	practitioner (GP), or who referred themselves, for physiotherapy for a non-urgent musculoskeletal
16	problem were invited to take part. Patients were randomised to PhysioDirect or usual care on a two
17	to one basis to increase the chances of the PhysioDirect service being fully utilised.
18	
19	Interventions
20	The intervention has been reported in detail elsewhere ^{14,22} . Patients randomised to the PhysioDirect
21	service received an invitation to telephone a senior (band 6 or above) specially trained
22	physiotherapist, who assessed their musculoskeletal problem with the aid of previously developed
23	computerised templates. ²² These templates were provided by Huntingdonshire Primary Care Trust,
24	which has been operating a similar service since 2001. Patients were then sent appropriate advice
25	leaflets about self-management and exercises to try at home, and invited to phone again and/or

1	make a face-to-face appointment if necessary. Patients randomised to usual care were put on the
2	usual service waiting list for face-to-face assessment and treatment.
3	
4	Outcome measures
5	We used the EQ-5D-3L ²⁴ , valued using the UK tariff, ²⁵ to estimate QALYs gained for the cost-utility
6	analysis. The primary outcome for the trial was the physical component summary (PCS) measure
7	from the SF-36v2 questionnaire ²⁶ and secondary clinical outcomes included: the Measure Yourself
8	Medical Outcomes Profile (MYMOP); ²⁷ a Global Improvement Score – a single question about overall
9	improvement; a composite measure of response to treatment including pain, function and overall
10	improvement (OMERACT OARSI); ²⁸ patient satisfaction; and waiting time to first treatment advice
11	from a physiotherapist. All outcomes (except the global improvement score and waiting time to first
12	treatment advice) were measured at baseline, 6 weeks and 6 months and were obtained from a self
13	completed questionnaire administered at these three time points.
14	
15	Resource use
16	The analysis was based on costs related to the reason for which the patient was referred to the
17	physiotherapy service. We identified relevant resources in discussion with participating
18	physiotherapists and service managers. Direct costs to the health care provider included: cost of
19	initial and follow-up physiotherapy consultations; primary and community consultations; hospital
20	care; and prescribed medication. Patient and carer costs included: telephone calls to the
21	PhysioDirect service; travel; over the counter medication; prescription costs; private therapy and
22	purchase of equipment; extra domestic help; and loss of earnings. Lost productivity was estimated
23	separately in relation to time off work to attend physiotherapy appointments and time off because
24	of the musculoskeletal condition itself.
25	

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1	Patient level data about all physiotherapy appointments and consultations were recorded either
2	automatically by computer or by the physiotherapist treating the patient. For those in the
3	intervention group, the PhysioDirect assessment software recorded which physiotherapist
4	conducted each telephone call, and the duration of each call. In addition to the time logged on to
5	the system physiotherapists had to carry out administrative activities following each telephone call,
6	such as collating information to send to the patient by post. The time spent on these activities was
7	estimated from information available at one site (Bristol) where manual recording of the entire
8	encounter supplemented the electronic recording.

9

10 Physiotherapists assigned to the PhysioDirect service were required to be available throughout the 11 time the service was 'open' but they were not usually fully engaged in dealing with PhysioDirect 12 patients during these hours. We conducted an observational time and motion study at each of the 13 four sites to determine how they occupied their non-PhysioDirect contact time in order to apportion 14 costs appropriately. Time and motion data were collected at points in the study when the sites were 15 expected to be fully operational, and across a mix of day, time of day, and location. The capital costs 16 required to run a telephone services are potentially less than for a face-to-face service. Each site 17 provided information about space and equipment required to run their telephone service and we 18 used this to estimate an overall percentage reduction of capital costs for these compared with a 19 standard face-to-face service.

20

Data about all face-to-face appointments were recorded routinely. These data included the length of
appointment, the grade of the physiotherapist seen, and information about missed appointments.

23

Information about other NHS resource use was collected, where possible, from general practice
records and supplemented by information gained directly from patients. General practice notes
were scrutinised for patient level data on primary care consultations and prescribed medication. We

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1	included all consultations at which the musculoskeletal condition for which the patient was referred
2	to physiotherapy was mentioned and these were recorded by type of consultation (for example,
3	face-to-face, telephone, out of hours, home visit) and by type of professional seen (for example, GP,
4	nurse). It was not feasible to distinguish between medication prescribed for the condition for which
5	the patient was referred for physiotherapy and any other musculoskeletal problem so we included
6	all medication of a potentially relevant type, defined using British National Formulary (BNF) ²⁹ coding.
7	These were: Analgesics (chapters 4.7.1 – 4.7.2); Non-steroidal anti-inflammatory drugs (10.1.1);
8	Local corticosteroid injections (10.1.2.2); and Drugs for the relief of soft-tissue inflammation (10.3).
9	
10	A questionnaire was administered to participants at 6 weeks and 6 months after randomisation to
11	obtain resource use data not available elsewhere. These included information about hospital care
12	related to the condition for which the patient was referred to physiotherapy: visits to Accident &
13	Emergency, outpatient appointments, and inpatient stays. Information about personal expenditure
14	relevant to the patient's musculoskeletal condition was also gained from the questionnaire at 6
15	weeks and 6 months. We asked about the cost of travel to physiotherapy and other health care
16	appointments, expenditure on over the counter medication, prescription costs, use of private
17	therapies and their cost, expenditure on equipment or devices, and extra help at home. In addition,
18	participants were asked about any time off work, and the associated loss of earnings, because of

their condition or to attend health care appointments relating to the condition including usual carephysiotherapy and PhysioDirect.

22 Valuation of resource use

Table 1 gives the unit costs and sources used to value the health care resources. We used Curtis³⁰ to
 value primary and community health care and Department of Health reference costs³¹ for all
 hospital-based care. The cost of prescribed medication was estimated from that published in the
 BNF,²⁹ adjusted to allow for the discount available to the NHS, and the professional fee and

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1	container allowance in accordance with the Drug Tariff for England. ³² Personal expenditure was
2	reported directly by the participants, the exception being travel by car, which was reported as
3	mileage and costed using the AA schedule of motoring costs. ³³ Time off work was valued using the
4	median gross weekly earnings by age and sex. ³⁴
5	
6	Table 1 here
7	
8	The cost of face-to-face physiotherapy consultations was estimated by adapting the methods of
9	Curtis ³⁰ to obtain a different unit cost for each band of staff at each site. National median pay rates,
10	by band, ³⁶ were adjusted to allow for National Insurance, superannuation, and overheads, as per
11	Curtis, then further adjusted to allow for band and site specific non-contact time. Information about
12	the proportion of time physiotherapists on each grade typically spend in direct contact with patients
13	was provided by the four physiotherapy service managers. This provided us with a cost per hour for
14	each band of staff at each site.
15	
16	The unit cost of physiotherapists working in the PhysioDirect service was estimated in a similar way,
17	but allowing for the reduced cost of capital and overheads; information from the site managers
18	indicated this to be about 50%. To obtain a cost per hour of telephone contact we used information
19	from the computerised records of the PhysioDirect service, which identified the proportion of time
20	spent by physiotherapists actually dealing with PhysioDirect patients. We then combined this with
21	data from the time and motion study, which identified activities undertaken during non-contact
22	time, for example, administration relating to face-to-face appointments or general administration, to
23	give a cost per hour for each band of staff at each site.
24	
25	All costs were valued in £ sterling at 2009 prices, adjusted for inflation where necessary. ³⁰
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Data analysis

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2	We investigated the amount of each resource used by patients in each group using frequencies,
3	means and medians. Mean total cost per participant was derived by combining resource use with
4	unit costs.
5	
6	QALYs were derived from responses to the EQ-5D-3L at baseline, 6 weeks and 6 months using
7	valuations from the UK general population. ²⁵ These values, representing health-related quality of life
8	on a scale between zero (death) and 1 (best imaginable health), were used to compute QALYs
9	experienced over the 6 month period using the area under the curve approach and adjusting for any
10	difference between the groups at baseline. ³⁷
11	
12	A cost-consequences matrix was constructed using all available data. We compared costs from all
13	three perspectives (health care provider, patients and carers, lost productivity) with the SF-36v2 PCS,
14	MYMOP, Global Improvement Score, OMERACT OARSI, patient satisfaction, waiting time, and QALYs.
15	
16	The cost-utility analysis was carried out using data on patients for whom we had complete NHS cost
17	and QALY data. An incremental cost-effectiveness ratio (ICER) was constructed, comparing the
18	difference in mean total cost per patient with mean difference in QALYS. Uncertainty around the
19	ICER was captured by replicating it 5000 times using the bootstrapping technique, estimating a
20	confidence interval around the net monetary benefit, and constructing a cost-effectiveness
21	acceptability curve.
22	
23	We used the multiple imputation by chained equation procedure to address the issue of missing cost
24	and EQ-5D data. ³⁸ This technique uses a regression model to estimate missing values from known
25	values. In addition to cost and EQ-5D-3L variables the imputation model also included randomisation

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1	group, age, sex, and SF36v2 PCS. Stata v12 ³⁹ was used to generate five datasets using 10 switching
2	procedures.
3	
4	Discounting was not carried out because the analysis was restricted to costs and outcomes over a
5	period of less than a year. All analyses were conducted using Microsoft Excel and Stata v12. 39
6	
7	Sensitivity Analyses
8	We addressed three areas of uncertainty using one/two-way sensitivity analyses. First, we estimated
9	the cost of running the PhysioDirect service if it was operating at full capacity. It is likely that this was
10	not achieved during the trial because of: low demand due to exclusions and non-participation in the
11	trial; inflexible staffing levels to ensure consistency throughout the trial period; and the 'one-way'
12	system generally used, where physiotherapists waited for patients to call them but did not routinely
13	contact patients themselves (notwithstanding some limited use of answer-machines). Data from the
14	Bristol service, which continued to operate beyond the trial period and was then able to tailor
15	staffing levels to demand, were used to estimate the cost of running a more 'efficient but feasible'
16	PhysioDirect service once the trial had ended.
17	
18	The second area of uncertainty addressed hospital costs. Patients in the trial were recruited from
19	primary care and for these, use of secondary care is infrequent but relatively expensive and this can
20	have a disproportionate effect on mean total cost. We tested this by excluding hospital costs from
21	the total.
22	
23	The third and fourth sensitivity analyses used the imputed missing data as described above first with
24	data collected during the trial and second by combining with results of the first sensitivity analysis,
25	mimicking an 'efficient but feasible' service.
26	

1	
2	RESULTS
3	A total of 2,249 patients took part in the trial, 1506 allocated to PhysioDirect and 743 to usual care.
4	The mean age was 60, with slightly more females than males (60% vs 40%); they were
5	overwhelmingly white (97%), just over half (60%) were employed and all but a few were referred for
6	physiotherapy by their GP. Nearly all participants (2,223=99%) gave permission to access their GP
7	notes to obtain data about primary care encounters and prescribed medication. 81% returned
8	questionnaires at both 6 weeks and 6 months though not all participants completed all sections at
9	both time points. We had complete NHS cost and QALY data for 840 (56%) PhysioDirect and 432
10	(58%) usual care participants.
11	
12	Resource use
13	Table 2 gives information about the different types of physiotherapy consultations by patients in
14	each group. Of the 1506 patients in the PhysioDirect group, 39% (586) were managed solely over the
15	telephone and only 46% (695) had any face-to-face consultations. In total, patients in the usual care
16	group had, on average, 0.38 (95% CI: 0.12 to 0.63) more consultations than those in the PhysioDirect
17	group and the mean total duration of all consultations was 20 minutes longer (95% CI: 12 to 28).
18	
19	Table 2 here
20	
21	Tables 3 and 4 give information about NHS and personal resource use. Just over a third of patients
22	(35%) had a GP consultation during the 6 months and 40% received a prescription for
23	musculoskeletal pain-related medication. There was very little difference between the two groups in
24	terms of health care use and the only important difference in personal expenditure was travel to
25	physiotherapy appointments.
26	

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1	Tables 3 and 4 here
2	
3	Costs and consequences
4	Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data
5	are included giving variable denominators for each category. Comparing the two groups, there are
6	small differences in cost in some categories but for most of these the confidence intervals indicate
7	there is no evidence of a difference between the groups.
8	
9	Table 5 here
10	
11	Table 6 combines the results of the cost analysis with the full range of primary and secondary
12	outcomes, including QALYs.
13	
14	Table 6 here
15	
16	Results are presented for all available data, with cost categories combined. Again, denominators
17	vary within the table and they also differ from those in table 5 because sub-categories have been
18	collapsed. There was no evidence of a difference in the primary clinical outcome (the SF36v2 PCS)
19	between the groups, suggesting that PhysioDirect led to similar outcomes as usual physiotherapy
20	care. Patients in the PhysioDirect group had their first assessment and telephone advice 27 days
21	earlier than those in the usual care group, however patient satisfaction was slightly lower in those
22	receiving PhysioDirect. QALYs were higher in the PhysioDirect group by 0.009, which equates to
23	about 3.3 extra days of full health over a year.
24	
25	Cost-utility analysis

1	The cost-utility analysis presented in Table 7 uses complete cases, that is, we include only those		
2	patients for whom we had complete NHS cost and QALY data: 432 (58%) from the usual care group		
3	and 840 (56%) from PhysioDirect. The small extra cost of caring for patients in the PhysioDirect		
4	group was compensated for by the extra QALY gain, giving an incremental cost-effectiveness ratio of		
5	£2,889. If society is willing to pay £20,000 per QALY ²³ the net monetary benefit is £117 (95% CI -£96		
6	to £310) and there is 0.88 probability that the intervention is cost-effective. This is illustrated in the		
7	cost-effectiveness acceptability curve in figure 1.		
8			
9	Table 7 here		
10	Figure 1 here		
11			
12	Sensitivity Analysis		
13	The results of the four sensitivity analyses are shown in table 8 and figure 2. Scenario (1) indicates		
14	the potential cost-effectiveness of a more efficient PhysioDirect service. During the trial PhysioDirect		
15	clinic opening hours, physiotherapists spent about 35% of their time on the phone or dealing with		
16	directly related administration; in Bristol after the trial, this was increased to 57%. Under this		
17	scenario, the cost per patient in the PhysioDirect group was ± 14.53 less than under trial conditions		
18	and £2.11 less per patient in the usual care group. The ICER is therefore lower, at £1,045, the NMB		
19	correspondingly higher at £127 (λ =£20,000). At low levels of λ , the probability of PhysioDirect being		
20	cost-effective under this scenario is higher than with the base case, though at λ =£20,000 it reaches a		
21	similar value (see figures 1 and 2).		
22			
23	Table 8 here		
24	Figure 2 here		
25			

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1	The effect of removing hospital costs from the analysis is shown in sensitivity analysis (2). Hospital
2	costs accounted for 75% of all NHS costs yet only 19% (n=252) participants reported using any
3	secondary care. Hospital use was evenly divided between the two groups so removing these from
4	the analysis made very little difference to incremental analysis.
5	
6	The effect of imputing missing NHS cost and QALY data is explored in sensitivity analysis (3). Using
7	these data the cost of the interventions is lower but this is offset by higher NHS costs, giving a higher
8	mean total cost in both groups, by £21.41 in the usual care group and £6.58 in the PhysioDirect
9	group. QALYs using imputed data are lower, by 0.005 in the usual care group and by 0.010 in the
10	PhysioDirect group. The net effect is a reduction of both incremental cost and incremental QALYs,
11	giving an ICER of £2,260. Uncertainty around the ICER is reduced, as seen by the flatter CEAC in
12	figure 2.
13	
14	Sensitivity analysis (4) combines analyses (1) and (3) by using imputed cost data in the 'efficient
15	service' scenario. The results suggest a possible cost saving of £6.02 per patient; the probability that
16	the service is cost-effective at λ =£20,000 is 0.72.
17	
18	
19	DISCUSSION
20	Statement of principal findings
21	The results of this economic evaluation suggest that PhysioDirect services for patients with
22	musculoskeletal problems require careful management if they are to be a cost-effective alternative
23	to usual physiotherapy care. There was very little difference between the two groups in terms of
24	either outcomes or costs, and the finding that PhysioDirect is cost-effective is based on evidence
25	that it provides very slightly greater QALY benefits at very slightly greater cost.
26	

Clearer cost savings were observed in the sensitivity analysis that replicated the post-trial service, once greater flexibility in working arrangements was implemented. Without the restrictions of a trial environment staffing was adjusted to meet the anticipated demand, a call-back service was employed which accommodated fluctuations in activity during each session, referrals added to the system were adjusted regularly to reflect actual staffing and the number of patients waiting for a call-back and a higher throughput of patients led to greater economies of scale. These changes ensured physiotherapists within the PhysioDirect service spent a higher proportion of their PhysioDirect clinic time on the telephone with patients. There was no evidence of a difference between PhysioDirect and usual care in cost to patients and their families, or to society through the costs of lost production.

12 Strengths and weaknesses of the study

The study has a number of strengths. It is the first study assessing the cost-effectiveness of a PhysioDirect service including a large sample of patients with a wide range of musculoskeletal problems based across a number of locations.¹⁴ It uses a rigorous study design and conforms to CONSORT guidelines.⁴⁰ Follow up from participating patients was good, a high proportion of the resource use data were collected from GP records, and there was collection of resource use information outside of the main health service perspective. Nevertheless, there are also limitations. The proportion of eligible individuals consenting to participate in the trial was only 50%.²² Further, a particular difficulty in conducting economic evaluation with new service developments is ensuring that they are fully utilised.⁴¹ Although there was a clear run-in period prior to data collection for the trial (ranging from 4 to 12 weeks in each of the four sites), to ensure that services were operating as well as they could, and a 2:1 randomisation ratio in favour of PhysioDirect was used, there was still considerable underutilisation of the new service. This was ameliorated by including a more fully utilised service within the sensitivity analysis. Finally, because the differences in both costs and effects are small, there is still some uncertainty around the findings.

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2	The meaning of the study and implications for policy makers
3	If the aim of health services is to achieve maximum health gain from an investment in health care,
4	then PhysioDirect has a high probability of being more cost-effective than usual physiotherapy care.
5	This research also, however, suggests that it cannot be assumed that PhysioDirect will reduce costs,
6	although it could potentially do so if PhysioDirect services are managed efficiently. Both the costs
7	and cost-effectiveness of services will depend on the productivity of physiotherapist time. If
8	physiotherapists are able to use most of their time dealing directly with patients during sessions
9	when they are available on the telephone, then the service will be less costly. This is most likely to be
10	achieved by operating a call-back service and/or by operating the service on a large scale to even out
11	fluctuations in demand. Further efficiencies may also be achieved if these services are, in the future,
12	provided in conjunction with direct access for patients (rather than following referral from another
13	health care professional), given that patients who self-refer are likely to contact the service with
14	musculoskeletal problems of shorter duration, ⁴² and such patients may be particularly appropriate
15	for the initial assessment and advice provided by a PhysioDirect service. More generally, the study
16	has broader implications for telephone services, particularly around the implicit assumption that
17	such services will inevitably be money saving. Here this assumption was found to be false, largely
18	because the physiotherapists' time was underutilised during PhysioDirect clinic hours. Thus, for all
19	such services, it will be important for policy makers to ensure that easy assumptions about the costs
20	of these services are properly assessed in relation to factors such as how efficiently the service is
21	run, and what proportion of patients are subsequently invited for face to face care following an
22	initial telephone call.
23	

24 Unanswered questions and future research

As services evolve, further research should explore the costs and benefits of PhysioDirect under
 different scenarios. These might include: comparing different skill levels of staff operating the

service; the inclusion of patient self-referrals in addition to GP referrals; the use, or otherwise, of computerised support in assessing the patient; the extension to internet services (possibly combined with cameras);⁴³ and the use of mobile 'smartphone' technology, for example in rapid assessment of musculoskeletal injuries. In particular, however, it will be important to assess the costs and benefits of services once they are more established and provided on a wider scale. The costs and benefits of telehealth more generally need further exploration in relation to their cost effectiveness particularly given the negative findings of the Whole Systems Demonstrator project evaluating telehealth support and treatment for patients with long term conditions.⁴⁴ It would be helpful to identify those characteristics that are likely to make services both more cost-effective and less costly. are me.,

References

- Munro J, Nicholl, J, O'Cathain A et al. Impact of NHS Direct on demand for immediate care: observational study. *Br Med J* 2000;321:150-153.
- 2. Lattimer V, Sassi F, George S et al. Cost analysis of nurse telephone consultation in out of hours primary care: evidence from a randomised controlled trial. *Br Med J* 2000;320:1053-1057.
- Lattimer V, George S, Thompson F et al. Safety and effectiveness of nurse telephone consultation in out of hours primary care: randomised controlled trial. The South Wiltshire Out of Hours Project (SWOOP) Group. *Br Med J* 1998;317:1054-1059.
- Pinnock H, Bawden R, Proctor S et al. Accessibility, acceptability, and effectiveness in primary care of routine telephone review of asthma: pragmatic, randomised controlled trial. *Br Med J* 2003;326:477-479.
- Bunn F, Byrne G, Kendall S. Telephone consultation and triage: effects on health care use and patient satisfaction. *Cochrane Database of Systematic Reviews*. (4):CD004180, 2004. 2004;CD004180.
- 6. McKinstry B, Watson P, Pinnock H et al. Telephone consulting in primary care: a triangulated qualitative study of patients and providers. *Br J Gen Pract* 2009;59:e209-e218.
- 7. Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain* 2003;102:167-178.
- Jordan K, Ong BN, Croft P. Previous consultation and self reported health status as predictors of future demand for primary care. J Epidemiol Commun Health 2003;57:109-113.
- 9. McKormick A, Fleming D, and Charlton J *Morbidity statistics from general practice. Fourth national study 1991-1992 Serise MB5 no.3*. London: 1995.

- 10. Andersson GB. Epidemiological features of chronic low-back pain. Lancet 1999; 354: 581-585.
- 11. Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain 2000;84:95-103.
- 12. National Institute for Health and Clinical Excellence *Low back pain: early management of persistent non-specific low back pain. NICE clinical guideline 88.* 2009.
- Department of Health. Physiotherapy Services Summary Information for 2004-2005, England http://www.hscic.gov.uk/searchcatalogue?productid=4306&kwd=K&gran=Government+Office+ Regions&sort=Relevance&size=10&page=1#top (accessed 10.06.2013)
- 14. Salisbury C, Montgomery AA, Hollinghurst S et al. Effectiveness of PhysioDirect telephone assessment and advice services for patients with musculoskeletal problems: pragmatic randomised controlled trial. *Br Med J* 2013;346:f43.
- 15. Hodgson K. Kidderminster helpline proves a success. Physiotherapy Frontline 2001;7:22-23.
- 16. Taylor S, Ellis I, and Gallagher M. Patient satisfaction with a new physiotherapy telephone service for back pain patients. *Physiotherapy* 2002;88:645-657.
- 17. Clayson M and Woolvine M. Back pain direct clinic: a collaboration between general practitioners and physiotherapists. *Work Based Learning in Primary Care* 2004;2:38-43.
- Turner D. An exploratory study of physiotherapy telephone assessment. International Journal of Therapy and Rehabilitation 2009;16:97-105.
- 19. Russell T, Truter P, Blumke R, Richardson B. The diagnostic accuracy of telerehabilitation for nonarticular lower-limb musculoskeletal disorders. *Telemed J & E-Health* 2010;16:585-594.
- 20. Patel S, Hossain FS, Colaco HB et al. The accuracy of primary care teams in diagnosing disorders of the shoulder. *J Eval Clin Pract* 2011;17:118-122.

23 of 40	BMJ Open
	21. Jette DU, Ardleigh K, Chandler K et al. Decision-making ability of physical therapists: physical therapy intervention or medical referral. <i>Phys Ther</i> 2006;86:1619-1629.
	22. Salisbury C, Foster NE, Hopper C et al. A pragmatic randomised controlled trial of the
	effectiveness and cost-effectiveness of 'PhysioDirect' telephone assessment and advice services for physiotherapy. <i>Health Technology Assessment (Winchester, England)</i> /20;17:1-157.
	23. National Institute for Health and Clinical Excellence. Guide to the Methods of Technology Appraisal http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf
	(accessed 10.06.2013) 24. Brooks R, with the EuroQol Group. EuroQol: the current state of play. <i>Health Policy</i> 1996;53-72.
	25. Dolan P, Gudex C, Kind P et al. <i>A social tariff for EuroQol: Results from a UK general population survey</i> . University of York, 1-9-1995.
	26. Quality Metric. A community for measuring health outcomes using SF tools. http://www.sf- 36.org/ (accessed 10.06.2013)
	27. Paterson, C. Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 survey. <i>Br Med J</i> 1996;312:1016-1020.
	28. Pham T, Van Der Heijde D, Lassere M et al. Outcome variables for osteoarthritis clinical trials: The OMERACT-OARSI set of responder criteria. <i>J Rheumatol</i> 2003;30:1648-1654.
	29. British National Formulary. British National Formulary. http://www.bnf.org/bnf (accessed 10.06.2013)
	30. Curtis L. Unit costs of health and social care 2009. PSSRU, University of Kent, 2010.

31. Department of Health. NHS Reference costs 2009-2010.
https://www.gov.uk/government/publications/nhs-reference-costs-2009-2010 (accessed 10.06.2013)
32. National Health Service. NHS Drug tariff.

http://www.nhsbsa.nhs.uk/PrescriptionServices/924.aspx (accessed 10.06.2013)

33. The Automobile Association. The AA schedule of motoring costs.

http://www.theaa.com/motoring_advice/running_costs/index.html (accessed 10.06.2013)

- 34. Office for National Statistics. Annual survey of hours and earnings 2009 http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2009revised/index.html (accessed 10.06.2013)
- 35. Royal College of Nursing. Agenda for change pay rates http://www.nhscareers.nhs.uk/workingin-the-nhs/pay-and-benefits/agenda-for-change-pay-rates (accessed 10.06.2013)
- 36. Scott A, Simoens S, Heaney D, et al. What does GP out of hours care cost? An analysis of different models of out of hours care in Scotland. *Scot Med J* 2004;49:61-66.
- 37. Manca A, Hawkins N, Sculpher M. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. *Health Econ* 2005;14:487-496.
- 38. van Buuren S, Boshuizen HC, Knook D L. Multiple Imputation of missing blood pressure covariaties in survival analysis. *Stat Med* 1999;18:681-694:
- 39. StataCorp Statistical Software: Release 11. College Station, TX: StataCorp LP. 2009.
- 40. The CONSORT Group. CONSORT: the transparent reporting of trials http://www.consortstatement.org (accessed 10.06.2013)

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41. Coast J, Hensher M, Mulligan J, et al. Conceptual and practical difficulties with the economic evaluation of health services developments. J *Health Serv Res Policy* 2000;5:42-48.

42. Leemrijse CJ, Swinkels IC, Veenhof C. Direct access to physical therapy in the Netherlands: results from the first year in community-based physical therapy. Phys Ther. 2008 88(8):936-46

43. Li LC, Townsend AF, Badley EM. Self-management interventions in the digital age: new approaches to support people with rheumatologic conditions. Best Pract Res Clin Rheumatol. 2012 26(3):321-33.

44. Henderson C, Knapp M, Ferbnandez J-L. Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial. Br Med J 2013;34

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27 28	16	CS was principal investigator on the trial, SH took the lead on the economic evaluation. JC, NF, SG,		
29	17	JH, and AM were co-applicants and contributed to the conception and design. SH, JC and JB carried		
30 31	18	out the analysis with help from CS and AM, and all authors contributed to the interpretation of the		
32	19	data. SH and JC wrote the first draft of the paper with all authors contributing to subsequent		
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43 44	26	Gamlin and Nick Deane who developed the PhysioDirect assessment algorithms and software used		
45	27	in this trial.		
46 47	28	Data sharing		
48		The datasets will be made freely available on application to any bone-fide suitable qualified		
49 50		researcher upon submission of a protocol which provides a research question and research design		
51		which could be addressed by the data from this study, has been peer reviewed and received		
52 53		ethical and research governance approvals. Users of the data will also be subject to a written		
53 54		agreement which complies with the MRC guidance. Data will be made available for sharing only after the publication of the final project report and the main papers in peer reviewed journals.		
55		and the publication of the final project report and the main papers in peer reviewed journals.		
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4	Table 1: Data sources and unit costs	
5	Table 1. Data sources and unit costs	
6		
7		Unit cost (£)
8	Primary and Community Care ³⁰	
9	General Practitioner	
10	Surgery	27.00
11	Telephone consultation	16.00
12	Home visit	91.00
13	Practice nurse	51.00
14		10.00
15	Surgery	
16 17	Telephone consultation	5.93
18	Health Care Assistant/phlebotomist	
19	Surgery	6.92
20	District Nurse	
21	Home visit	16.33
22		
23	Out of Hours ⁴¹	
24	General practitioner	23.50
25		
26	Hospital care ³¹	
27		
28	A&E	103.00
29		By Healthcare Resource Group,
30	Outpatient visits	differentiated by first and follow-up
31	Inpatient stays	By Healthcare Resource Group
32		by mediated resource croup
33		
34	Prescribed medication ²⁹	per item, by name, strength and amount
35		
36	Mileage ³³	0.4612
37		
38 39	Time off work ³⁴	Median national wage by age and sex
40		
40 41		
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Table 2: Number of physiotherapy consultations and mean duration, by type and group

		Usual care (n=743)	PhysioDirect (n=1506
Face-to-face	mean (SD) number	3.11(2.63)	1.91(2.72
appointments	mean (SD) total	107.51(88.92)	64.20(89.31
	duration (minutes)		
Telephone	mean (SD) number	0.13(0.44)	0.96 (0.63
appointments	mean (SD) total	4.21(14.64)	27.37(19.92
	duration (minutes)	(,	
Home visits	mean (SD) number	0.00 (0.06)	0.00 (0.06
	mean (SD) total	0.14(2.27)	0.12(2.12
	duration (minutes)	0.11(2.27)	0.12(2.12
All physiotherapy	mean (SD) number	3.25(2.70)	2.87(2.94
contacts	mean (SD) total	111.86(90.50)	91.70 (95.40)
	duration (minutes)		

Table 3: Health services resource use,	, by group. All available data.
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2 3 4 5 6 7					
4 5					
6 7	Table 3: Health services resource use, by group	. All availab	le data.		
8 9					
10		Mean (SD) number of cons	ultations	
11 12					
13 14		n	usual care	n	PhysioDirect
15 16	GP consultations	739	0.77(1.47)	1484	0.87 (1.68)
17			, , , , , , , , , , , , , , , , , , ,		, , , , , , , , , , , , , , , , , , ,
18 19	Nurse consultations	739	0.04 (0.22)	1484	0.06 (0.32)
20 21	Other primary care consultations	739	0.02(0.14)	1484	0.02 (0.17)
22			0.02(0.2.)	2.0.	0.02 (0.27)
23 24	Total number of primary care contacts	739	0.83(1.56)	1484	0.96 (1.84)
25 26					
27 28					
29	Number of prescriptions	728	1.36 (2.73)	1469	1.68 (3.72)
30 31					
32 33					
34	A&E (visits)	467	0.02 (0.01)	912	0.03 (0.01)
35 36					/
37 38	Out-patient (consultations)	467	0.17 (0.83)	910	0.35 (1.03)
39 40	In-patient stays (Finished Consultant Episodes)	465	0.01 (0.10)	910	0.01 (0.10)
41					
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Table 4: Patient and societal resource use, by group. All available data.

Number (%) reporting:	n	usual care	n	PhysioDirect
Expenditure on travel to physiotherapy	462	242 (52.4)	1232	308 (25.8)
Expenditure on travel to primary care	669	116 (17.3)	1337	237 (17.7)
Expenditure on over-the-counter medication	506	256 (50.6)	1028	512 (49.8)
Expenditure on prescriptions	559	264 (47.2)	1085	508 (46.8)
Expenditure on private therapy	484	89 (18.4)	934	167 (17.9)
Equipment purchase	480	139 (29.0)	939	233 (24.8)
Payments for extra domestic help	459	35 (7.6)	928	76 (8.2)
Loss of earnings	598	30 (5.5)	1209	64 (5.3)
Any time off to attend physiotherapy consultation	692	218 (31.5)	1416	380 (26.8)
Work has been affected because of condition	477	141 (29.6)	959	317 (33.1)



Table 5: Mean total cost per patient, by group and category. All available data^a.

3 4		ost pei	patient, by grou	p anu ca	legory. An available	uala .
5						Incremental difference
6 7			usual care			
8		n	mean (SD) cost	n	mean (SD) cost	(95% Confidence
9 10 11			mean (SD) cost			Interval)
12 13	Physiotherapy services					
14						
15	Face-to-face appointments	743	£64.42 (£53.00)	1506	£38.76 (£53.92)	-£25.66 (-£30.37 to -£20.95)
16 17	Telephone appointments	743	£5.22 (£18.01)	1506	£35.17 (£26.34)	£29.94 (£27.84 to £32.05)
18	Home visits	743	£0.08 (£1.33)	1506	£0.08 (£1.46)	£0.00 (-£0.12 to £0.13)
19	Total physiotherapy cost	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.69)
20 21	Primary care services		6			
22 23	GP consultations	739	£19.21 (£35.91)	1484	£21.69 (£41.66)	£2.48 (-£1.04 to £6.00)
24 25 26	Nurse consultations	739	£0.44 (£2.37)	1484	£0.61 (£3.17)	£0.16 (-£0.10 to £0.42)
27	Other primary care					
28 29	consultations	739	£0.03 (£0.57)	1484	£0.07 (£1.31)	£0.05 (-£0.05 to £0.15)
30 31	Total primary care cost	739	£19.68 (£36.68)	1484	£22.37 (£42.83)	£2.69 (-£0.92 to £6.30)
32 33 34	Medication cost	728	£11.04 (£51.61)	1469	£10.33 (£55.43)	-£0.72 (-£5.53 to £4.10)
35 36	Hospital services					
37 38	A&E	467	£1.99 (£17.12)	912	£3.17 (£20.84)	£1.18 (-£1.01 to £3.37)
39 40 41	Out-patient	467	£30.74 (£98.36)	910	£38.35 (£126.05)	£7.61 (-£5.50 to £20.72)
41 42 43	In-patient	465	£51.02 (£520.48)	910	£34.99 (£399.62)	-£16.03 (-£65.70 to £33.64)
44 45	Total hospital cost	459	£83.04 (£561.68)	899	£77.00 (£446.24)	-£6.04 (-£60.99 to £48.91)
46 47	Personal expenditure					
48 49	Cost of all calls to	740	CO 07 (CO 00)	1500	C1 75 (C1 20)	£0.79 (£0.68 to £0.89)
50 51	physiotherapy service	743	£0.97 (£0.99)	1506	£1.75 (£1.29)	
52 53	Travel to physiotherapy	462	£6.11 (£11.48)	1232	£3.11 (£8.51)	-£3.01 (-£4.01 to -£2.00)
54 55	Travel for primary care	669	£0.65 (£2.93)	1337	£0.75 (£4.10)	£0.11 (-£0.24 to £0.45)
56 57 58	Over-the-counter medication	490	£7.67 (£14.09)	987	£8.61 (£22.38)	£0.94 (-£1.23 to £3.11)

Cost of prescriptions	553	£2.72 (£8.95)	1076	£2.67 (£8.33)	-£0.05 (-£0.93 to £0.82
Private therapy	475	£21.98 (£70.34)	915	£39.34 (£296.94)	£17.36 (-£9.76 to £44.48
Equipment purchase	473	£17.16 (£169.12)	924	£9.12 (£56.42)	-£8.04 (-£20.08 to £4.00
Extra domestic help	451	£10.93 (£64.31)	905	£13.68 (£96.02)	£2.75 (-£7.07 to £12.56
Cost associated with loss of	598	£46.69 (409.72)	1209	£82.78 (£885.85)	£36.09 (-£38.63 to £110.81
earnings					
Value of time off work					
Time off work to attend	598	£12.90 (£38.99)	1211	£11.91 (£57.86)	£0.95 (-£3.81 to £5.70
physiotherapy Time off work associated with		£265.92			
the condition	452	(£1350.82)	884	£226.61(£1139.84)	£111.31 (-£159.04 to £379.67

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Table 6: Cost-consequences. All available data^a.

	n (%)	usual care	n (%)	PhysioDirect	Incremental difference (95% Confidence Interval)
Mean (SD) Cost					
Total physiotherapy cost	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.69)
Cost of NHS services including physiotherapy	453 (61%)	£189.19 (£557.61)	888 (59%)	£196.43 (£472.02)	£7.24 (-£49.68 to £64.10)
Total personal expenditure	310 (42%)	£121.10 (£571.15)	714 (47%)	£166.40 (£1040.27)	£45.30 (-£78.01 to £168.61)
Total value of all time off work ^b	451 (61%)	£276.75 (£1355.00)	883 (59%)	£240.74 (£1147.20)	-£36.01 (-£174.69 to £102.66)
Consequences ^c					Difference/odds ratio (95% confidence interval) ^d
SF36v2 PCS	629 (85%)	44.18 (10.84)	1283 (85%)	43.50 (10.94)	-0.01 (-0.80 to 0.79)
MYMOP ^e	518 (70%)	2.40 (1.38)	1033 (69%)	2.40 (1.43)	-0.02 (-0.16 to 0.11)
Global improvement score	501 (67%)	4.07 (1.40)	1001 (66%)	4.01 (1.44)	-0.08 (-0.23 to 0.08)
Response to treatment (OMERACT OARSI)	510 (69%)	197 (38.6%)	1029 (68%)	430 (41.8%)	1.14 (0.92 to 1.43)
Waiting time to first assessment and advice	618 (83%)	34 (20 to 55) ^f	1281 (85%)	7 (4 to 15) ^f	0.32 (0.29 to 0.35) ^g
Patient overall satisfaction	367 (49%	79.7 (26.5)	739 (49%)	75.9 (28.3)	-3.8 (-7.3 to -0.3)
QALYs ^h	454 (61%)	0.322 (0.079)	881 (58%)	0.331 (0.082)	0.009 (-0.000 to 0.018)
a	·				
 ^a Uses all available data, so denon ^b Total of time off to attend physiot ^c At 6 month follow-up time point 		, ,	ion		
^d Adjusted for outcome at baseline	, gender, age, r	eferral problem, PCT			
^e Lower score is better					
^f Median (IQR)					
⁹ Accelerated failure time analysis ^h Adjusted for outcome at baseline					
Adjusted for outcome at baseline					

Table 7: Cost-effectiveness analysis. Includes cases with complete data on NHS costs and QALYs

n	usual care	n	PhysioDirect	Incremental difference
	mean (SD) cost		Mean (SD) cost	(95% CI
432	£78.77 (£57.08)	840	£86.75 (£65.47)	£7.98 (£0.69 to £15.27
432	£100.91 (£502.02)	840	£112.23 (£476.91)	£11.32 (-£45.08 to £67.72
432	£179.68 (£504.73)	840	£198.98 (482.12)	£19.30 (-£37.60 to £76.19
432	0.325 (0.077)	840	0.332 (0.081)	0.007 (-0.003 to 0.016
R)				£2,88
ased on boot	strapped results:			
				£117 (-£86 to £310
t-effective				0.8
				£184 (-£106 to £461
t-effective				0.90
	432 432 432 432 432 R) pased on boot	432 £78.77 (£57.08) 432 £100.91 (£502.02) 432 £179.68 (£504.73) 432 0.325 (0.077)	mean (SD) cost 432 £78.77 (£57.08) 840 432 £100.91 (£502.02) 840 432 £179.68 (£504.73) 840 432 0.325 (0.077) 840 R) t-effective	mean (SD) cost Mean (SD) cost 432 £78.77 (£57.08) 840 £86.75 (£65.47) 432 £100.91 (£502.02) 840 £112.23 (£476.91) 432 £179.68 (£504.73) 840 £198.98 (482.12) 432 0.325 (0.077) 840 0.332 (0.081)

Table 8: Sensitivity Analysis

	n	Usual care mean (SD)	n	PhysioDirect mean (SD)	Incremental difference (95% confidence interval)
(1) mimicking an efficient service					
Cost of physiotherapy	432	£76.56 (£55.34)	840	£72.22 (£61.55)	-£4.34 (-£11.25 to £2.5
Cost of NHS services	432	£100.91 (£502.02)	840	£112.23 (476.91)	£11.32 (-£45.08 to £67.7
Total cost	432	£177.46 (£504.49)	840	£184.44 (£481.83)	£6.98 (-£49.89 to £63.8
Incremental cost-effectiveness ra Median Net Monetary Benefit (95	•	•	results:		£1,04
λ=£20,000					£127 (-£74 to £31
λ=£30,000					£193 (-£95 to £47
(2) Excluding hospital costs					
Cost of physiotherapy	448	£78.49 (£57.14)	869	£86.84 (£65.25)	£8.35 (£1.21 to £15.5
Cost of NHS services excluding					
secondary care	448	£33.75 (£76.46)	869	£33.49 (£63.76)	-£0.25 (-£8.05 to £7.5
Total cost of NHS services					£8.10 (-£3.21 to £19.4
including physiotherapy	448	£112.23 (£99.621)	869	£120.33 (£98.85)	18.10 (-13.21 (0 113.4
Incremental cost-effectiveness ra	tio (ICER	3)			£1,08
Median Net Monetary Benefit (95	5% CI) ba	ased on bootstrapped	results:		
λ=£20,000					£142 (-£41 to £32
λ=£30,000					£217 (-£56 to £48
(3) Imputed data					
Cost of physiotherapy	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.6
Cost of NHS services	743	£131.37 (£465.49)	1506	£131.51 (£384.36)	£0.17 (-£36.13 to £36.4
Total cost of NHS services	743		1506	£205.55 (£390.04)	£4.46 (-£32.22 to £41.1
including physiotherapy		£201.09 (£467.51)			L4.40 (*E32.22 (U E41.1
Quality Adjusted Life Years	743	0.320 (0.003)	1506	0.322 (0.002)	0.002 (-0.006 to 0.00

Page 36 of 40

	B	MJ Op	en	
Incremental cost-effectiveness ratic	(ICER)			£2,260
Median Net Monetary Benefit (95%	CI) based on bootstrappe	d results	:	
λ=£20,000				£34 (-£119 to £193)
λ=£30,000				£52 (-£172 to £285)
(4) Imputed data and 'efficient' ser Cost of physiotherapy	vice 743 £67.61 (£54.19)	1506	£61.41 (£59.13	-£6.20 (-£11.26 to -£1.14)
Cost of NHS services	743 £131.37 (£465.49)	1506	£131.54 (384.36)	£0.17 (-£36.13 to £36.48)
Total cost of NHS services	743 £198.98 (£467.48)	1506	£192.95 (£389.52)	-£6.02 (-£42.68 to £30.63)
Quality Adjusted Life Years	743 0.320 (0.003)	1506	0.322(0.002)	0.002 (-0.006 to 0.009)
Incremental cost-effectiveness ratio	(ICER)			-£3,054
Median Net Monetary Benefit (95% λ=£20,000	Cl) based on bootstrappe	d results	:	£47 (-£113 to £202)
λ=£30,000				£67 (-£165 to £293)

Figure 1. Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different levels of willingness to pay for one Quality Adjusted Life Year

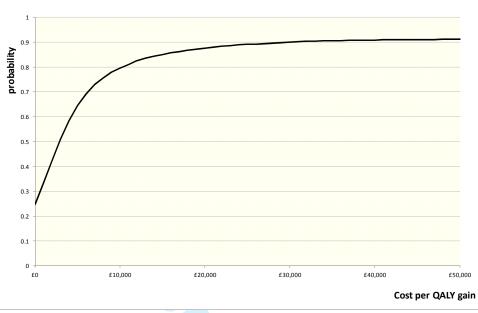
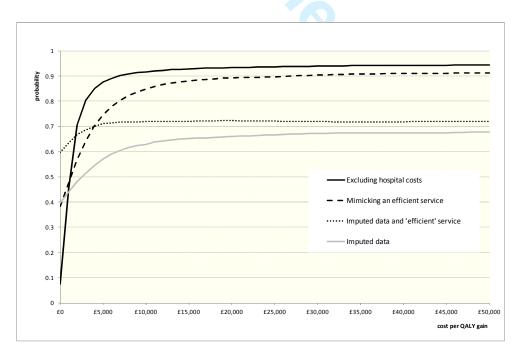


Figure 2. Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different levels of willingness to pay for one Quality Adjusted Life Year: Sensitivity Analyses



			Reported on	
	Item		page No/	
Section/item	No	Recommendation	line No	
Title and abstract				
Title	1	Identify the study as an economic evaluation or use more specific		
		terms such as "cost-effectiveness analysis", and describe the	1/1-3	
		interventions compared.		
Abstract	2	Provide a structured summary of objectives, perspective, setting,		
		methods (including study design and inputs), results (including base	P2-3	
		case and uncertainty analyses), and conclusions.		
Introduction				
Background and	3	Provide an explicit statement of the broader context for the study.		
objectives		Present the study question and its relevance for health policy or	- // // // //	
		practice decisions.	5/1 - 6/20	
Methods				
Target population and	4	Describe characteristics of the base case population and subgroups		
subgroups		analysed, including why they were chosen.	7/12-16	
Setting and location	5	State relevant aspects of the system(s) in which the decision(s)		
		need(s) to be made.	7/12-16	
Study perspective	6	Describe the perspective of the study and relate this to the costs being		
		evaluated.	7/1-9	
Comparators	7	Describe the interventions or strategies being compared and state why	= (2.2 - 2.42	
		they were chosen.	7/20 - 8/2	
Time horizon	8	State the time horizon(s) over which costs and consequences are being		
		evaluated and say why appropriate.	6/25 - 7/1	
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and		
		say why appropriate.	13/4-5	
Choice of health	10	Describe what outcomes were used as the measure(s) of benefit in the		
outcomes		evaluation and their relevance for the type of analysis performed.	8/5-13	
Measurement of	11a	Single study-based estimates: Describe fully the design features of the		
effectiveness		single effectiveness study and why the single study was a sufficient	6/25-7/1	
		source of clinical effectiveness data.	7/12-17	
	11b	Synthesis-based estimates: Describe fully the methods used for		
		identification of included studies and synthesis of clinical effectiveness	n/a	
		data.		

Measurement and	12	If applicable, describe the population and methods used to elicit	8/5-6
valuation of preference		preferences for outcomes.	12/6-7
based outcomes			12/0 /
Estimating resources	13a	Single study-based economic evaluation: Describe approaches used to	
and costs		estimate resource use associated with the alternative interventions.	
		Describe primary or secondary research methods for valuing each	8/16 - 11/23
		resource item in terms of its unit cost. Describe any adjustments made	
		to approximate to opportunity costs.	
	13b	Model-based economic evaluation: Describe approaches and data	
		sources used to estimate resource use associated with model health	
		states. Describe primary or secondary research methods for valuing	n/a
		each resource item in terms of its unit cost. Describe any adjustments	
		made to approximate to opportunity costs.	
Currency, price date,	14	Report the dates of the estimated resource quantities and unit costs.	
and conversion		Describe methods for adjusting estimated unit costs to the year of	
		reported costs if necessary. Describe methods for converting costs into	11/25
		a common currency base and the exchange rate.	
Choice of model	15	Describe and give reasons for the specific type of decision-analytical	
		model used. Providing a figure to show model structure is strongly	n/a
		recommended.	
Assumptions	16	Describe all structural or other assumptions underpinning the decision-	,
		analytical model.	n/a
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could	
		include methods for dealing with skewed, missing, or censored data;	
		extrapolation methods; methods for pooling data; approaches to	12/7-10
		validate or make adjustments (such as half cycle corrections) to a	12/23-13/2
		model; and methods for handling population heterogeneity and	
		uncertainty.	
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability	
		distributions for all parameters. Report reasons or sources for	
		distributions used to represent uncertainty where appropriate.	n/a
		Providing a table to show the input values is strongly recommended.	
Incremental costs and	19	For each intervention, report mean values for the main categories of	
outcomes		estimated costs and outcomes of interest, as well as mean differences	15/1-23
		between the comparator groups. If applicable, report incremental cost-	Tables 5,6,7
		effectiveness ratios.	

Characterising	20a	Single study-based economic evaluation: Describe the effects of	16/1-7
uncertainty		sampling uncertainty for the estimated incremental cost and	Table 7
		incremental effectiveness parameters, together with the impact of	Figure 1
		methodological assumptions (such as discount rate, study perspective).	16/13 - 17/16
			Table 8
			Figure 2
	20b	Model-based economic evaluation: Describe the effects on the results	
		of uncertainty for all input parameters, and uncertainty related to the	n/a
		structure of the model and assumptions.	
Characterising	21	If applicable, report differences in costs, outcomes, or cost-	
heterogeneity		effectiveness that can be explained by variations between subgroups of	
		patients with different baseline characteristics or other observed	n/a
		variability in effects that are not reducible by more information.	
Discussion			
Study findings,	22	Summarise key study findings and describe how they support the	
limitations,		conclusions reached. Discuss limitations and the generalisability of the	
generalisability, and		findings and how the findings fit with current knowledge.	17/21 - 18/26
current knowledge			
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the	
		identification, design, conduct, and reporting of the analysis. Describe	26/6-11
		other non-monetary sources of support.	
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in	
		accordance with journal policy. In the absence of a journal policy, we	
		recommend authors comply with International Committee of Medical	26/1-3

For consistency, the CHEERS statement checklist format is based on the format of the CONSORT statement checklist



A pragmatic randomised controlled trial of 'PhysioDirect' telephone assessment and advice services for patients with musculoskeletal problems: economic evaluation

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A pragmatic randomised controlled trial of 'PhysioDirect' telephone assessment and advice services for patients with musculoskeletal problems: economic evaluation

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Key Words: economic evaluation; physiotherapy; telehealth; primary care; cost & cost analysis

A pragmatic randomised controlled trial of 'PhysioDirect' telephone assessment and advice services for patients with musculoskeletal problems: economic evaluation

ABSTRACT

Objectives

To compare the cost-effectiveness of PhysioDirect with usual physiotherapy care for patients with musculoskeletal problems.

Design

(i) Cost-consequences comparing cost to the NHS, to patients, and the value of lost productivity with a range of outcomes. (ii) Cost-utility analysis comparing cost to the NHS with Quality Adjusted Life Years (QALYs)

Setting

Four physiotherapy services in England

Participants

Adults (18+) referred by their general practitioner or self-referred for physiotherapy.

Interventions

PhysioDirect involved telephone assessment and advice followed by face-to-face care if needed. Usual care patients were placed on a waiting list for face-to-face care.

Primary and secondary outcomes

Primary clinical outcome: physical component summary from the SF-36v2 at six months. Also included in the cost-consequences: Measure Yourself Medical Outcomes Profile; a Global Improvement Score; response to treatment; patient satisfaction; waiting time. Outcome for the cost-utility analysis: QALYs

Results

2249 patients took part (1506 PhysioDirect; 743 usual care).

(i) Cost-consequences: there was no evidence of a difference between the two groups in the cost of physiotherapy, other NHS services, personal costs or value of time off work. Outcomes were also similar.

(ii) Cost-utility analysis based on complete cases (n=1,272). Total NHS costs, including the cost of physiotherapy were higher in the PhysioDirect group by £19.30 (95% CI: -£37.60 to £76.19) and there was a QALY gain of 0.007 (95% CI: -0.003 to 0.016). The incremental cost-effectiveness ratio was £2,889 and the net monetary benefit at λ =£20,000 was £117 (95% CI: -£86 to £310)

Conclusions

PhysioDirect may be a cost-effective alternative to usual physiotherapy care, though only with careful management of staff time. Physiotherapists providing the service must be more fully occupied than was possible under trial conditions: consideration should be given to the scale of operation, opening times of the service, and flexibility in the methods used to contact patients.

Article Summary

Article focus

- What is the cost of providing PhysioDirect telephone assessment and advice, followed by face-to-face care if needed, to adults with musculoskeletal pain problems, compared with usual physiotherapy care?
- What are the patient benefits of PhysioDirect compared with usual care?
- Is PhysioDirect a cost-effective alternative to usual care for primary care patients with musculoskeletal conditions?

Key messages

- There was very little difference between the two groups in terms of cost or outcomes
- PhysioDirect has potential to be a cost-effective alternative to usual care but requires careful management of staff resources

Strengths and limitations of this study

- Findings are based on a large sample of patients with a wide range of musculoskeletal problems based in diverse locations
- The study takes a broad perspective, including the health care provider, patients, and a valuation of lost productivity
- Physiotherapists were constrained by trial conditions and were underutilised

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1 INTRODUCTION

There is a trend to explore the use of new technology in the delivery of health care, particularly the use of telephone assessment and triage, as for example in NHS Direct.¹ These services aim to better manage patient demand, and research has shown that telephone based services can be safe, clinically accurate, cost-effective, acceptable to patients, and reduce the workload of clinicians,²⁻⁵ although there have been some concerns about using telephone triage in patients presenting with acute health problems.⁶

8

9 Musculoskeletal pain problems are one of the most common causes of disability. Over a quarter of 10 all patients registered in general practice will consult at least once for a musculoskeletal problem each year,^{7,8} with musculoskeletal pain accounting for around 15% of all GP consultations.⁹ This high 11 prevalence of musculoskeletal problems¹⁰ results in large direct and indirect healthcare costs: for 12 13 example, low back pain alone has recently been estimated to cost the UK economy £15.84 billion a vear.^{11, 12} Most patients are managed with advice and analgesia but many are referred to 14 physiotherapists, with 1.23 million new referrals each year from GPs and 4.4 million in total.¹³ 15 16 Ensuring timely access to physiotherapy has long been an issue within the UK NHS, with waiting 17 times of more than four months in some areas. Patients may suffer unnecessary pain and disability, 18 and there are high productivity losses: for example, back pain accounts for some 120 million days of certified absence from work each year.¹⁴ Delay may also cause NHS inefficiencies on the one hand as 19 20 some patients recover and do not attend their physiotherapy appointment when it finally arrives, 21 whilst on the other, some patients continue to access more expensive forms of treatment whilst 22 awaiting their appointment.

23

In response to these problems, physiotherapy services have drawn on the new service models and a
range of 'PhysioDirect' services have been developed. These vary in format though they commonly
involve a physiotherapist assessing a patient's musculoskeletal pain problem over the telephone,

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1	sometimes supported by computerised assessment templates, offering tailored, self-management
2	advice supplemented by written advice sent by post. Alternatively if the assessment findings
3	suggest that face-to-face care is needed this is arranged, and patients who are initially managed by
4	telephone advice can phone back for further advice and/or face-to-face treatment. ¹⁵ There is,
5	however, limited evidence about the costs and benefits of this approach within physiotherapy. Local
6	evaluations and non-randomised studies suggest that these services may be popular with patients ¹⁶⁻
7	¹⁸ and diagnoses made by physiotherapists over the telephone are comparable to diagnoses reached
8	in face-to-face assessments ¹⁹⁻²¹ although there is some concern that the experience of the
9	physiotherapist providing the telephone assessment might be important. ^{19,22}
10	
11	In particular there is no information about the costs or cost-effectiveness of PhysioDirect services,

12 despite: (i) a major underlying rationale for their development being to generate greater efficiency

13 in the use of resources; and (ii) a ready presumption that telephone-based services result in lower

14 costs (by assuming that services better use physiotherapy time, use less costly telephone

15 consultations and reduce rates of appointment non-attendance). Without such evidence, preferably

16 generated alongside high quality primary evidence obtained using rigorous study designs, it remains

17 unclear whether such services should be more widely implemented. This paper reports the results of

18 an economic evaluation conducted alongside a randomised controlled trial powered to generate

19 evidence on whether PhysioDirect services for primary care patients with musculoskeletal problems

- 20 produce equivalent outcomes to usual face-to-face services.
- 21

22

23 **METHOD**

24 Study design

25 We conducted an economic evaluation alongside a randomised controlled trial to establish the cost-

26 effectiveness of PhysioDirect compared with usual care based only on face-to-face treatment over a

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1	period of 6 months. The trial and its clinical findings have been reported in full elsewhere. ^{15,23} The
2	aim of the evaluation was to provide information about the long-run costs and benefits of the
3	alternative methods of running a physiotherapy service for this patient group so with that in mind
4	we excluded the initial set up costs associated with establishing the new telephone service, including
5	the training undertaken by the practitioners. ²⁴ As the nature of the intervention suggests there could
6	be an impact on patients' costs, and as it is known that musculoskeletal conditions account for a
7	considerable amount of time off work ¹⁴ we chose to use a cost-consequences approach, comparing
8	cost from all three perspectives (health care provider, patients and carers, lost productivity) with a
9	range of clinical outcomes. ^{25,26} However, the perspective of greatest interest to UK policy makers is
10	the health and social care provider ²³ so we also conducted a cost-utility analysis to compare cost to
11	the National Health Service (NHS) with Quality-Adjusted Life-Years (QALYs).
12	
13	Setting and participants
14	We recruited adults aged 18 and over from four community physiotherapy services in England –

15 Bristol, Somerset, Stoke-on-Trent, and Cheshire – which provided diversity in terms of socio-

16 economic status and a mix of urban and rural communities. All patients referred by their general

17 practitioner (GP), or who referred themselves, for physiotherapy for a non-urgent musculoskeletal

18 problem were invited to take part. Patients were randomised to PhysioDirect or usual care on a two

19 to one basis to increase the chances of the PhysioDirect service being fully utilised.

20

21 Interventions

The intervention has been reported in detail elsewhere^{15,25}. Patients randomised to the PhysioDirect
service received an invitation to telephone a senior (band 6 or above) specially trained
physiotherapist, who assessed their musculoskeletal problem with the aid of previously developed
computerised templates.²³ These templates were provided by Huntingdonshire Primary Care Trust,
which has been operating a similar service since 2001. Patients were then sent appropriate advice

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leaflets about self-management and exercises to try at home, and invited to phone again and/or
 make a face-to-face appointment if necessary. If the service was engaged when the patient called
 the call was answered by a receptionist who added the patient to a 'call-back' list and the
 physiotherapist would return the call when they were free. Patients randomised to usual care were

5 put on the usual service waiting list for face-to-face assessment and treatment.

6

#### 7 Outcome measures

We used the EQ-5D-3L²⁸, valued using the UK tariff,²⁹ to estimate QALYs gained for the cost-utility 8 9 analysis. The primary outcome for the trial was the physical component summary (PCS) measure from the SF-36v2 guestionnaire³⁰ and secondary clinical outcomes included: the Measure Yourself 10 Medical Outcomes Profile (MYMOP);³¹ a Global Improvement Score – a single question about overall 11 12 improvement; a composite measure of response to treatment including pain, function and overall improvement (OMERACT OARSI);³² patient satisfaction; and waiting time to first treatment advice 13 from a physiotherapist. All outcomes (except the global improvement score and waiting time to first 14 15 treatment advice) were measured at baseline, 6 weeks and 6 months and were obtained from a self 16 completed guestionnaire administered at these three time points.

17

#### 18 **Resource use**

19 The analysis was based on costs related to the reason for which the patient was referred to the

20 physiotherapy service. We identified relevant resources in discussion with participating

21 physiotherapists and service managers. Direct costs to the health care provider included: cost of

- 22 initial and follow-up physiotherapy consultations; primary and community consultations; hospital
- 23 care; and prescribed medication. Patient and carer costs included: telephone calls to the
- 24 PhysioDirect service; travel; over the counter medication; prescription costs; private therapy and
- 25 purchase of equipment; extra domestic help; and loss of earnings. Lost productivity was estimated

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1	separately in relation to time off work to attend physiotherapy appointments and time off because
2	of the musculoskeletal condition itself.
3	
4	Patient level data about all physiotherapy appointments and consultations were recorded either
5	automatically by computer or by the physiotherapist treating the patient. For those in the
6	intervention group, the PhysioDirect assessment software recorded which physiotherapist
7	conducted each telephone call, and the duration of each call. In addition to the time logged on to
8	the system physiotherapists had to carry out administrative activities following each telephone call,
9	such as collating information to send to the patient by post. The time spent on these activities was
10	estimated from information available at one site (Bristol) where manual recording of the entire
11	encounter supplemented the electronic recording.
12	
13	Physiotherapists assigned to the PhysioDirect service were required to be available throughout the
14	time the service was 'open' but they were not usually fully engaged in dealing with PhysioDirect
15	patients during these hours. We conducted an observational time and motion study at each of the
16	four sites to determine how they occupied their non-PhysioDirect contact time in order to apportion
17	costs appropriately. Time and motion data were collected at points in the study when the sites were
18	expected to be fully operational, and across a mix of day, time of day, and location. The capital costs
19	required to run a telephone service are potentially less than for a face-to-face service. Each site
20	provided information about space and equipment required to run their telephone service and we
21	used this to estimate an overall percentage reduction of capital costs for these compared with a
22	standard face-to-face service.
23	
24	Data about all face-to-face appointments were recorded routinely. These data included the length of
25	appointment, the grade of the physiotherapist seen, and information about missed appointments.
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1	Information about other NHS resource use was collected, where possible, from general practice
2	records and supplemented by information gained directly from patients. General practice notes
3	were scrutinised for patient level data on primary care consultations and prescribed medication. We
4	included all consultations at which the musculoskeletal condition for which the patient was referred
5	to physiotherapy was mentioned and these were recorded by type of consultation (for example,
6	face-to-face, telephone, out of hours, home visit) and by type of professional seen (for example, GP,
7	nurse). It was not feasible to distinguish between medication prescribed for the condition for which
8	the patient was referred for physiotherapy and any other musculoskeletal problem so we included
9	all medication of a potentially relevant type, defined using British National Formulary (BNF) ³³ coding.
10	These were: Analgesics (chapters 4.7.1 – 4.7.2); Non-steroidal anti-inflammatory drugs (10.1.1);
11	Local corticosteroid injections (10.1.2.2); and Drugs for the relief of soft-tissue inflammation (10.3).
12	
13	A questionnaire was administered to participants at 6 weeks and 6 months after randomisation to
14	obtain resource use data not available elsewhere. The questionnaire was designed specifically for
15	this study but was similar in content and structure to others used for the same purpose ³⁴ Questions
16	included information about hospital care related to the condition for which the patient was referred
17	to physiotherapy: visits to Accident & Emergency, outpatient appointments, and inpatient stays.
18	Information about personal expenditure relevant to the patient's musculoskeletal condition was also
19	gained from the questionnaire at 6 weeks and 6 months. We asked about the cost of travel to
20	physiotherapy and other health care appointments, expenditure on over the counter medication,
21	prescription costs, use of private therapies and their cost, expenditure on equipment or devices, and
22	extra help at home. In addition, participants were asked about any time off work, and the associated
23	loss of earnings, because of their condition or to attend health care appointments relating to the
24	condition including usual care physiotherapy and PhysioDirect.

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#### Valuation of resource use

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1	Table 1 gives the unit costs and sources used to value the health care resources. We used Curtis ³⁵ to
2	value primary and community health care and Department of Health reference costs ³⁶ for all
3	hospital-based care. The cost of prescribed medication was estimated from that published in the
4	BNF, ³³ adjusted to allow for the discount available to the NHS, and the professional fee and
5	container allowance in accordance with the Drug Tariff for England. ³⁷ Personal expenditure was
6	reported directly by the participants, the exception being travel by car, which was reported as
7	mileage and costed using the AA schedule of motoring costs. ³⁸ Time off work was valued using the
8	median gross weekly earnings by age and sex. ³⁹
9	

The cost of face-to-face physiotherapy consultations was estimated by adapting the methods of Curtis³⁵ to obtain a different unit cost for each band of staff at each site. National median pay rates, by band,⁴⁰ were adjusted to allow for National Insurance, superannuation, and overheads, as per Curtis, then further adjusted to allow for band and site specific non-contact time. Information about the proportion of time physiotherapists on each grade typically spend in direct contact with patients was provided by the four physiotherapy service managers. This provided us with a cost per hour for each band of staff at each site.

Table 1 here

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The unit cost of physiotherapists working in the PhysioDirect service was estimated in a similar way, but allowing for the reduced cost of capital and overheads; information from the site managers indicated this to be about 50%. To obtain a cost per hour of telephone contact we used information from the computerised records of the PhysioDirect service, which identified the proportion of time spent by physiotherapists actually dealing with PhysioDirect patients. We then combined this with data from the time and motion study, which identified activities undertaken during non-contact

1	time, for example, administration relating to face-to-face appointments or general administration, to
2	give a cost per hour for each band of staff at each site.
3	
4	All costs were valued in £ sterling at 2009 prices, adjusted for inflation where necessary. ³⁵
5	
6	Data analysis
7	We investigated the amount of each resource used by patients in each group using frequencies,
8	means and medians. Mean total cost per participant was derived by combining resource use with
9	unit costs.
10	
11	QALYs were derived from responses to the EQ-5D-3L at baseline, 6 weeks and 6 months using
12	valuations from the UK general population. ²⁹ These values, representing health-related quality of life
13	on a scale between zero (death) and 1 (best imaginable health), were used to compute QALYs
14	experienced over the 6 month period using the area under the curve approach and adjusting for any
15	difference between the groups at baseline. ⁴³
16	
17	A cost-consequences matrix was constructed using all available data. We compared costs from all
18	three perspectives (health care provider, patients and carers, lost productivity) with the SF-36v2 PCS,
19	MYMOP, Global Improvement Score, OMERACT OARSI, patient satisfaction, waiting time, and QALYs.
20	
21	The cost-utility analysis was carried out using data on all patients for whom we had complete NHS
22	cost and QALY data. An incremental cost-effectiveness ratio (ICER) was constructed, comparing the
23	difference in mean total cost per patient with mean difference in QALYs, thus the lower the ICER, the
24	greater the cost-effectiveness and the better the value for money. Uncertainty around the ICER was
25	captured using the bootstrapping technique: 5000 replicates of the cost and QALY data were created
26	by sampling from the original data, with replacement. The range and spread of the 5000 ICERs was

1	used to construct a cost-effectiveness acceptability curve to indicate the likelihood of the
2	intervention being cost-effective. The net monetary benefit (NMB) of the intervention was
3	estimated from the point estimate of the ICER for values of societal willingness-to-pay of £20,000
4	and £30,000 per QALY. If the NMB is positive at a given level of willingness to pay, the intervention is
5	regarded as cost-effective. Confidence intervals around the NMB were formed from the
6	bootstrapped estimates.
7	
8	We used the multiple imputation by chained equation procedure to address the issue of missing cost
9	and EQ-5D data. ⁴⁴ This technique uses a regression model to estimate missing values from known
10	values. In addition to cost and EQ-5D-3L variables the imputation model also included randomisation
11	group, age, sex, and SF36v2 PCS. Stata v12 ⁴⁵ was used to generate five datasets using 10 switching
12	procedures.
13	
14	Discounting was not carried out because the analysis was restricted to costs and outcomes over a
15	period of less than a year. All analyses were conducted using Microsoft Excel and Stata v12.44
16	
17	Sensitivity Analyses
18	We addressed three areas of uncertainty using four one/two-way sensitivity analyses. First, we
19	estimated the cost of running the PhysioDirect service if it was operating at full capacity. It is likely
20	that this was not achieved during the trial because of: low demand due to exclusions and non-
21	participation in the trial; inflexible staffing levels to ensure consistency throughout the trial period;
22	and the 'one-way' system generally used, where physiotherapists waited for patients to call them
23	but did not routinely contact patients themselves (notwithstanding some limited use of answer-
24	machines). Data from the Bristol service, which continued to operate beyond the trial period and
25	was then able to tailor staffing levels to demand, were used to estimate the cost of running a more
26	'efficient but feasible' PhysioDirect service once the trial had ended.

1	
2	The second area of uncertainty addressed hospital costs. Patients in the trial were recruited from
3	primary care and for these use of secondary care is infrequent but relatively expensive and this can
4	have a disproportionate effect on mean total cost. We tested this by excluding hospital costs from
5	the total.
6	
7	The third area of uncertainty tested the effect of using imputed data rather than complete cases; the
8	third sensitivity analysis used trial data with missing values imputed.
9	
10	Finally, in a two-way sensitivity analysis, we re-estimated the results of the first, (mimicking an
11	'efficient but feasible' service) in this instance using the imputed dataset.
12	
13	
14	RESULTS
15	A total of 2,249 patients were recruited between July 2009 and December 2009, and followed up
16	until June 2010, 1506 allocated to PhysioDirect and 743 to usual care. The mean age was 60, with
17	slightly more females than males (60% vs 40%); they were overwhelmingly white (97%), just over
18	half (60%) were employed and all but a few were referred for physiotherapy by their GP. Lower limb
19	problems were the most prevalent (30%) reason for referral, 27% patients had a lumbar problem
20	and 23% upper limb problems. Nearly all participants (2,223=99%) gave permission to access their
21	GP notes to obtain data about primary care encounters and prescribed medication. 81% returned
22	questionnaires at both 6 weeks and 6 months though not all participants completed all sections at
23	both time points. We had complete NHS cost and QALY data for 840 (56%) PhysioDirect and 432
24	(58%) usual care participants.
25	
26	Resource use

1	Table 2 gives information about the different types of physiotherapy consultations by patients in
2	each group. Of the 1506 patients in the PhysioDirect group, 39% (586) were managed solely over the
3	telephone and only 46% (695) had any face-to-face consultations. In total, patients in the usual care
4	group had, on average, 0.38 (95% CI: 0.12 to 0.63) more consultations than those in the PhysioDirect
5	group and the mean total duration of all consultations was 20 minutes longer (95% CI: 12 to 28).
6	
7	Table 2 here
8	
9	Tables 3 and 4 give information about NHS and personal resource use. Just over a third of patients
10	(35%) had a GP consultation during the 6 months and 40% received a prescription for
11	musculoskeletal pain-related medication. There was very little difference between the two groups in
12	terms of health care use and the only notable difference in personal expenditure was travel to
13	physiotherapy appointments.
14	
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16 17 18 19	Costs and consequences Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data are included giving variable denominators for each category. Comparing the two groups, there are
16 17 18 19 20	Costs and consequences Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data are included giving variable denominators for each category. Comparing the two groups, there are small differences in cost in some categories but for most of these the confidence intervals indicate
16 17 18 19 20 21	Costs and consequences Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data are included giving variable denominators for each category. Comparing the two groups, there are small differences in cost in some categories but for most of these the confidence intervals indicate
16 17 18 19 20 21 22	Costs and consequences Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data are included giving variable denominators for each category. Comparing the two groups, there are small differences in cost in some categories but for most of these the confidence intervals indicate there is no evidence of a difference between the groups.
16 17 18 19 20 21 22 23	Costs and consequences Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data are included giving variable denominators for each category. Comparing the two groups, there are small differences in cost in some categories but for most of these the confidence intervals indicate there is no evidence of a difference between the groups.
16 17 18 19 20 21 22 23 24	Costs and consequences Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data are included giving variable denominators for each category. Comparing the two groups, there are small differences in cost in some categories but for most of these the confidence intervals indicate there is no evidence of a difference between the groups. <i>Table 5 here</i>
<ol> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> </ol>	Costs and consequences Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data are included giving variable denominators for each category. Comparing the two groups, there are small differences in cost in some categories but for most of these the confidence intervals indicate there is no evidence of a difference between the groups. <i>Table 5 here</i> Table 6 combines the results of the cost analysis with the full range of primary and secondary

1	
2	Table 6 here
3	
4	Results are presented for all available data, with cost categories combined. Denominators vary
5	within the table and they also differ from those in table 5 because sub-categories have been
6	collapsed. There was no evidence of a difference in the primary clinical outcome (the SF36v2 PCS)
7	between the groups, suggesting that PhysioDirect led to similar outcomes as usual physiotherapy
8	care. Patients in the PhysioDirect group had their first assessment and telephone advice 27 days
9	earlier than those in the usual care group, however patient satisfaction was slightly lower in those
10	receiving PhysioDirect. QALYs were higher in the PhysioDirect group by 0.009, which equates to
11	about 3.3 extra days of full health over a year.
12	
13	Cost-utility analysis
14	The cost-utility analysis presented in Table 7 uses complete cases, that is, we include only those
15	patients for whom we had complete NHS cost and QALY data: 432 (58%) from the usual care group
16	and 840 (56%) from PhysioDirect. The small extra cost of caring for patients in the PhysioDirect
17	group was compensated for by the extra QALY gain, giving an incremental cost-effectiveness ratio of
18	£2,889. Values below £20,000 are regarded by NICE to indicate a cost-effective intervention ²⁷ At this
19	threshold level of willingness to pay for a QALY there is a positive net monetary benefit of £117 (95%
20	CI -£96 to £310) and there is 0.88 probability that the intervention is cost-effective. This is illustrated
21	in the cost-effectiveness acceptability curve in figure 1.
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23	Table 7 here
24	Figure 1 here
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26	Sensitivity Analysis

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1	The results of the four sensitivity analyses are shown in table 8 and figure 2. Scenario (1) indicates
2	the potential cost-effectiveness of a more efficient PhysioDirect service. During the trial PhysioDirect
3	clinic opening hours, physiotherapists spent about 35% of their time on the phone or dealing with
4	directly related administration; in Bristol after the trial, this was increased to 57%. Under this
5	scenario, the cost per patient in the PhysioDirect group was £14.53 less than under trial conditions
6	and £2.11 less per patient in the usual care group. The ICER is therefore lower, at £1,045, the NMB
7	correspondingly higher at £127 ( $\lambda$ =£20,000). At low levels of $\lambda$ , the probability of PhysioDirect being
8	cost-effective under this scenario is higher than with the base case, though at $\lambda$ =£20,000 it reaches a
9	similar value (see figures 1 and 2).
10	
11	Table 8 here
12	Figure 2 here
13	
14	The effect of removing hospital costs from the analysis is shown in sensitivity analysis (2). Hospital
15	costs accounted for 75% of all NHS costs yet only 19% (n=252) participants reported using any
16	secondary care. Hospital use was evenly divided between the two groups so removing these from
16 17	secondary care. Hospital use was evenly divided between the two groups so removing these from the analysis made very little difference to incremental analysis.
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17 18	the analysis made very little difference to incremental analysis.
17 18 19	the analysis made very little difference to incremental analysis. The effect of imputing missing NHS cost and QALY data is explored in sensitivity analysis (3). Using
17 18 19 20	the analysis made very little difference to incremental analysis. The effect of imputing missing NHS cost and QALY data is explored in sensitivity analysis (3). Using these data the cost of the interventions is lower but this is offset by higher NHS costs, giving a higher
17 18 19 20 21	the analysis made very little difference to incremental analysis. The effect of imputing missing NHS cost and QALY data is explored in sensitivity analysis (3). Using these data the cost of the interventions is lower but this is offset by higher NHS costs, giving a higher mean total cost in both groups, by £21.41 in the usual care group and £6.58 in the PhysioDirect
17 18 19 20 21 22	the analysis made very little difference to incremental analysis. The effect of imputing missing NHS cost and QALY data is explored in sensitivity analysis (3). Using these data the cost of the interventions is lower but this is offset by higher NHS costs, giving a higher mean total cost in both groups, by £21.41 in the usual care group and £6.58 in the PhysioDirect group. QALYs using imputed data are lower, by 0.005 in the usual care group and by 0.010 in the
17 18 19 20 21 22 23	the analysis made very little difference to incremental analysis. The effect of imputing missing NHS cost and QALY data is explored in sensitivity analysis (3). Using these data the cost of the interventions is lower but this is offset by higher NHS costs, giving a higher mean total cost in both groups, by £21.41 in the usual care group and £6.58 in the PhysioDirect group. QALYs using imputed data are lower, by 0.005 in the usual care group and by 0.010 in the PhysioDirect group. The net effect is a reduction of both incremental cost and incremental QALYs,

1	Sensitivity analysis (4) combines analyses (1) and (3) by using imputed cost data in the 'efficient
2	service' scenario. In this case the results indicate that PhysioDirect is, on average, cheaper than usual
3	care with a possible saving of £6.02 per patient, which gives a negative value for the ICER, indicating
4	the intervention is superior in terms of both cost and outcome. The probability that the service is
5	cost-effective at $\lambda$ =£20,000 is 0.72.
6	
7	
8	DISCUSSION
9	Statement of principal findings
10	The results of this economic evaluation suggest that PhysioDirect services for patients with
11	musculoskeletal problems require careful management if they are to be a cost-effective alternative
12	to usual physiotherapy care. There was very little difference between the two groups in terms of
13	either outcomes or costs, and the finding that PhysioDirect is cost-effective is based on evidence
14	that it provides very slightly greater QALY benefits at very slightly greater cost.
15	
16	Clearer cost savings were observed in the sensitivity analysis that replicated the post-trial service,
17	once greater flexibility in working arrangements was implemented. Without the restrictions of a trial
18	environment staffing was adjusted to meet the anticipated demand, a call-back service was
19	employed which accommodated fluctuations in activity during each session, referrals added to the
20	system were adjusted regularly to reflect actual staffing and the number of patients waiting for
21	a call-back and a higher throughput of patients led to greater economies of scale. These changes
22	ensured physiotherapists within the PhysioDirect service spent a higher proportion of their
23	PhysioDirect clinic time on the telephone with patients. There was no evidence of a difference
24	between PhysioDirect and usual care in cost to patients and their families, or to society through the
25	costs of lost production.
26	

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1	Strengths and weaknesses of the study
2	The study has a number of strengths. It is the first study assessing the cost-effectiveness of a
3	PhysioDirect service including a large sample of patients with a wide range of musculoskeletal
4	problems based across a number of locations. ¹⁵ It uses a rigorous study design and conforms to
5	CONSORT guidelines. ⁴⁶ The follow up rate from participating patients was in line with other primary
6	care trials, ^{47,48} a high proportion of the resource use data were collected from GP records, and there
7	was collection of resource use information outside of the main health service perspective. The cost
8	consequences analysis provides complete information on costs from different perspectives
9	compared with a range of outcomes so although this approach is sometimes criticised for leaving the
10	reader to evaluate the findings it does have the advantage of transparency. Furthermore, in this
11	study we have also presented a cost-utility analysis that conforms to the recommendations of NICE.
12	Nevertheless, there are also limitations. The practices recruited to the trial had a low proportion of
13	ethnic minority patients, a slightly lower proportion of patients from deprived areas were judged to
14	be eligible, and the proportion of eligible individuals consenting to participate in the trial was only
15	50%. ²³ These factors limit the generalisability of the results though none of these selection effects
16	was large. Further, a particular difficulty in conducting economic evaluation with new service
17	developments is ensuring that they are fully utilised, ²⁴ particularly when conducting analysis from a
18	long-run perspective, as here. Although there was a clear run-in period prior to data collection for
19	the trial (ranging from 4 to 12 weeks in each of the four sites), to ensure that services were
20	operating as well as they could, and a 2:1 randomisation ratio in favour of PhysioDirect was used,
21	there was still considerable underutilisation of the new service. This was ameliorated by including a
22	more fully utilised service within the sensitivity analysis. It should also be noted that, because of the
23	use of a long-run perspective in the analysis, set up costs, which may, in the short-term be important
24	in a financially constrained service, are not included here. Finally, because the differences in both
25	costs and effects are small, there is still some uncertainty around the findings.
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#### 1 The meaning of the study and implications for policy makers

2 If the aim of health services is to achieve maximum health gain from an investment in health care, 3 then PhysioDirect has a high probability of being more cost-effective than usual physiotherapy care. 4 This research also, however, suggests that it cannot be assumed that PhysioDirect will reduce costs, 5 although it could potentially do so if PhysioDirect services are managed efficiently. Both the costs 6 and cost-effectiveness of services will depend on the productivity of physiotherapist time. If 7 physiotherapists are able to use most of their time dealing directly with patients during sessions 8 when they are available on the telephone, then the service will be less costly. This is most likely to be 9 achieved by operating a call-back service and/or by operating the service on a large scale to even out 10 fluctuations in demand. Operating a system on larger scale might also offer other economies of 11 scale, particularly in terms of infrastructure. Further efficiencies may also be achieved if these 12 services are, in the future, provided in conjunction with direct access for patients (rather than 13 following referral from another health care professional), given that patients who self-refer are likely to contact the service with musculoskeletal problems of shorter duration,⁴⁹ and such patients may 14 15 be particularly appropriate for the initial assessment and advice provided by a PhysioDirect service. 16 More generally, the study has broader implications for telephone services, particularly around the implicit assumption that such services will inevitably be money saving. Here this assumption was 17 18 found to be false, largely because the physiotherapists' time was underutilised during PhysioDirect 19 clinic hours. Thus, for all such services, it will be important for policy makers to ensure that easy 20 assumptions about the costs of these services are properly assessed in relation to factors such as 21 how efficiently the service is run, and what proportion of patients are subsequently invited for face 22 to face care following an initial telephone call.

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#### 24 Unanswered questions and future research

As services evolve, further research should explore the costs and benefits of PhysioDirect under
 different scenarios. These might include: comparing different skill levels of staff operating the

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service; the inclusion of patient self-referrals in addition to GP referrals; the use, or otherwise, of computerised support in assessing the patient; the extension to internet services (possibly combined with cameras);⁵⁰ and the use of mobile 'smartphone' technology, for example in rapid assessment of musculoskeletal injuries. In particular, however, it will be important to assess the costs and benefits of services once they are more established and provided on a wider scale. The costs and benefits of telehealth more generally need further exploration in relation to their cost effectiveness particularly given the negative findings of the Whole Systems Demonstrator project evaluating telehealth support and treatment for patients with long term conditions.⁵¹ It would be helpful to identify those are likely ... characteristics that are likely to make services both more cost-effective and less costly.

#### References

- Munro J, Nicholl, J, O'Cathain A et al. Impact of NHS Direct on demand for immediate care: observational study. *Br Med J* 2000;321:150-153.
- 2. Lattimer V, Sassi F, George S et al. Cost analysis of nurse telephone consultation in out of hours primary care: evidence from a randomised controlled trial. *Br Med J* 2000;320:1053-1057.
- Lattimer V, George S, Thompson F et al. Safety and effectiveness of nurse telephone consultation in out of hours primary care: randomised controlled trial. The South Wiltshire Out of Hours Project (SWOOP) Group. *Br Med J* 1998;317:1054-1059.
- Pinnock H, Bawden R, Proctor S et al. Accessibility, acceptability, and effectiveness in primary care of routine telephone review of asthma: pragmatic, randomised controlled trial. *Br Med J* 2003;326:477-479.
- Bunn F, Byrne G, Kendall S. Telephone consultation and triage: effects on health care use and patient satisfaction. *Cochrane Database of Systematic Reviews*. (4):CD004180, 2004. 2004;CD004180.
- 6. McKinstry B, Watson P, Pinnock H et al. Telephone consulting in primary care: a triangulated qualitative study of patients and providers. *Br J Gen Pract* 2009;59:e209-e218.
- 7. Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain* 2003;102:167-178.
- Jordan K, Ong BN, Croft P. Previous consultation and self reported health status as predictors of future demand for primary care. J Epidemiol Commun Health 2003;57:109-113.
- 9. McKormick A, Fleming D, and Charlton J *Morbidity statistics from general practice. Fourth national study 1991-1992 Serise MB5 no.3*. London: 1995.

- 10. Balage F, Mannion A, Pellise F, et al. Non-specific low back pain. *Lancet* 2012;379(9814):482-91.
- 11. Chuang L-H, Soares M, Tilbrook H, et al. A Pragmatic multicentred randomized controlled trial of yoga for chroonic low back pain: economic evaluation. *Spine* 2012;37(18):1593-1601.
- 12. National Institute for Health and Clinical Excellence *Low back pain: early management of persistent non-specific low back pain. NICE clinical guideline 88.* 2009.
- Department of Health. Physiotherapy Services Summary Information for 2004-2005, England https://catalogue.ic.nhs.uk/publications/hospital/outpatients/nhs-phys-serv-summ-eng-2004-05/nhs-phys-serv-summ-eng-2004-05-rep.pdf (accessed 16.08.2013)
- 14. Maniadakis N, Gray A. The economic burden of back pain in the UK. *Pain* 2000;84:95-103.
- 15. Salisbury C, Montgomery AA, Hollinghurst S et al. Effectiveness of PhysioDirect telephone assessment and advice services for patients with musculoskeletal problems: pragmatic randomised controlled trial. *Br Med J* 2013;346:f43.
- 16. Hodgson K. Kidderminster helpline proves a success. Physiotherapy Frontline 2001;7:22-23.
- 17. Taylor S, Ellis I, and Gallagher M. Patient satisfaction with a new physiotherapy telephone service for back pain patients. *Physiotherapy* 2002;88:645-657.
- 18. Clayson M and Woolvine M. Back pain direct clinic: a collaboration between general practitioners and physiotherapists. *Work Based Learning in Primary Care* 2004;2:38-43.
- 19. Turner D. An exploratory study of physiotherapy telephone assessment. *International Journal of Therapy and Rehabilitation* 2009;16:97-105.
- 20. Russell T, Truter P, Blumke R, Richardson B. The diagnostic accuracy of telerehabilitation for nonarticular lower-limb musculoskeletal disorders. *Telemed J & E-Health* 2010;16:585-594.

- 21. Patel S, Hossain FS, Colaco HB et al. The accuracy of primary care teams in diagnosing disorders of the shoulder. *J Eval Clin Pract* 2011;17:118-122.
- 22. Jette DU, Ardleigh K, Chandler K et al. Decision-making ability of physical therapists: physical therapy intervention or medical referral. *Phys Ther* 2006;86:1619-1629.
- 23. Salisbury C, Foster NE, Hopper C et al. A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of 'PhysioDirect' telephone assessment and advice services for physiotherapy. *Health Technology Assessment (Winchester, England)* /20;17:1-157.
- 24. Coast J, Hensher M, Mulligan J, et al. Conceptual and practical difficulties with the economic evaluation of health services developments. J *Health Serv Res Policy* 2000;5:42-48.
- 25. Coast, J. Is economic evaluation in touch with society's health values? *Br Med J* 2004;(329):1233-1236.
- 26. Drummond M, Brown R, Fendrick M, et al. Use of Pharmacoeconomics Information—Report of the ISPOR Task Force on Use of Pharmacoeconomic/Health Economic Information in Health-Care Decision Making. *Value in Health* 2003;6 (4):407-416.
- National Institute for Health and Clinical Excellence. Guide to the Methods of Technology Appraisal http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf (accessed 16.08.2013)
- 28. Brooks R, with the EuroQol Group. EuroQol: the current state of play. *Health Policy* 1996;53-72.
- 29. Dolan P, Gudex C, Kind P et al. *A social tariff for EuroQol: Results from a UK general population survey*. University of York, 1-9-1995.
- Quality Metric. A community for measuring health outcomes using SF tools. http://www.sf-36.org/ (accessed 16.08.2013)

31.	Paterson, C. Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 survey. <i>Br Med J</i> 1996;312:1016-1020.
32.	Pham T, Van Der Heijde D, Lassere M et al. Outcome variables for osteoarthritis clinical trials: The OMERACT-OARSI set of responder criteria. <i>J Rheumatol</i> 2003;30:1648-1654.
33.	British National Formulary. British National Formulary. http://www.bnf.org/bnf (accessed 16.08.2013)
34.	Database of Instruments for Resource Use Measurement (DIRUM) http://www.dirum.org (accessed 16.08.2013)
35.	Curtis L. Unit costs of health and social care 2009. PSSRU, University of Kent, 2010.
36.	Department of Health. NHS Reference costs 2009-2010. https://www.gov.uk/government/publications/nhs-reference-costs-2009-2010 (accessed 16.08.2013)
37.	National Health Service. NHS Drug tariff. http://www.nhsbsa.nhs.uk/PrescriptionServices/924.aspx (accessed 16.08.2013)
38.	The Automobile Association. The AA schedule of motoring costs. http://www.theaa.com/motoring_advice/running_costs/index.html (accessed 16.08.2013)
39.	Office for National Statistics. Annual survey of hours and earnings 2009 http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2009- revised/index.html (accessed 16.08.2013)
40.	Royal College of Nursing. Agenda for change – pay rates http://www.nhscareers.nhs.uk/working- in-the-nhs/pay-and-benefits/agenda-for-change-pay-rates (accessed 16.08.2013)

- 41. Scott A, Simoens S, Heaney D, et al. What does GP out of hours care cost? An analysis of different models of out of hours care in Scotland. *Scot Med J* 2004;49:61-66.
- 42. O'Dowd A. Cost of out of hours care was 22% higher than predicted in England. *Br Med J* 2006;332:1113.4.
- 43. Manca A, Hawkins N, Sculpher M. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. *Health Econ* 2005;14:487-496.
- 44. van Buuren S, Boshuizen HC, Knook D L. Multiple Imputation of missing blood pressure covariaties in survival analysis. *Stat Med* 1999;18:681-694:
- 45. StataCorp Statistical Software: Release 11. College Station, TX: StataCorp LP. 2009.
- 46. The CONSORT Group. CONSORT: the transparent reporting of trials http://www.consortstatement.org (accessed 16.08.2013)
- 47. Stamuli E, Bloor K, MacPherson H, et al. Cost-effectiveness of acupuncture for irritable bowel syndrome: findings from an economic evaluation conducted alongside a pragmatic randomised controlled trial in primary care. BMC Gastroenterology 2012; 12:149.
- 48. Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet 2011; 378 (9802): 1560-71.49. Leemrijse CJ, Swinkels IC, Veenhof C. Direct access to physical therapy in the Netherlands: results from the first year in community-based physical therapy. *Phys Ther*. 2008;88(8):936-46
- Li LC, Townsend AF, Badley EM. Self-management interventions in the digital age: new approaches to support people with rheumatologic conditions. *Best Pract Res Clin Rheumatol*. 2012;26(3):321-33.

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51. Henderson C, Knapp M, Ferbnandez J-L, et al. Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial. *Br Med J* 2013;34.j2065.

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20	CS was principal investigator on the trial, SH took the lead on the economic evaluation. JC, NF, SG,
21	JH, and AM were co-applicants and contributed to the conception and design. SH, JC and JB carried
22	out the analysis with help from CS and AM, and all authors contributed to the interpretation of the
23	data. SH and JC wrote the first draft of the paper with all authors contributing to subsequent
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25	
26	
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30	
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1 2 3	1	of the Trial Steering Committee and Data Monitoring Committee: and Iill Gamlin and Nick Deane
4		
$\begin{array}{c} 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ 23\\ 24\\ 25\\ 26\\ 27\\ 28\\ 29\\ 30\\ 31\\ 32\\ 33\\ 34\\ 35\\ 36\\ 37\\ 38\\ 39\\ 40\\ 41\\ 42\\ 43\\ 44\\ 45\\ 46\\ 47\\ 48\\ 49\\ 50\\ 51\\ 52\\ 53\\ \end{array}$	1	of the Trial Steering Committee and Data Monitoring Committee; and Jill Gamlin and Nick Deane who developed the PhysioDirect assessment algorithms and software used in this trial.
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#### Table 1: Data sources and unit costs

	Unit cost (£)
Primary and Community Care ³⁵	
General Practitioner	
Surgery	27.00
Telephone consultation	16.00
Home visit	91.00
Practice nurse	
Surgery	10.00
Telephone consultation	5.93
Health Care Assistant/phlebotomist	
Surgery	6.92
District Nurse	
Home visit	16.33
41 42	
Out of Hours ^{41,42}	
General practitioner	23.50
Hospital care ³⁶	
A&E	103.00
	By Healthcare Resource Group,
Outpatient visits	differentiated by first and follow-up
Inpatient stays	By Healthcare Resource Group
Prescribed medication ³³	per item, by name, strength and amount
Mileage ³⁸	0.4612
Time off work ³⁹	Median national wage by age and sex

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### Table 2: Number of physiotherapy consultations and mean duration, by type and group

		Usual care (n=743)	PhysioDirect (n=1506
Face-to-face	mean (SD) number	3.11(2.63)	1.91(2.72
appointments	mean (SD) total	107.51(88.92)	64.20(89.31
	duration (minutes)	107.51(00.52)	01120(05.51
Telephone	mean (SD) number	0.13(0.44)	0.96 (0.63
appointments	mean (SD) total	4.21(14.64)	27.37(19.92
	duration (minutes)		
Home visits	mean (SD) number	0.00 (0.06)	0.00 (0.06
	mean (SD) total	0.14(2.27)	0.12(2.12
	duration (minutes)		
All physiotherapy	mean (SD) number	3.25(2.70)	2.87(2.94
contacts	mean (SD) total	111 86(00 50)	
	duration (minutes)	111.86(90.50)	91.70 (95.40
For peer re	eview only - http://bmjop	en.bmj.com/site/about/g	uidelines.xhtml

Table 3: Health services resource use, by group. All available data.

_	n	usual care	n	PhysioDirect
GP consultations	739	0.77(1.47)	1484	0.87 (1.68)
Nurse consultations	739	0.04 (0.22)	1484	0.06 (0.32)
Other primary care consultations	739	0.02(0.14)	1484	0.02 (0.17)
Total number of primary care contacts	739	0.83(1.56)	1484	0.96 (1.84)
Number of prescriptions	728	1.36 (2.73)	1469	1.68 (3.72)
A&E (visits)	467	0.02 (0.01)	912	0.03 (0.01)
Out-patient (consultations)	467	0.17 (0.83)	910	0.35 (1.03)
In-patient stays (Finished Consultant Episodes)	465	0.01 (0.10)	910	0.01 (0.10)

### Mean (SD) number of consultations

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#### Table 4: Patient and societal resource use, by group. All available data.

Number (%) reporting:	n	usual care	n	PhysioDirect
Expenditure on travel to physiotherapy	462	242 (52.4)	1232	308 (25.8)
Expenditure on travel to primary care	669	116 (17.3)	1337	237 (17.7)
Expenditure on over-the-counter medication	506	256 (50.6)	1028	512 (49.8)
Expenditure on prescriptions	559	264 (47.2)	1085	508 (46.8)
Expenditure on private therapy	484	89 (18.4)	934	167 (17.9)
Equipment purchase	480	139 (29.0)	939	233 (24.8)
Payments for extra domestic help	459	35 (7.6)	928	76 (8.2)
Loss of earnings	598	30 (5.5)	1209	64 (5.3)
Any time off to attend physiotherapy consultation	692	218 (31.5)	1416	380 (26.8)
Work has been affected because of condition	477	141 (29.6)	959	317 (33.1)



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# Table 5: Mean total cost per patient, by group and category. All available data^a.

		usual care		PhysioDirect	Incremental difference (95% Confidence
	n	mean (SD) cost	n	mean (SD) cost	Interval)
Physiotherapy services					
Face-to-face appointments	743	£64.42 (£53.00)	1506	£38.76 (£53.92)	-£25.66 (-£30.37 to -£20.95)
Telephone appointments	743	£5.22 (£18.01)	1506	£35.17 (£26.34)	£29.94 (£27.84 to £32.05)
Home visits	743	£0.08 (£1.33)	1506	£0.08 (£1.46)	£0.00 (-£0.12 to £0.13)
Total physiotherapy cost	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.69)
Primary care services					
GP consultations	739	£19.21 (£35.91)	1484	£21.69 (£41.66)	£2.48 (-£1.04 to £6.00)
Nurse consultations	739	£0.44 (£2.37)	1484	£0.61 (£3.17)	£0.16 (-£0.10 to £0.42)
Other primary care consultations	739	£0.03 (£0.57)	1484	£0.07 (£1.31)	£0.05 (-£0.05 to £0.15)
Total primary care cost	739	£19.68 (£36.68)	1484	£22.37 (£42.83)	£2.69 (-£0.92 to £6.30)
Medication cost	728	£11.04 (£51.61)	1469	£10.33 (£55.43)	-£0.72 (-£5.53 to £4.10)
Hospital services					
A&E	467	£1.99 (£17.12)	912	£3.17 (£20.84)	£1.18 (-£1.01 to £3.37)
Out-patient	467	£30.74 (£98.36)	910	£38.35 (£126.05)	£7.61 (-£5.50 to £20.72)
In-patient	465	£51.02 (£520.48)	910	£34.99 (£399.62)	-£16.03 (-£65.70 to £33.64)
Total hospital cost	459	£83.04 (£561.68)	899	£77.00 (£446.24)	-£6.04 (-£60.99 to £48.91)
Personal expenditure					
Cost of all calls to physiotherapy service	743	£0.97 (£0.99)	1506	£1.75 (£1.29)	£0.79 (£0.68 to £0.89)
Travel to physiotherapy	462	£6.11 (£11.48)	1232	£3.11 (£8.51)	-£3.01 (-£4.01 to -£2.00)
Travel for primary care	669	£0.65 (£2.93)	1337	£0.75 (£4.10)	£0.11 (-£0.24 to £0.45)
Over-the-counter medication	490	£7.67 (£14.09)	987	£8.61 (£22.38)	£0.94 (-£1.23 to £3.11)
Cost of prescriptions	553	£2.72 (£8.95)	1076	£2.67 (£8.33)	-£0.05 (-£0.93 to £0.82)

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3	Private therapy	475	£21.98 (£70.34)	915	£39.34 (£296.94)	£17.36 (-£9.76 to £44.48)
4						
5	Equipment purchase	473	£17.16 (£169.12)	924	£9.12 (£56.42)	-£8.04 (-£20.08 to £4.00)
6				521	20122 (200112)	
7	Extra domestic help	451	£10.93 (£64.31)	905	£13.68 (£96.02)	£2.75 (-£7.07 to £12.56)
8	Extra domestic help	431	E10.95 (E04.51)	903	E15.08 (E90.02)	
9	Cost associated with loss of					
10	cost associated with loss of	598	£46.69 (409.72)	1209	£82.78 (£885.85)	£36.09 (-£38.63 to £110.81)
11	earnings				( ,	
12						
13	Value of time off work					
14 15						
16	Time off work to attend					
17		598	£12.90 (£38.99)	1211	£11.91 (£57.86)	£0.95 (-£3.81 to £5.70)
18	physiotherapy					
19	Time off work associated with		£265.92			
20	Time on work associated with	452	1205.52	884	£226.61(£1139.84)	£111.31 (-£159.04 to £379.67)
21	the condition		(£1350.82)		(()	
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# Table 6: Cost-consequences. All available data^a.

	n (%)	usual care	n (%)	PhysioDirect	Incremental difference (95% Confidence Interval)
Mean (SD) Cost					
Total physiotherapy cost	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.69)
Cost of NHS services including physiotherapy	453 (61%)	£189.19 (£557.61)	888 (59%)	£196.43 (£472.02)	£7.24 (-£49.68 to £64.10)
Total personal expenditure	310 (42%)	£121.10 (£575)	714 (47%)	£166.40 (£1040.27)	£45.30 (-£78.01 to £168.61)
Total value of all time off work ^b	451 (61%)	£276.75 (£1355.00)	883 (59%)	£240.74 (£1147.20)	-£36.01 (-£174.69 to £102.66)
Consequences ^c					Difference/odds ratio (95% confidence interval) ^d
SF36v2 PCS	629 (85%)	44.18 (10.84)	1283 (85%)	43.50 (10.94)	-0.01 (-0.80 to 0.79)
MYMOP ^e	518 (70%)	2.40 (1.38)	1033 (69%)	2.40 (1.43)	-0.02 (-0.16 to 0.11)
Global improvement score	501 (67%)	4.07 (1.40)	1001 (66%)	4.01 (1.44)	-0.08 (-0.23 to 0.08)
Response to treatment (OMERACT OARSI )	510 (69%)	197 (38.6%)	1029 (68%)	430 (41.8%)	1.14 (0.92 to 1.43)
Waiting time to first assessment and advice	618 (83%)	34 (20 to 55) ^f	1281 (85%)	7 (4 to 15) ^f	0.32 (0.29 to 0.35) ^g
Patient overall satisfaction	367 (49%	79.7 (26.5)	739 (49%)	75.9 (28.3)	-3.8 (-7.3 to -0.3)
QALYs ^h	454 (61%)	0.322 (0.079)	881 (58%)	0.331 (0.082)	0.009 (-0.000 to 0.018)
^a Uses all available data, so denor ^b Total of time off to attend physio ^c At 6 month follow-up time point ^d Adjusted for outcome at baseline	therapy and ass	sociated with the con			
^e Lower score is better					
^f Median (IQR)					
⁹ Accelerated failure time analysis ^h Adjusted for outcome at baseline					

### Table 7: Cost-effectiveness analysis. Includes cases with complete data on NHS costs and QALYs

	n	usual care	n	PhysioDirect	Incremental difference
_		mean (SD) cost		Mean (SD) cost	(95% C
Cost of physiotherapy	432	£78.77 (£57.08)	840	£86.75 (£65.47)	£7.98 (£0.69 to £15.2
Cost of NHS services other than	432	£100.91 (£502.02)	840	£112.23 (£476.91)	£11.32 (-£45.08 to £67.7
physiotherapy					
Total cost including physiotherapy	432	£179.68 (£504.73)	840	£198.98 (482.12)	£19.30 (-£37.60 to £76.1
QALYs	432	0.325 (0.077)	840	0.332 (0.081)	0.007 (-0.003 to 0.01
Incremental cost-effectiveness ratio (ICER)	8	0			£2,8
Median Net Monetary Benefit (95% CI) based	l on boot	strapped results:			
λ=£20,000					£117 (-£86 to £31
probability of intervention being cost-eff	ective				0.8
λ=£30,000					£184 (-£106 to £46
probability of intervention being cost-eff	ective				0.9

# Table 8: Sensitivity Analysis

Table 6. Sensitivity Analysis		Usual care		PhysioDirect	Incremental difference
	n	mean (SD)	n	mean (SD)	(95% confidence interval)
(1) mimicking an efficient service					
Cost of physiotherapy	432	£76.56 (£55.34)	840	£72.22 (£61.55)	-£4.34 (-£11.25 to £2.57)
Cost of NHS services	432	£100.91 (£502.02)	840	£112.23 (476.91)	£11.32 (-£45.08 to £67.72
Total cost	432	£177.46 (£504.49)	840	£184.44 (£481.83)	£6.98 (-£49.89 to £63.85)
Incremental cost-effectiveness ratio (I Median Net Monetary Benefit (95% Cl	,	n hootstrappod rosult	<b></b>		£1,045
$\lambda$ =£20,000	j baseu u	in bootstrapped result	5.		£127 (-£74 to £319)
λ=£30,000					£193 (-£95 to £473)
(2) Excluding hospital costs					
Cost of physiotherapy	448	£78.49 (£57.14)	869	£86.84 (£65.25)	£8.35 (£1.21 to £15.50)
Cost of NHS services excluding secondary care	448	£33.75 (£76.46)	869	£33.49 (£63.76)	-£0.25 (-£8.05 to £7.54)
Total cost of NHS services including	448	£112.23 (£99.621)	869	£120.33 (£98.85)	£8.10 (-£3.21 to £19.41)
physiotherapy	++0		005	1120.33 (130.03)	10.10 ( 13.21 (0 113.41)
Incremental cost-effectiveness ratio (I	-				£1,084
Median Net Monetary Benefit (95% Cl	) based o	on bootstrapped results	s:		
λ=£20,000					£142 (-£41 to £324)
λ=£30,000					£217 (-£56 to £489)
(3) Imputed data					
Cost of physiotherapy	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.69)
Cost of NHS services	743	£131.37 (£465.49)	1506	£131.51 (£384.36)	£0.17 (-£36.13 to £36.48)
Total cost of NHS services including physiotherapy	743	£201.09 (£467.51)	1506	£205.55 (£390.04)	£4.46 (-£32.22 to £41.14)
Quality Adjusted Life Years	743	0.320 (0.003)	1506	0.322 (0.002)	0.002 (-0.006 to 0.009)
Incremental cost-effectiveness ratio (I	CER)				£2,260
Median Net Monetary Benefit (95% CI	) based o	n bootstrapped results	s:		
λ=£20,000					£34 (-£119 to £193)
λ=£30,000					£52 (-£172 to £285)
(4) Imputed data and 'efficient' servic	e				
Cost of physiotherapy	743	£67.61 (£54.19)	1506	£61.41 (£59.13	-£6.20 (-£11.26 to -£1.14)
Cost of NHS services	743	£131.37 (£465.49)	1506	£131.54 (384.36)	£0.17 (-£36.13 to £36.48)
Total cost of NHS services including physiotherapy	743	£198.98 (£467.48)	1506	£192.95 (£389.52)	-£6.02 (-£42.68 to £30.63)
Quality Adjusted Life Years	743	0.320 (0.003)	1506	0.322(0.002)	0.002 (-0.006 to 0.009)
Incremental cost-effectiveness ratio (I	CER)				-£3,054
Median Net Monetary Benefit (95% Cl	) based o	n bootstrapped result	s:		
λ=£20,000					£47 (-£113 to £202)
λ=£30,000					£67 (-£165 to £293)

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Figure 1. Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different levels of willingness to pay for one Quality Adjusted Life Year

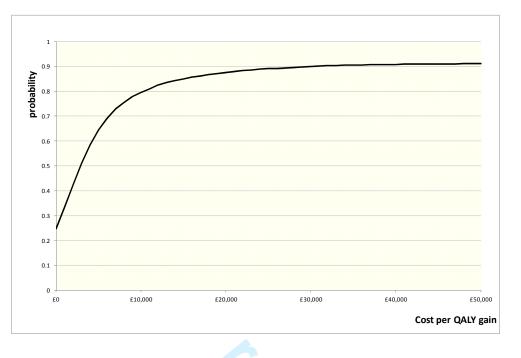
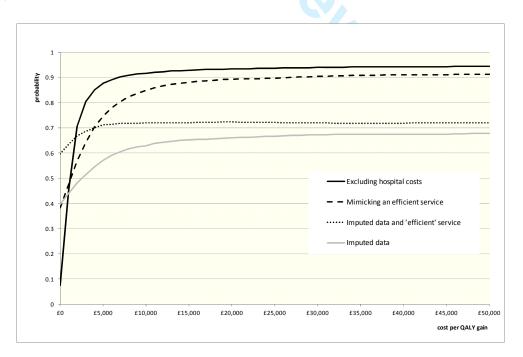


Figure 2. Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different levels of willingness to pay for one Quality Adjusted Life Year: Sensitivity Analyses



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# A pragmatic randomised controlled trial of 'PhysioDirect' telephone assessment and advice services for patients with musculoskeletal problems: economic evaluation

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Key Words: economic evaluation; physiotherapy; telehealth; primary care; cost & cost analysis

### ABSTRACT

#### Objectives

To compare the cost-effectiveness of PhysioDirect with usual physiotherapy care for patients with musculoskeletal problems.

#### Design

 (i) Cost-consequences comparing cost to the NHS, to patients, and the value of lost productivity with a range of outcomes. (ii) Cost-utility analysis comparing cost to the NHS with Quality Adjusted Life Years (QALYs)

### Setting

Four physiotherapy services in England

#### Participants

Adults (18+) referred by their general practitioner or self-referred for physiotherapy.

#### Interventions

PhysioDirect involved telephone assessment and advice followed by face-to-face care if needed. Usual care patients were placed on a waiting list for face-to-face care.

#### Primary and secondary outcome-measures

Primary clinical outcome: physical component summary measure from the SF-36v2 at six months. <u>Also included in the cost-consequences</u>Secondary outcomes included: Measure Yourself Medical Outcomes Profile; a Global Improvement Score; response to treatment; patient satisfaction; waiting time.

Outcome for the cost-utility analysis: QALYs

#### Results

2249 patients took part (1506 PhysioDirect; 743 usual care).

(i) Cost-consequences: there was no evidence of a difference between the two groups in the cost of physiotherapy, other NHS services, personal costs or value of time off work. Outcomes were also similar.

(ii) Cost-utility analysis based on complete cases (n=1,272). Total NHS costs, including the cost of physiotherapy were higher in the PhysioDirect group by £19.30 (95% CI: -£37.60 to £76.19) and there was a QALY gain of 0.007 (95% CI: -0.003 to 0.016). The incremental cost-effectiveness ratio was £2,889 and the net monetary benefit at  $\lambda$ =£20,000 was £117 (95% CI: -£86 to £310)

#### Conclusions

 PhysioDirect may be a cost-effective alternative to usual physiotherapy care, though only with careful management of staff time. Physiotherapists providing the service must be more fully occupied than was possible under trial conditions: consideration should be given to the scale of operation, opening times of the service, and flexibility in the methods used to contact patients.

#### **Article Summary**

Article focus

- What is the cost of providing PhysioDirect telephone assessment and advice, followed by face-to-face care if needed, to adults with musculoskeletal pain problems, compared with usual physiotherapy care?
- What are the patient benefits of PhysioDirect compared with usual care?
- Is PhysioDirect a cost-effective alternative to usual care for primary care patients with musculoskeletal conditions?

Key messages

- There was very little difference between the two groups in terms of cost or outcomes
- PhysioDirect has potential to be a cost-effective alternative to usual care but requires careful management of staff resources

Strengths and limitations of this study

- Findings are based on a large sample of patients with a wide range of musculoskeletal problems based in diverse locations
- The study takes a broad perspective, including the health care provider, patients, and a valuation of lost productivity
- Physiotherapists were constrained by trial conditions and were underutilised

### INTRODUCTION

There is a trend to explore the use of new technology in the delivery of health care, particularly the
use of telephone assessment and triage, as for example in NHS Direct.¹ These services aim to better
manage patient demand, and research has shown that telephone based services can be safe,
clinically accurate, cost-effective, acceptable to patients, and reduce the workload of clinicians,²⁻⁵
although there have been some concerns about using telephone triage in patients presenting with
acute health problems.⁶

Musculoskeletal pain problems are one of the most common causes of disability. Over a quarter of all patients registered in general practice will consult at least once for a musculoskeletal problem each year,^{7,8} with musculoskeletal pain accounting for around 15% of all GP consultations.⁹ This high prevalence of musculoskeletal problems¹⁰ results in large direct and indirect healthcare costs:_⁴⁰ estimated for for example, low back pain alone has recently been estimated to cost the UK economy £15.84 billion a yearat £10,668 million for the UK in 1998¹¹ and rising substantially since then. 11,12 Most patients are managed with advice and analgesia but many are referred to physiotherapists, with 1.23 million new referrals each year from GPs and 4.4 million in total.¹³ Ensuring timely access to physiotherapy has long been an issue within the UK NHS, with waiting times of more than four months in some areas. Patients may suffer unnecessary pain and disability, and there are high productivity losses: for example, back pain accounts for some 120 million days of certified absence from work each year.¹⁴¹ Delay may also cause NHS inefficiencies on the one hand as some patients recover and do not attend their physiotherapy appointment when it finally arrives, whilst on the other, some patients continue to access more expensive forms of treatment whilst awaiting their appointment. 

In response to these problems, physiotherapy services have drawn on the new service models and a
 range of 'PhysioDirect' services have been developed. These vary in format though they commonly

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1	involve a physiotherapist assessing a patient's musculoskeletal pain problem over the telephone,
2	sometimes supported by computerised assessment templates, offering tailored, self-management
3	advice supplemented by written advice sent by post. Alternatively if the assessment findings
4	suggest that face-to-face care is needed this is arranged, and patients who are initially managed by
5	telephone advice can phone back for further advice and/or face-to-face treatment. ¹⁵⁴ There is,
6	however, limited evidence about the costs and benefits of this approach within physiotherapy. Local
7	evaluations and non-randomised studies suggest that these services may be popular with patients ¹⁶⁵⁻
8	¹⁸⁷ and diagnoses made by physiotherapists over the telephone are comparable to diagnoses
9	reached in face-to-face assessments ¹⁹⁹⁻²¹⁹ although there is some concern that the experience of the
10	physiotherapist providing the telephone assessment might be important. ^{198,224}
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12	In particular there is no information about the costs or cost-effectiveness of PhysioDirect services,
13	despite: (i) a major underlying rationale for their development being to generate greater efficiency
14	in the use of resources; and (ii) a ready presumption that telephone-based services result in lower
15	costs (by assuming that services better use physiotherapy time, use less costly telephone
16	consultations and reduce rates of appointment non-attendance). Without such evidence, preferably
17	generated alongside high quality primary evidence obtained using rigorous study designs, it remains
18	unclear whether such services should be more widely implemented. This paper reports the results of
19	an economic evaluation conducted alongside a randomised controlled trial powered to generate
20	evidence on whether PhysioDirect services for primary care patients with musculoskeletal problems
21	produce equivalent outcomes to usual face-to-face services.
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24	METHOD
25	Study design
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	We conducted an economic evaluation alongside a randomised controlled trial to establish the cost-	
	effectiveness of PhysioDirect compared with usual care based only on face-to-face treatment over a	
	period of 6 months. The trial and its clinical findings have been reported in full elsewhere. ^{154,232} The	
	aim of the evaluation was to provide information about the long-run costs and benefits of the	
	alternative methods of running a physiotherapy service for this patient group so with that in mind	
	we excluded the initial set up costs associated with establishing the new telephone service, including	
	the training undertaken by the practitioners, ²⁴ As the nature of the intervention suggests there could	Formatted: Superscript, Not Highlight
	be an impact on patients' costs, and as it is known that musculoskeletal conditions account for a	
	considerable amount of time off work ¹⁴ we chose to use a cost-consequences approach, comparing	
	cost from all three perspectives (health care provider, patients and carers, lost productivity) with a	
	range of clinical outcomes. ^{25,26} However, the perspective of greatest interest to UK policy makers is	Formatted: Superscript
	the health and social care provider ²³ so we also conducted a cost-utility analysis to compare cost to	Formatted: Superscript
	the National Health Service (NHS) with Quality-Adjusted Life-Years (QALYs). However, the nature of	
	the intervention suggests there could be an impact on patients' costs, and as it is known that	
	musculoskeletal conditions account for a considerable amount of time off work ^{10,11} -we included	
	these perspectives in the analysis. We used a cost-consequences approach to compare cost from all	
	three perspectives (health care provider, patients and carers, lost productivity) with a range of	
	clinical outcomes and used a cost utility analysis to compare cost to the National Health Service	
	(NHS) with Quality-Adjusted Life-Years (QALYs).	
	The primary perspective for the economic evaluation was the health and social care provider, as that	
	is of greatest interest to UK policy makers. ²³ However, the nature of the intervention suggests there	
	could be an impact on patients' costs, and as it is known that musculoskeletal conditions account for	
	<del>a considerable amount of time off work^{19,11} we included these perspectives in the analysis. We used</del>	
	a cost-consequences approach to compare cost from all three perspectives (health care provider,	
	patients and carers, lost productivity) with a range of clinical outcomes and used a cost-utility	
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1	analysis to compare cost to the National Health Service (NHS) with Quality-Adjusted Life-Years	
2	<del>(QALYs).</del>	
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4	Setting and participants	
5	We recruited adults aged 18 and over from four community physiotherapy services in England –	
6	Bristol, Somerset, Stoke-on-Trent, and Cheshire – which provided diversity in terms of socio-	
7	economic status and a mix of urban and rural communities. All patients referred by their general	
8	practitioner (GP), or who referred themselves, for physiotherapy for a non-urgent musculoskeletal	
9	problem were invited to take part. Patients were randomised to PhysioDirect or usual care on a two	
10	to one basis to increase the chances of the PhysioDirect service being fully utilised.	
11		
12	Interventions	
13	The intervention has been reported in detail elsewhere ^{154,252} . Patients randomised to the	
14	PhysioDirect service received an invitation to telephone a senior (band 6 or above) specially trained	
15	physiotherapist, who assessed their musculoskeletal problem with the aid of previously developed	
16	computerised templates. ²³² These templates were provided by Huntingdonshire Primary Care Trust,	
17	which has been operating a similar service since 2001. Patients were then sent appropriate advice	
18	leaflets about self-management and exercises to try at home, and invited to phone again and/or	
19	make a face-to-face appointment if necessary. If the service was engaged when the patient called	
20	the call was answered by a receptionist who added the patient to a 'call-back' list and the	Formatted: Font: 11 pt, Not Italic, Font color:
21	physiotherapist would return the call when they were free. Patients randomised to usual care were	Auto, Pattern: Clear  Formatted: Font: 11 pt, Not Italic, Font color: Auto, Pattern: Clear
22	put on the usual service waiting list for face-to-face assessment and treatment.	Formatted: Font: 11 pt, Not Italic, Font color: Auto, Pattern: Clear
23		<b>Formatted:</b> Font: 11 pt, Not Italic, Font color: Auto, Pattern: Clear
24	Outcome measures	
25	We used the EQ-5D-3L ²⁸⁴ , valued using the UK tariff, ²⁹⁵ to estimate QALYs gained for the cost-utility	
26	analysis. The primary outcome for the trial was the physical component summary (PCS) measure	
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> from the SF-36v2 questionnaire²⁶³⁰ and secondary clinical outcomes included: the Measure Yourself 1 Medical Outcomes Profile (MYMOP);  $\frac{2731}{2}$  a Global Improvement Score – a single question about 2 3 overall improvement; a composite measure of response to treatment including pain, function and overall improvement (OMERACT OARSI);²⁸³² patient satisfaction; and waiting time to first treatment 4 5 advice from a physiotherapist. All outcomes (except the global improvement score and waiting time 6 to first treatment advice) were measured at baseline, 6 weeks and 6 months and were obtained from a self completed questionnaire administered at these three time points. 7 8 9 **Resource use** 10 The analysis was based on costs related to the reason for which the patient was referred to the 11 physiotherapy service. We identified relevant resources in discussion with participating 12 physiotherapists and service managers. Direct costs to the health care provider included: cost of 13 initial and follow-up physiotherapy consultations; primary and community consultations; hospital care; and prescribed medication. Patient and carer costs included: telephone calls to the 14 PhysioDirect service; travel; over the counter medication; prescription costs; private therapy and 15 16 purchase of equipment; extra domestic help; and loss of earnings. Lost productivity was estimated 17 separately in relation to time off work to attend physiotherapy appointments and time off because 18 of the musculoskeletal condition itself. 19 20 Patient level data about all physiotherapy appointments and consultations were recorded either 21 automatically by computer or by the physiotherapist treating the patient. For those in the 22 intervention group, the PhysioDirect assessment software recorded which physiotherapist

conducted each telephone call, and the duration of each call. In addition to the time logged on to
the system physiotherapists had to carry out administrative activities following each telephone call,
such as collating information to send to the patient by post. The time spent on these activities was

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6 7	1	estimated from information available at one site (Bristol) where manual recording of the entire
, 8 9	2	encounter supplemented the electronic recording.
10 11	3	
12	4	Physiotherapists assigned to the PhysioDirect service were required to be available throughout the
13 14	5	time the service was 'open' but they were not usually fully engaged in dealing with PhysioDirect
15 16	6	patients during these hours. We conducted an observational time and motion study at each of the
17 18	7	four sites to determine how they occupied their non-PhysioDirect contact time in order to apportion
19 20	8	costs appropriately. Time and motion data were collected at points in the study when the sites were
21 22	9	expected to be fully operational, and across a mix of day, time of day, and location. The capital costs
23 24	10	required to run a telephone services are potentially less than for a face-to-face service. Each site
25 26	11	provided information about space and equipment required to run their telephone service and we
27 28	12	used this to estimate an overall percentage reduction of capital costs for these compared with a
29 30	13	standard face-to-face service.
31 32	14	
33 34	15	Data about all face-to-face appointments were recorded routinely. These data included the length of
35 36	16	appointment, the grade of the physiotherapist seen, and information about missed appointments.
37 38	17	
39	18	Information about other NHS resource use was collected, where possible, from general practice
40 41 42	19	records and supplemented by information gained directly from patients. General practice notes
42 43	20	were scrutinised for patient level data on primary care consultations and prescribed medication. We
44 45	21	included all consultations at which the musculoskeletal condition for which the patient was referred
46 47	22	to physiotherapy was mentioned and these were recorded by type of consultation (for example,
48 49	23	face-to-face, telephone, out of hours, home visit) and by type of professional seen (for example, GP,
50 51	24	nurse). It was not feasible to distinguish between medication prescribed for the condition for which
52 53	25	the patient was referred for physiotherapy and any other musculoskeletal problem so we included
54 55	26	all medication of a potentially relevant type, defined using British National Formulary (BNF) ²⁹³³
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2 (10.1.1); Local corticosteroid injections (10.1.2.2); and Drugs for the relief of soft-tissue inflammation 3 (10.3). 4 A questionnaire was administered to participants at 6 weeks and 6 months after randomisation to 5 6 obtain resource use data not available elsewhere. The questionnaire was designed specifically for 7 this study but was similar in content and structure to others used for the same purpose³⁴ Questions 8 These-included information about hospital care related to the condition for which the patient was 9 referred to physiotherapy: visits to Accident & Emergency, outpatient appointments, and inpatient 10 stays. Information about personal expenditure relevant to the patient's musculoskeletal condition 11 was also gained from the questionnaire at 6 weeks and 6 months. We asked about the cost of travel 12 to physiotherapy and other health care appointments, expenditure on over the counter medication, 13 prescription costs, use of private therapies and their cost, expenditure on equipment or devices, and extra help at home. In addition, participants were asked about any time off work, and the associated 14 loss of earnings, because of their condition or to attend health care appointments relating to the 15 16 condition including usual care physiotherapy and PhysioDirect. 17 18 Valuation of resource use Table 1 gives the unit costs and sources used to value the health care resources. We used Curtis⁴⁰³⁵ 19 to value primary and community health care and Department of Health reference costs^{36±} for all 20 21 hospital-based care. The cost of prescribed medication was estimated from that published in the BNF,²⁹³³ adjusted to allow for the discount available to the NHS, and the professional fee and 22 container allowance in accordance with the Drug Tariff for England.³²² Personal expenditure was 23 24 reported directly by the participants, the exception being travel by car, which was reported as mileage and costed using the AA schedule of motoring costs.³⁸³ Time off work was valued using the 25

coding. These were: Analgesics (chapters 4.7.1 – 4.7.2); Non-steroidal anti-inflammatory drugs

median gross weekly earnings by age and sex.³⁹⁴

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12 13	4	The cost of face-to-face physiotherapy consultations was estimated by adapting the methods of	
14 15	5	Curtis ³⁵⁹ to obtain a different unit cost for each band of staff at each site. National median pay rates,	
16 17	6	by band, 3640 were adjusted to allow for National Insurance, superannuation, and overheads, as per	
18 19	7	Curtis, then further adjusted to allow for band and site specific non-contact time. Information about	
20	8	the proportion of time physiotherapists on each grade typically spend in direct contact with patients	
21 22	9	was provided by the four physiotherapy service managers. This provided us with a cost per hour for	
23 24	10	each band of staff at each site.	
25 26	11		
27 28	12	The unit cost of physiotherapists working in the PhysioDirect service was estimated in a similar way,	
29 30	13	but allowing for the reduced cost of capital and overheads; information from the site managers	
31 32	14	indicated this to be about 50%. To obtain a cost per hour of telephone contact we used information	
33 34	15	from the computerised records of the PhysioDirect service, which identified the proportion of time	
35 36	16	spent by physiotherapists actually dealing with PhysioDirect patients. We then combined this with	
37 38	17	data from the time and motion study, which identified activities undertaken during non-contact	
39	18	time, for example, administration relating to face-to-face appointments or general administration, to	
40 41	19	give a cost per hour for each band of staff at each site.	
42 43	20		
44 45	21	All costs were valued in £ sterling at 2009 prices, adjusted for inflation where necessary. ³⁵⁰	
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Data analysis We investigated the amount of each resource used by patients in each group using frequencies, means and medians. Mean total cost per participant was derived by combining resource use with unit costs. QALYs were derived from responses to the EQ-5D-3L at baseline, 6 weeks and 6 months using valuations from the UK general population.²⁹⁵ These values, representing health-related quality of life on a scale between zero (death) and 1 (best imaginable health), were used to compute QALYs experienced over the 6 month period using the area under the curve approach and adjusting for any difference between the groups at baseline.³⁷⁴³ A cost-consequences matrix was constructed using all available data. We compared costs from all three perspectives (health care provider, patients and carers, lost productivity) with the SF-36v2 PCS, MYMOP, Global Improvement Score, OMERACT OARSI, patient satisfaction, waiting time, and QALYs. The cost-utility analysis was carried out using data on <u>all</u> patients for whom we had complete NHS cost and QALY data. An incremental cost-effectiveness ratio (ICER) was constructed, comparing the difference in mean total cost per patient with mean difference in QALYs, thus the lower the ICER, the greater the cost-effectiveness and the better the value for money. Uncertainty around the ICER was captured by using the bootstrapping technique: 5000 replicates of the cost and QALY data were created by sampling from the original data, with replacement. The range and spread of the 5000 ICERs was used to replicating it 5000 times using the bootstrapping technique, construct a costeffectiveness acceptability curve to indicate the likelihood of the intervention being cost-effective. The net monetary benefit (NMB) of the intervention was estimated from the point estimate of the ICER for values of societal willingness-to-pay of £20,000 and £30,000 per QALY. If the NMB is positive

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1 at a given level of willingness to pay, the intervention is regarded as cost-effective. Confidence 2 intervals around the NMB were formed from the bootstrapped estimates. 3 estimating a confidence interval around the net monetary benefit, and constructing a cost-4 ctiveness acceptability cu 5 We used the multiple imputation by chained equation procedure to address the issue of missing cost 6 7 and EQ-5D data.³⁸⁴⁴ This technique uses a regression model to estimate missing values from known 8 values. In addition to cost and EQ-5D-3L variables the imputation model also included randomisation group, age, sex, and SF36v2 PCS. Stata v12²⁹⁴⁵ was used to generate five datasets using 10 switching 9 10 procedures. 11 12 Discounting was not carried out because the analysis was restricted to costs and outcomes over a period of less than a year. All analyses were conducted using Microsoft Excel and Stata v12.³⁹⁴⁴ 13 14 **Sensitivity Analyses** 15 16 We addressed three areas of uncertainty using four one/two-way sensitivity analyses. First, we 17 estimated the cost of running the PhysioDirect service if it was operating at full capacity. It is likely that this was not achieved during the trial because of: low demand due to exclusions and non-18 participation in the trial; inflexible staffing levels to ensure consistency throughout the trial period; 19 20 and the 'one-way' system generally used, where physiotherapists waited for patients to call them 21 but did not routinely contact patients themselves (notwithstanding some limited use of answermachines). Data from the Bristol service, which continued to operate beyond the trial period and 22 23 was then able to tailor staffing levels to demand, were used to estimate the cost of running a more 24 'efficient but feasible' PhysioDirect service once the trial had ended. 25 14

The second area of uncertainty addressed hospital costs. Patients in the trial were recruited from primary care and for these, use of secondary care is infrequent but relatively expensive and this can have a disproportionate effect on mean total cost. We tested this by excluding hospital costs from the total. The third area of uncertainty tested the effect of using imputed data rather than complete cases; the third and fourth sensitivity analysies used the trial imputed missing data with missing values imputed. Finally, in a two-way sensitivity as described above first with data collected during the trial and analysis, we re-estimated second by combthe ining with results of the first-sensitivity analysis, (mimicking an 'efficient but feasible' service) in this instance using the imputed dataset. RESULTS A total of 2,249 patients were recruited between July 2009 and December 2009, and followed up until June 2010took part in the trial, 1506 allocated to PhysioDirect and 743 to usual care. The mean age was 60, with slightly more females than males (60% vs 40%); they were overwhelmingly white (97%), just over half (60%) were employed and all but a few were referred for physiotherapy by their GP. Lower limb problems were the most prevalent (30%) reason for referral, 27% patients had a lumbar problem and 23% upper limb problems. Nearly all participants (2,223=99%) gave permission to access their GP notes to obtain data about primary care encounters and prescribed medication. 81% returned questionnaires at both 6 weeks and 6 months though not all participants completed all sections at both time points. We had complete NHS cost and QALY data for 840 (56%) PhysioDirect and 432 (58%) usual care participants. 

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6 7	1	Resource use
8 9	2	Table 2 gives information about the different types of physiotherapy consultations by patients in
10 11	3	each group. Of the 1506 patients in the PhysioDirect group, 39% (586) were managed solely over the
12 13	4	telephone and only 46% (695) had any face-to-face consultations. In total, patients in the usual care
14 15	5	group had, on average, 0.38 (95% CI: 0.12 to 0.63) more consultations than those in the PhysioDirect
16 17	6	group and the mean total duration of all consultations was 20 minutes longer (95% CI: 12 to 28).
18	7	
19 20	8	Table 2 here
21 22	9	
23 24	10	Tables 3 and 4 give information about NHS and personal resource use. Just over a third of patients
25 26	11	(35%) had a GP consultation during the 6 months and 40% received a prescription for
27 28	12	musculoskeletal pain-related medication. There was very little difference between the two groups in
29	13	terms of health care use and the only important notable difference in personal expenditure was
30 31 32	14	travel to physiotherapy appointments.
33	15	
34 35	16	Tables 3 and 4 here
36 37	17	
38 39	18	Costs and consequences
40 41	19	Table 5 summarises the mean cost per patient, by group, for each category of cost. All available data
42 43	20	are included giving variable denominators for each category. Comparing the two groups, there are
44 45	21	small differences in cost in some categories but for most of these the confidence intervals indicate
46 47	22	there is no evidence of a difference between the groups.
48	23	
49 50	24	Table 5 here
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5 6 7	1	Table 6 combines the results of the cost analysis with the full range of primary and secondary	
8	2	outcomes, including QALYs.	
9 10			
11	3		
12 13	4	Table 6 here	
14 15	5		
16 17	6	Results are presented for all available data, with cost categories combined. DAgain, denominators	
18 19	7	vary within the table and they also differ from those in table 5 because sub-categories have been	
20	8	collapsed. There was no evidence of a difference in the primary clinical outcome (the SF36v2 PCS)	
21 22	9	between the groups, suggesting that PhysioDirect led to similar outcomes as usual physiotherapy	
23 24	10	care. Patients in the PhysioDirect group had their first assessment and telephone advice 27 days	
25 26	11	earlier than those in the usual care group, however patient satisfaction was slightly lower in those	
27 28	12	receiving PhysioDirect. QALYs were higher in the PhysioDirect group by 0.009, which equates to	
29 30	13	about 3.3 extra days of full health over a year.	
31 32	14		
33 34	15	Cost-utility analysis	
35 36	16	The cost-utility analysis presented in Table 7 uses complete cases, that is, we include only those	
37	17	patients for whom we had complete NHS cost and QALY data: 432 (58%) from the usual care group	
38 39	18	and 840 (56%) from PhysioDirect. The small extra cost of caring for patients in the PhysioDirect	
40 41	19	group was compensated for by the extra QALY gain, giving an incremental cost-effectiveness ratio of	
42 43	20	£2,889. Values below £20,000 are regarded by NICE to indicate a cost-effective intervention ²⁷ At this	<b>Formatted:</b> Superscript
44 45	21	threshold level of If society is willingness to pay for a £20,000 per-QALY ²³ there is a positive net	
46 47	22	monetary benefit of is-£117 (95% CI -£96 to £310) and there is 0.88 probability that the intervention	
48 49	23	is cost-effective. This is illustrated in the cost-effectiveness acceptability curve in figure 1.	
50 51	24		
52 53	25	Table 7 here	
54	26	Figure 1 here	
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8 9	2	Sensitivity Analysis	
10	3	The results of the four sensitivity analyses are shown in table 8 and figure 2. Scenario (1) indicates	
11 12	4	the potential cost-effectiveness of a more efficient PhysioDirect service. During the trial PhysioDirect	
13 14	5	clinic opening hours, physiotherapists spent about 35% of their time on the phone or dealing with	
15			
16 17	6	directly related administration; in Bristol after the trial, this was increased to 57%. Under this	
18 19	7	scenario, the cost per patient in the PhysioDirect group was £14.53 less than under trial conditions	
20 21	8	and £2.11 less per patient in the usual care group. The ICER is therefore lower, at £1,045, the NMB	
22	9	correspondingly higher at £127 ( $\lambda$ =£20,000). At low levels of $\lambda$ , the probability of PhysioDirect being	
23 24	10	cost-effective under this scenario is higher than with the base case, though at $\lambda$ =£20,000 it reaches a	
25 26	11	similar value (see figures 1 and 2).	
27 28	12		
29 30	13	Table 8 here	
31	14	Figure 2 here	
32 33	15		
34 35	16	The effect of removing hospital costs from the analysis is shown in sensitivity analysis (2). Hospital	
36 37	17	costs accounted for 75% of all NHS costs yet only 19% (n=252) participants reported using any	
38 39	18	secondary care. Hospital use was evenly divided between the two groups so removing these from	
40 41	19	the analysis made very little difference to incremental analysis.	
42 43	20		
44 45	21	The effect of imputing missing NHS cost and QALY data is explored in sensitivity analysis (3). Using	
46	22	these data the cost of the interventions is lower but this is offset by higher NHS costs, giving a higher	
47 48	23	mean total cost in both groups, by $\pm 21.41$ in the usual care group and $\pm 6.58$ in the PhysioDirect	
49 50	24	group. QALYs using imputed data are lower, by 0.005 in the usual care group and by 0.010 in the	
51 52 53	25	PhysioDirect group. The net effect is a reduction of both incremental cost and incremental QALYs,	
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1	giving an ICER of £2,260. Uncertainty around the ICER is reduced, as seen by the flatter CEAC in
2	figure 2.
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4	Sensitivity analysis (4) combines analyses (1) and (3) by using imputed cost data in the 'efficient
5	service' scenario. In this case the results indicate that PhysioDirect is, on average, cheaper than usual
6	care with a possible saving of £6.02 per patient, which gives a negative value for the ICER, indicating
7	the intervention is superior in terms of both cost and outcome. The results suggest a possible cost
8	saving of £6.02 per patient; the probability that the service is cost-effective at $\lambda$ =£20,000 is 0.72.
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11	DISCUSSION
12	Statement of principal findings
13	The results of this economic evaluation suggest that PhysioDirect services for patients with
14	musculoskeletal problems require careful management if they are to be a cost-effective alternative
15	to usual physiotherapy care. There was very little difference between the two groups in terms of
16	either outcomes or costs, and the finding that PhysioDirect is cost-effective is based on evidence
17	that it provides very slightly greater QALY benefits at very slightly greater cost.
18	
19	Clearer cost savings were observed in the sensitivity analysis that replicated the post-trial service,
20	once greater flexibility in working arrangements was implemented. Without the restrictions of a trial
21	environment staffing was adjusted to meet the anticipated demand, a call-back service was
22	employed which accommodated fluctuations in activity during each session, referrals added to the $\sim$
23	system were adjusted regularly to reflect actual staffing and the number of patients waiting for
24	a call-back and a higher throughput of patients led to greater economies of scale. These changes
25	ensured physiotherapists within the PhysioDirect service spent a higher proportion of their
26	PhysioDirect clinic time on the telephone with patients. There was no evidence of a difference
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6 7	1	between PhysioDirect and usual care in cost to patients and their families, or to society through the	
8	2	costs of lost production.	
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13	4	Strengths and weaknesses of the study	
14 15	5	The study has a number of strengths. It is the first study assessing the cost-effectiveness of a	
16 17	6	PhysioDirect service including a large sample of patients with a wide range of musculoskeletal	
18 19	7	problems based across a number of locations. ¹⁵⁴ It uses a rigorous study design and conforms to	
20	8	CONSORT guidelines. ⁴⁶⁹ The fFollow up rate from participating patients was in line with other	
21 22	9	primary care trialsgood, 47,48 a high proportion of the resource use data were collected from GP	Formatted: Superscript
23 24	10	records, and there was collection of resource use information outside of the main health service	
25 26	11	perspective. Nevertheless, there are also limitations The cost consequences analysis provides	
27 28	12	complete information on costs from different perspectives compared with a range of outcomes so	
29 30	13	although this approach is sometimes criticised for leaving the reader to evaluate the findings it does	
31	14	have the advantage of transparency. Furthermore, in this study we have also presented a cost-utility	
32 33	15	analysis that conforms to the recommendations of NICE. The proportion of eligible individuals	
34 35	16	consenting to participate in the trial was only 50%. ²² -Nevertheless, there are also limitations. The	
36 37	17	practices recruited to the trial had a low proportion of ethnic minority patients, a slightly lower	
38 39	18	proportion of patients from deprived areas were judged to be eligible, and the proportion of eligible	
40 41	19	individuals consenting to participate in the trial was only 50%. ²³ These factors limit the	Formatted: Check spelling and grammar, Not Superscript/ Subscript
42 43	20	generalisability of the results though none of these selection effects was large. Further, a particular	
44 45	21	difficulty in conducting economic evaluation with new service developments is ensuring that they	
46	22	are fully utilised ₂ . ⁴⁴²⁴ particularly when conducting analysis from a long-run perspective, as here.	
47 48	23	Although there was a clear run-in period prior to data collection for the trial (ranging from 4 to 12	
49 50	24	weeks in each of the four sites), to ensure that services were operating as well as they could, and a	
51 52	25	2:1 randomisation ratio in favour of PhysioDirect was used, there was still considerable	
53 54	26	underutilisation of the new service. This was ameliorated by including a more fully utilised service	
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> within the sensitivity analysis. It should also be noted that, because of the use of a long-run perspective in the analysis, set up costs, which may, in the short-term be important in a financially constrained service, are not included here. Finally, because the differences in both costs and effects are small, there is still some uncertainty around the findings. The meaning of the study and implications for policy makers If the aim of health services is to achieve maximum health gain from an investment in health care, then PhysioDirect has a high probability of being more cost-effective than usual physiotherapy care. This research also, however, suggests that it cannot be assumed that PhysioDirect will reduce costs, although it could potentially do so if PhysioDirect services are managed efficiently. Both the costs and cost-effectiveness of services will depend on the productivity of physiotherapist time. If physiotherapists are able to use most of their time dealing directly with patients during sessions when they are available on the telephone, then the service will be less costly. This is most likely to be achieved by operating a call-back service and/or by operating the service on a large scale to even out fluctuations in demand. Operating a system on larger scale might also offer other economies of scale, particularly in terms of infrastructure. Further efficiencies may also be achieved if these services are, in the future, provided in conjunction with direct access for patients (rather than following referral from another health care professional), given that patients who self-refer are likely to contact the service with musculoskeletal problems of shorter duration, ⁴⁹² and such patients may be particularly appropriate for the initial assessment and advice provided by a PhysioDirect service. More generally, the study has broader implications for telephone services, particularly around the implicit assumption that such services will inevitably be money saving. Here this assumption was found to be false, largely because the physiotherapists' time was underutilised during PhysioDirect clinic hours. Thus, for all such services, it will be important for policy makers to ensure that easy assumptions about the costs of these services are properly assessed in relation to factors such as

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6 7	1	how efficiently the service is run, and what proportion of patients are subsequently invited for face
8 9	2	to face care following an initial telephone call.
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12 13	4	Unanswered questions and future research
14 15	5	As services evolve, further research should explore the costs and benefits of PhysioDirect under
16 17	6	different scenarios. These might include: comparing different skill levels of staff operating the
18 19	7	service; the inclusion of patient self-referrals in addition to GP referrals; the use, or otherwise, of
20 21	8	computerised support in assessing the patient; the extension to internet services (possibly combined
22	9	with cameras); ⁴⁴⁵⁰ and the use of mobile 'smartphone' technology, for example in rapid assessment
23 24	10	of musculoskeletal injuries. In particular, however, it will be important to assess the costs and
25 26	11	benefits of services once they are more established and provided on a wider scale. The costs and
27 28	12	benefits of telehealth more generally need further exploration in relation to their cost effectiveness
29 30	13	particularly given the negative findings of the Whole Systems Demonstrator project evaluating
31 32	14	telehealth support and treatment for patients with long term conditions. ⁴⁴⁵¹ It would be helpful to
33 34	15	identify those characteristics that are likely to make services both more cost-effective and less
35 36 37	16	costly.
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#### References

- Munro J, Nicholl, J, O'Cathain A et al. Impact of NHS Direct on demand for immediate care: observational study. *Br Med J* 2000;321:150-153.
- 2. Lattimer V, Sassi F, George S et al. Cost analysis of nurse telephone consultation in out of hours primary care: evidence from a randomised controlled trial. *Br Med J* 2000;320:1053-1057.
- Lattimer V, George S, Thompson F et al. Safety and effectiveness of nurse telephone consultation in out of hours primary care: randomised controlled trial. The South Wiltshire Out of Hours Project (SWOOP) Group. Br Med J 1998;317:1054-1059.
- Pinnock H, Bawden R, Proctor S et al. Accessibility, acceptability, and effectiveness in primary care of routine telephone review of asthma: pragmatic, randomised controlled trial. *Br Med J* 2003;326:477-479.
- Bunn F, Byrne G, Kendall S. Telephone consultation and triage: effects on health care use and patient satisfaction. *Cochrane Database of Systematic Reviews.* (4):CD004180, 2004. 2004;CD004180.
- 6. McKinstry B, Watson P, Pinnock H et al. Telephone consulting in primary care: a triangulated qualitative study of patients and providers. *Br J Gen Pract* 2009;59:e209-e218.
- Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain* 2003;102:167-178.
- Jordan K, Ong BN, Croft P. Previous consultation and self reported health status as predictors of future demand for primary care. J Epidemiol Commun Health 2003;57:109-113.
- McKormick A, Fleming D, and Charlton J Morbidity statistics from general practice. Fourth national study 1991-1992 Serise MB5 no.3. London: 1995.

10. Balage F, Mannion A, Pellise F, et al. Non-specific low back pain. Lancet 2012;379(9814):482-91.	<b>Formatted:</b> Font: Italic
Andersson GB. Epidemiological features of chronic low-back pain. Lancet 1999; 354: 581-585.	
11Chuang L-H, Soares M, Tilbrook H, et al. A Pragmatic multicentred randomized controlled trial of	
yoga for chroonic low back pain: economic evaluation, Spine 2012;37(18):1593-1601.	<b>Formatted:</b> Font: Italic
Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain 2000;84:95-103.	
12. National Institute for Health and Clinical Excellence Low back pain: early management of	<b>Formatted:</b> Indent: Hanging: 0.25"
persistent non-specific low back pain. NICE clinical guideline 88. 2009.	
13. Department of Health. Physiotherapy Services Summary Information for 2004-2005, England	<b>Formatted:</b> Indent: Hanging: 0.25"
https://catalogue.ic.nhs.uk/publications/hospital/outpatients/nhs-phys-serv-summ-eng-2004-	<b>Formatted:</b> Default Paragraph Font
05/nhs-phys-serv-summ-eng-2004-05-rep.pdf	
http://www.hscic.gov.uk/searchcatalogue?productid=4306&kwd=K&gran=Government+Office+	
Regions&sort=Relevance&size=10&page=1#top (accessed 160.086.2013)	
14. Maniadakis N, Gray A. The economic burden of back pain in the UK. Pain 2000;84:95-103.	
1 <u>5</u> 4. Salisbury C, Montgomery AA, Hollinghurst S et al. Effectiveness of PhysioDirect telephone	
assessment and advice services for patients with musculoskeletal problems: pragmatic	
randomised controlled trial. Br Med J 2013;346:f43.	
1 <u>6</u> 5. Hodgson K. Kidderminster helpline proves a success. <i>Physiotherapy Frontline</i> 2001;7:22-23.	
176. Taylor S, Ellis I, and Gallagher M. Patient satisfaction with a new physiotherapy telephone	
service for back pain patients. Physiotherapy 2002;88:645-657.	
24	

<u>1236.</u>

187. Clayson M and Woolvine M. Back pain direct clinic: a collaboration between general practitioners and physiotherapists. *Work Based Learning in Primary Care* 2004;2:38-43.

1<u>98</u>. Turner D. An exploratory study of physiotherapy telephone assessment. *International Journal of Therapy and Rehabilitation* 2009;16:97-105.

<u>2019</u>. Russell T, Truter P, Blumke R, Richardson B. The diagnostic accuracy of telerehabilitation for nonarticular lower-limb musculoskeletal disorders. *Telemed J & E-Health* 2010;16:585-594.

210. Patel S, Hossain FS, Colaco HB et al. The accuracy of primary care teams in diagnosing disorders of the shoulder. *J Eval Clin Pract* 2011;17:118-122.

221. Jette DU, Ardleigh K, Chandler K et al. Decision-making ability of physical therapists: physical therapy intervention or medical referral. *Phys Ther* 2006;86:1619-1629.

232. Salisbury C, Foster NE, Hopper C et al. A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of 'PhysioDirect' telephone assessment and advice services for physiotherapy. *Health Technology Assessment (Winchester, England)* /20;17:1-157.

23. National Institute for Health and Clinical Excellence. Guide to the Methods of Technology Appraisal http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf (accessed 10.06.2013)

<u>2441.</u>—Coast J, Hensher M, Mulligan J, et al. Conceptual and practical difficulties with the economic evaluation of health services developments. J *Health Serv Res Policy* 2000;5:42-48.

25. Coast, J. Is economic evaluation in touch with society's health values? <u>Br Med J 2004;(329):1233-</u>

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42
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5. Drummond M, Brown R, Fendrick M, et al. Use of Pharmacoeconomics Information—Report of	Formatted: Indent: Left: 0"
the ISPOR Task Force on Use of Pharmacoeconomic/Health Economic Information in Health-Care	
Decision Making. <u>Value in Health 2003;6 (4):407-416.</u>	Formatted: Font: Italic, No underline, Font color: Auto
7. National Institute for Health and Clinical Excellence. Guide to the Methods of Technology	Formatted: Indent: Left: 0", Hanging: 0.25
Appraisal http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf	
(accessed 16.08.2013)	
<ul> <li>Brooks R, with the EuroQol Group. EuroQol: the current state of play. <i>Health Policy</i> 1996;53-4-7</li> <li>72.</li> </ul>	( <b>Formatted:</b> Indent: Left: 0", Hanging: 0.25
25. Dolan P, Gudex C, Kind P et al. A social tariff for EuroQol: Results from a UK general	
population survey. University of York, 1-9-1995.	
226. Quality Metric. A community for measuring health outcomes using SF tools. http://www.sf-	
36.org/ (accessed 1 <u>6</u> 0.0 <u>8</u> 6.2013)	
127. Paterson, C. Measuring outcomes in primary care: a patient generated measure, MYMOP,	
compared with the SF-36 survey. <i>Br Med J</i> 1996;312:1016-1020.	
228. Pham T, Van Der Heijde D, Lassere M et al. Outcome variables for osteoarthritis clinical	
trials: The OMERACT-OARSI set of responder criteria. <i>J Rheumatol</i> 2003;30:1648-1654.	
329. British National Formulary. British National Formulary. http://www.bnf.org/bnf (accessed	
1 <u>6</u> <del>0</del> .2013)	<b>Formatted:</b> Default Paragraph Font, Font: (Default) Calibri, 11 pt, No underline, Font color: Auto, Do not check spelling or gramma Pattern: Clear
4. Database of Instruments for Resource Use Measurement (DIRUM)_http://www.dirum.org         (accessed 16.08.2013)	<b>Formatted:</b> Default Paragraph Font, Font: (Default) Calibri, 11 pt, No underline, Font color: Auto, Do not check spelling or gramma Pattern: Clear
20. Curtis L. <i>Unit costs of health and social care 2009</i> . PSSRU, University of Kent, 2010.	<b>Formatted:</b> Default Paragraph Font, Font: (Default) +Body (Calibri), Check spelling and grammar

3<u>6</u>¹. Department of Health. NHS Reference costs 2009-2010.

https://www.gov.uk/government/publications/nhs-reference-costs-2009-2010 (accessed

1<u>6</u>0.0<u>8</u>6.2013)

3<u>7</u><del>2</del>. National Health Service. NHS Drug tariff.

http://www.nhsbsa.nhs.uk/PrescriptionServices/924.aspx (accessed 1<u>6</u>0.0<u>8</u>6.2013)

383. The Automobile Association. The AA schedule of motoring costs.

http://www.theaa.com/motoring_advice/running_costs/index.html (accessed 160.086.2013)

394. Office for National Statistics. Annual survey of hours and earnings 2009

http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2009-

revised/index.html (accessed 160.086.2013)

<u>40</u>35. Royal College of Nursing. Agenda for change – pay rates

http://www.nhscareers.nhs.uk/working-in-the-nhs/pay-and-benefits/agenda-for-change-pay-

rates (accessed 1<u>6</u>0.0<u>8</u>6.2013)

<u>4136</u>. Scott A, Simoens S, Heaney D, et al. What does GP out of hours care cost? An analysis of different models of out of hours care in Scotland. *Scot Med J* 2004;49:61-66.

42. O'Dowd A. Cost of out of hours care was 22% higher than predicted in England. *Br Med J* 2006;332:1113.4.

2006;332:1113.4.

<u>43</u>37. Manca A, Hawkins N, Sculpher M. Estimating mean QALYs in trial-based cost-effectiveness analysis: the importance of controlling for baseline utility. *Health Econ* 2005;14:487-496.

<u>4438</u>. van Buuren S, Boshuizen HC, Knook D L. Multiple Imputation of missing blood pressure covariaties in survival analysis. *Stat Med* 1999;18:681-694:

<u>4539</u>. StataCorp Statistical Software: Release 11. College Station, TX: StataCorp LP. 2009.

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460. The CONSORT Group. CONSORT: the transparent reporting of trials http://www.consortstatement.org (accessed 160.086.2013)

<u>47. Stamuli E, Bloor K, MacPherson H, et al. Cost-effectiveness of acupuncture for irritable bowel</u> syndrome: findings from an economic evaluation conducted alongside a pragmatic randomised controlled trial in primary care. <u>BMC Gastroenterology 2012; 12:149</u>.

<u>48. Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet 2011;</u> <u>378 (9802): 1560-71.</u>

41. Coast J, Hensher M, Mulligan J, et al. Conceptual and practical difficulties with the economic

evaluation of health services developments. J Health Serv Res Policy 2000;5:42-48.

492. Leemrijse CJ, Swinkels IC, Veenhof C. Direct access to physical therapy in the Netherlands: results from the first year in community-based physical therapy. *Phys Ther*. 2008;-88(8):936-46

<u>5043</u>. Li LC, Townsend AF, Badley EM. Self-management interventions in the digital age: new approaches to support people with rheumatologic conditions. *Best Pract Res Clin Rheumatol*. 2012;-26(3):321-33.

5144. Henderson C, Knapp M, Ferbnandez J-L, et al. Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested
 economic evaluation in a pragmatic, cluster randomised controlled trial. *Br Med J* 2013;34.

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## **Competing interestes**

We have read and understood the BMJ Group policy on declaration of interests and declare the following interests: none.

### 6 Funding

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 Health.

#### 19 Aurthors' contributions

CS was principal investigator on the trial, SH took the lead on the economic evaluation. JC, NF, SG,
JH, and AM were co-applicants and contributed to the conception and design. SH, JC and JB carried
out the analysis with help from CS and AM, and all authors contributed to the interpretation of the
data. SH and JC wrote the first draft of the paper with all authors contributing to subsequent
revisions. All authors have seen and approved the final version.

#### Acknowledgments

We would like to dedicate this paper to the memory of Cherida Hopper, trial manager of the PhysioDirect study, who sadly died in June 2013.

We would like to thank the patients who contributed to this research; the physiotherapists,
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in the four primary care trusts; participating general practices; the research support staff in Bristol
and Keele; members of the Trial Steering Committee and Data Monitoring Committee; and Jill

1		
1 2 3 4 5 6 7 8 9 10 11 12	1 2	Gamlin and Nick Deane who developed the PhysioDirect assessment algorithms and software used in this trial.
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## Table 1: Data sources and unit costs

		Unit cost (£)	
	Primary and Community Care ³⁵⁹		
	General Practitioner		
	Surgery	27.00	
	Telephone consultation	16.00	
	Home visit	91.00	
	Practice nurse		
	Surgery	10.00	
	Telephone consultation	5.93	
	Health Care Assistant/phlebotomist		
	Surgery	6.92	
	District Nurse		
	Home visit	16.33	
	Out of Hours ^{41,42}		
	General practitioner	23.50	
1			
	Hospital care ^{36±}		
	A&E	103.00	
	Outpatient visits	By Healthcare Resource Group,	
		differentiated by first and follow-up	
	Inpatient stays	By Healthcare Resource Group	
	Prescribed medication ²⁹³³	per item, by name, strength and amount	
	Mileage ^{3<u>8</u>-}	0.4612	
	Time off work ^{3<u>9</u>4}	Median national wage by age and sex	

		Usual care (n=743)	PhysioDirect (n=1506)		
Face-to-face	mean (SD) number	3.11(2.63)	1.91(2.72)		
appointments	mean (SD) total	107.51(88.92)	64.20(89.31)		
	duration (minutes)				
Telephone	mean (SD) number	0.13(0.44)	0.96 (0.63)		
appointments	mean (SD) total	4.21(14.64)	27.37(19.92)		
	duration (minutes)				
Home visits	mean (SD) number	0.00 (0.06)	0.00 (0.06)		
	mean (SD) total	0.14(2.27)	0.12(2.12)		
	duration (minutes)		- 、 ,		
All physiotherapy	mean (SD) number	3.25(2.70)	2.87(2.94)		
contacts	mean (SD) total	111 96/00 50)	04 70 (05 40)		
	duration (minutes)	111.86(90.50)	91.70 (95.40)		
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Table 3: Health services resource use, by group. All available data.

Mean (SD) number of consultations n usual care n PhysioDirect GP consultations 0.77(1.47) 0.87 (1.68) Nurse consultations 0.04 (0.22) 0.06 (0.32) Other primary care consultations 0.02(0.14) 0.02 (0.17) Total number of primary care contacts 0.83(1.56) 0.96 (1.84) Number of prescriptions 1.36 (2.73) 1.68 (3.72) 0.02 (0.01) A&E (visits) 0.03 (0.01) Out-patient (consultations) 0.17 (0.83) 0.35 (1.03) In-patient stays (Finished Consultant Episodes) 0.01 (0.10) 0.01 (0.10) 

## Table 4: Patient and societal resource use, by group. All available data.

Number (%) reporting:	n	usual care	n	PhysioDirect
Expenditure on travel to physiotherapy	462	242 (52.4)	1232	308 (25.8)
Expenditure on travel to primary care	669	116 (17.3)	1337	237 (17.7)
Expenditure on over-the-counter medication	506	256 (50.6)	1028	512 (49.8)
Expenditure on prescriptions	559	264 (47.2)	1085	508 (46.8)
Expenditure on private therapy	484	89 (18.4)	934	167 (17.9)
Equipment purchase	480	139 (29.0)	939	233 (24.8)
Payments for extra domestic help	459	35 (7.6)	928	76 (8.2)
Loss of earnings	598	30 (5.5)	1209	64 (5.3)
Any time off to attend physiotherapy consultation	692	218 (31.5)	1416	380 (26.8)
Work has been affected because of condition	477	141 (29.6)	959	317 (33.1)

Table 5: Mean total cost per patient	, by group and category. All available data ^a .
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	# ¥		Incremental difference			
	usual care			PhysioDirect	(95% Confidence	
		mean (SD) cost mean (SD) cost	n	mean (SD) cost mean (SD) cost	Interval)	
Physiotherapy services	<u>n</u>	<u>incan (50) cost</u>	<u>n</u>	<u>incan (50) cost</u>		
Face-to-face appointments	743	£64.42 (£53.00)	1506	£38.76 (£53.92)	-£25.66 (-£30.37 to -£20.95)	
Telephone appointments	743	£5.22 (£18.01)	1506	£35.17 (£26.34)	£29.94 (£27.84 to £32.05)	
Home visits	743	£0.08 (£1.33)	1506	£0.08 (£1.46)	£0.00 (-£0.12 to £0.13)	
Total physiotherapy cost	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.69)	
Primary care services						
GP consultations	739	£19.21 (£35.91)	1484	£21.69 (£41.66)	£2.48 (-£1.04 to £6.00)	
Nurse consultations	739	£0.44 (£2.37)	1484	£0.61 (£3.17)	£0.16 (-£0.10 to £0.42)	
Other primary care consultations	739	£0.03 (£0.57)	1484	£0.07 (£1.31)	£0.05 (-£0.05 to £0.15)	
Total primary care cost	739	£19.68 (£36.68)	1484	£22.37 (£42.83)	£2.69 (-£0.92 to £6.30)	
Medication cost	728	£11.04 (£51.61)	1469	£10.33 (£55.43)	-£0.72 (-£5.53 to £4.10)	
Hospital services						
A&E	467	£1.99 (£17.12)	912	£3.17 (£20.84)	£1.18 (-£1.01 to £3.37)	
Out-patient	467	£30.74 (£98.36)	910	£38.35 (£126.05)	£7.61 (-£5.50 to £20.72)	
In-patient	465	£51.02 (£520.48)	910	£34.99 (£399.62)	-£16.03 (-£65.70 to £33.64)	
Total hospital cost	459	£83.04 (£561.68)	899	£77.00 (£446.24)	-£6.04 (-£60.99 to £48.91)	
Personal expenditure					2	
Cost of all calls to physiotherapy service	743	£0.97 (£0.99)	1506	£1.75 (£1.29)	£0.79 (£0.68 to £0.89)	
Travel to physiotherapy	462	£6.11 (£11.48)	1232	£3.11 (£8.51)	-£3.01 (-£4.01 to -£2.00)	
Travel for primary care	669	£0.65 (£2.93)	1337	£0.75 (£4.10)	£0.11 (-£0.24 to £0.45)	
ver-the-counter medication	490	£7.67 (£14.09)	987	£8.61 (£22.38)	£0.94 (-£1.23 to £3.11)	
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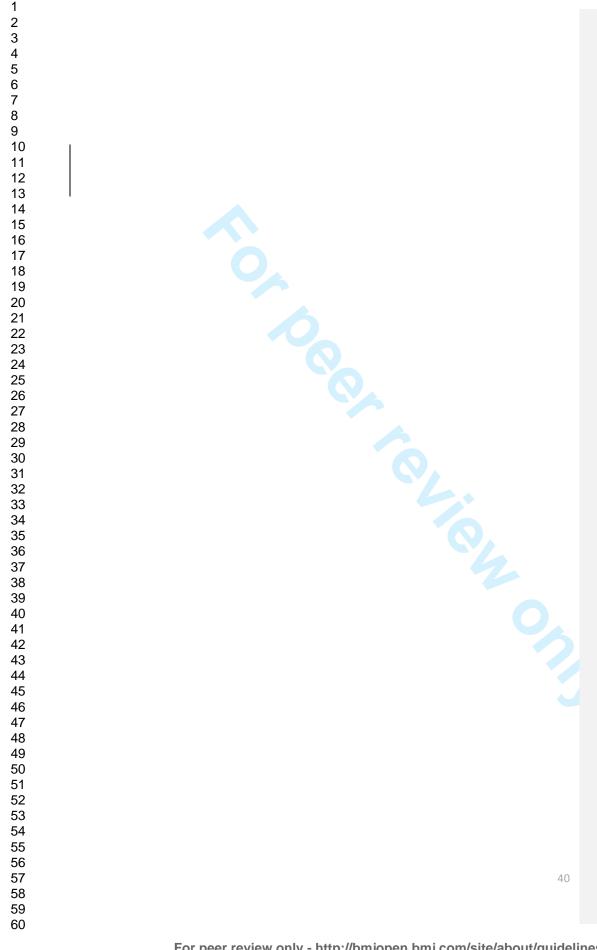
1 2						
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6 7	Private therapy	475	£21.98 (£70.34)	915	£39.34 (£296.94)	£17.36 (-£9.76 to £44.48)
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9	Equipment purchase	473	£17.16 (£169.12)	924	£9.12 (£56.42)	-£8.04 (-£20.08 to £4.00)
10	Extra domestic help	451	£10.93 (£64.31)	905	£13.68 (£96.02)	£2.75 (-£7.07 to £12.56)
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13	Cost associated with loss of	598	£46.69 (409.72)	1209	£82.78 (£885.85)	£36.09 (-£38.63 to £110.81)
14	earnings					
15 16	Value of time off work					
17						
18	Time off work to attend	598	£12.90 (£38.99)	1211	£11.91 (£57.86)	£0.95 (-£3.81 to £5.70)
19	physiotherapy					
20 21	Time off work associated with		£265.92			
22	the condition	452	(£1350.82)	884	£226.61(£1139.84)	£111.31 (-£159.04 to £379.67)
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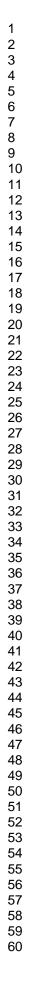
	n (%)	usual care	n (%)	PhysioDirect	Incremental difference (95% Confidence Interval)
Mean (SD) Cost					
Total physiotherapy cost	743	£69.73 (£56.17)	1506	£74.01	£4.28
Total physiotherapy cost	745	109.75 (150.17)	1500	(£63.97)	(-£1.12 to £9.69)
Cost of NHS services including	453 (61%)	£189.19	888 (59%)	£196.43	£7.24
physiotherapy	433 (01%)	(£557.61)	888 (35%)	(£472.02)	(-£49.68 to £64.10)
Total personal expenditure	310 (42%)	£121.10	714 (47%)	£166.40	£45.30
	510 (4276)	(£57 <del>1.1</del> 5)	/14 (4776)	(£1040.27)	(-£78.01 to £168.61)
Total value of all time off	451 (61%)	£276.75	883 (59%)	£240.74	-£36.01
work ^b	431 (01%)	(£1355.00)	883 (39%)	(£1147.20)	(-£174.69 to £102.66)
					Difference/odds ratio
Consequences ^c					(95% confidence interval) ^d
SF36v2 PCS	629 (85%)	44.18 (10.84)	1283 (85%)	43.50 (10.94)	-0.01 (-0.80 to 0.79)
MYMOP ^e	518 (70%)	2.40 (1.38)	1033 (69%)	2.40 (1.43)	-0.02 (-0.16 to 0.11)
Global improvement score	501 (67%)	4.07 (1.40)	1001 (66%)	4.01 (1.44)	-0.08 (-0.23 to 0.08)
Response to treatment (OMERACT OARSI )	510 (69%)	197 (38.6%)	1029 (68%)	430 (41.8%)	1.14 (0.92 to 1.43)
Waiting time to first assessment and advice	618 (83%)	34 (20 to 55) ^f	1281 (85%)	7 (4 to 15) ^f	0.32 (0.29 to 0.35) ^g
Patient overall satisfaction	367 (49%	79.7 (26.5)	739 (49%)	75.9 (28.3)	-3.8 (-7.3 to -0.3)
QALYs ^h	454 (61%)	0.322 (0.079)	881 (58%)	0.331 (0.082)	0.009 (-0.000 to 0.018)
Uses all available data, so denom					

	n	usual care	n	PhysioDirect	Incremental difference
		mean (SD) cost		Mean (SD) cost	(95% CI
Cost of physiotherapy	432	£78.77 (£57.08)	840	£86.75 (£65.47)	£7.98 (£0.69 to £15.27
Cost of NHS services other than	432	£100.91 (£502.02)	840	£112.23 (£476.91)	£11.32 (-£45.08 to £67.72
bhysiotherapy					
Total cost including physiotherapy	432	£179.68 (£504.73)	840	£198.98 (482.12)	£19.30 (-£37.60 to £76.19
QALYs	432	0.325 (0.077)	840	0.332 (0.081)	0.007 (-0.003 to 0.016
ncremental cost-effectiveness ratio (ICEF	R)	0			£2,88
Median Net Monetary Benefit (95% CI) b	ased on boot	strapped results:			_
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\=£30,000					£184 (-£106 to £461
probability of intervention being cost	-effective				0.9
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Cost of physiotherapy	432	£76.56 (£55.34)	840	£72.22 (£61.55)	-£4.34 (-£11.25 to £2.57)•	11	Formatted	[
Cost of NHS services	432	£100.91 (£502.02)	840	£112.23 (476.91)	£11.32 (-£45.08 to £67.72•	111	Formatted	
Total cost	432	£177.46 (£504.49)	840	£184.44 (£481.83)	£6.98 (-£49.89 to £63.85)•	644	Formatted	
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Cost of physiotherapy	448	£78.49 (£57.14)	869	£86.84 (£65.25)	£8.35 (£1.21 to £15.50)	137	Formatted	
Cost of NHS services excluding	440	600 75 (676 AC)	000	(22 40 (662 76)		1.15		
secondary care	448	£33.75 (£76.46)	869	£33.49 (£63.76)	-£0.25 (-£8.05 to £7.54)	$\sim$	Formatted	
Total cost of NHS services including					•	, N	Formatted	
-	448	£112.23 (£99.621)	869	£120.33 (£98.85)	£8.10 (-£3.21 to £19.41)		Formatted	[]
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Cost of physiotherapy	743	£69.73 (£56.17)	1506	£74.01 (£63.97)	£4.28 (-£1.12 to £9.69)	1	Formatted	
Cost of NHS services	743	£131.37 (£465.49)	1506	£131.51 (£384.36)	£0.17 (-£36.13 to £36.48)•	11.11	Formatted	
Total cost of NHS services including	743		1506	£205.55 (£390.04)	•		Formatted	_
physiotherapy		£201.09 (£467.51)		,,	£4.46 (-£32.22 to £41.14)	in mi	\	
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Quality Adjusted Life Years	743	0.320 (0.003)	1200	0.322 (0.002)	0.002 (-0.006 to 0.009)	1 mm	Formatted	
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(4) Imputed data and 'efficient' ser	vice					M.		(
Cost of physiotherapy	743	£67.61 (£54.19)	1506	£61.41 (£59.13	-£6.20 (-£11.26 to -£1.14)	( and	Formatted	
Cost of NHS services	743	£131.37 (£465.49)		£131.54 (384.36)	£0.17 (-£36.13 to £36.48)	1.541.50	Formatted	]
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Total cost of NHS services including	745	£198.98 (£467.48)	1200	£192.95 (£389.52)				
physiotherapy					£30.63)		Formatted	(
Quality Adjusted Life Years	743	0.320 (0.003)	1506	0.322(0.002)	0.002 (-0.006 to 0.009)	in an	Formatted	
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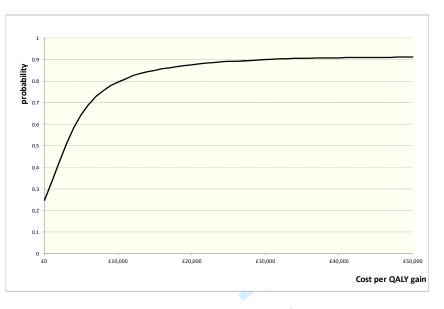
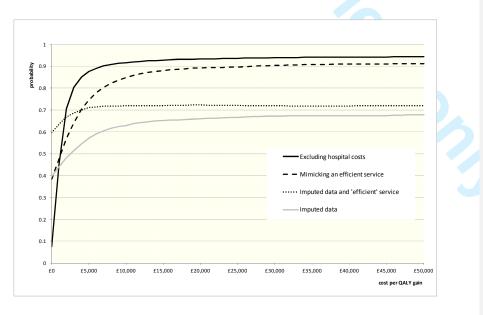


Figure 1. Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different levels of willingness to pay for one Quality Adjusted Life Year

Figure 2. Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different levels of willingness to pay for one Quality Adjusted Life Year: Sensitivity Analyses



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			Reported on
	Item		page No/
Section/item	No	Recommendation	line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific	
		terms such as "cost-effectiveness analysis", and describe the	1/1-3
		interventions compared.	
Abstract	2	Provide a structured summary of objectives, perspective, setting,	
		methods (including study design and inputs), results (including base	P2-3
		case and uncertainty analyses), and conclusions.	
Introduction			
Background and	3	Provide an explicit statement of the broader context for the study.	
objectives		Present the study question and its relevance for health policy or	
		practice decisions.	5/1 – 6/20
Methods			
Target population and	4	Describe characteristics of the base case population and subgroups	
subgroups		analysed, including why they were chosen.	7/14-18
Setting and location	5	State relevant aspects of the system(s) in which the decision(s)	
		need(s) to be made.	7/14-18
Study perspective	6	Describe the perspective of the study and relate this to the costs being	
		evaluated.	7/1-11
Comparators	7	Describe the interventions or strategies being compared and state why	_ / /_
		they were chosen.	7/22 - 8/5
Time horizon	8	State the time horizon(s) over which costs and consequences are being	
		evaluated and say why appropriate.	6/25 - 7/1
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and	
		say why appropriate.	13/14-15
Choice of health	10	Describe what outcomes were used as the measure(s) of benefit in the	
outcomes		evaluation and their relevance for the type of analysis performed.	8/8-16
Measurement of	11a	Single study-based estimates: Describe fully the design features of the	
effectiveness		single effectiveness study and why the single study was a sufficient	6/25-7/1
		source of clinical effectiveness data.	7/14-19
	11b	Synthesis-based estimates: Describe fully the methods used for	
		identification of included studies and synthesis of clinical effectiveness	n/a
		data.	

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Measurement and	12	If applicable, describe the population and methods used to elicit	8/8-9
valuation of preference		preferences for outcomes.	
based outcomes			12/11-12
Estimating resources	13a	Single study-based economic evaluation: Describe approaches used to	
and costs		estimate resource use associated with the alternative interventions.	
		Describe primary or secondary research methods for valuing each	9/19 - 12/2
		resource item in terms of its unit cost. Describe any adjustments made	
		to approximate to opportunity costs.	
	13b	Model-based economic evaluation: Describe approaches and data	
		sources used to estimate resource use associated with model health	
		states. Describe primary or secondary research methods for valuing	n/a
		each resource item in terms of its unit cost. Describe any adjustments	
		made to approximate to opportunity costs.	
Currency, price date,	14	Report the dates of the estimated resource quantities and unit costs.	
and conversion		Describe methods for adjusting estimated unit costs to the year of	12/4
		reported costs if necessary. Describe methods for converting costs into	12/4
		a common currency base and the exchange rate.	
Choice of model	15	Describe and give reasons for the specific type of decision-analytical	
		model used. Providing a figure to show model structure is strongly	n/a
		recommended.	
Assumptions	16	Describe all structural or other assumptions underpinning the decision-	~ /~
		analytical model.	n/a
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could	
		include methods for dealing with skewed, missing, or censored data;	
		extrapolation methods; methods for pooling data; approaches to	12/12-15
		validate or make adjustments (such as half cycle corrections) to a	13/8-12
		model; and methods for handling population heterogeneity and	
		uncertainty.	
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability	
		distributions for all parameters. Report reasons or sources for	- /-
		distributions used to represent uncertainty where appropriate.	n/a
		Providing a table to show the input values is strongly recommended.	
Incremental costs and	19	For each intervention, report mean values for the main categories of	
outcomes		estimated costs and outcomes of interest, as well as mean differences	15/17-16/11
		between the comparator groups. If applicable, report incremental cost-	Tables 5,6,7
		effectiveness ratios.	

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Characterising	20a	Single study-based economic evaluation: Describe the effects of	16/13-21
uncertainty		sampling uncertainty for the estimated incremental cost and	Table 7
		incremental effectiveness parameters, together with the impact of	Figure 1
		methodological assumptions (such as discount rate, study perspective).	16/26 - 18/5
			Table 8
			Figure 2
	20b	Model-based economic evaluation: Describe the effects on the results	
		of uncertainty for all input parameters, and uncertainty related to the	n/a
		structure of the model and assumptions.	
Characterising	21	If applicable, report differences in costs, outcomes, or cost-	
heterogeneity		effectiveness that can be explained by variations between subgroups of	
		patients with different baseline characteristics or other observed	n/a
		variability in effects that are not reducible by more information.	
Discussion			
Study findings,	22	Summarise key study findings and describe how they support the	
limitations,		conclusions reached. Discuss limitations and the generalisability of the	10/0 10/25
generalisability, and		findings and how the findings fit with current knowledge.	18/9 – 19/25
current knowledge		•	
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the	
		identification, design, conduct, and reporting of the analysis. Describe	28/6-11
		other non-monetary sources of support.	
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in	
		accordance with journal policy. In the absence of a journal policy, we	20/1 2
		recommend authors comply with International Committee of Medical	28/1-3
		Journal Editors recommendations.	

For consistency, the CHEERS statement checklist format is based on the format of the CONSORT statement checklist