

# A pragmatic randomised controlled trial of PhysioDirect telephone assessment and advice services for physiotherapy

<b>Submission date</b> 30/09/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/02/2014	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Chris Salisbury

### Contact details

Academic Unit of Primary Health Care  
School of Social and Community Medicine  
Canyng Hall  
39 Whatley Road  
Bristol  
United Kingdom  
BS8 2PS  
[c.salisbury@bristol.ac.uk](mailto:c.salisbury@bristol.ac.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

The MRC PhysioDirect trial

## Study objectives

To determine:

1. Whether PhysioDirect is at least as effective as usual models of physiotherapy based on patients going onto a waiting list and eventually receiving face-to-face care
2. The cost-effectiveness of PhysioDirect compared with usual care
3. Whether patients prefer PhysioDirect services rather than usual care; whether they find PhysioDirect more convenient and whether it addresses their perceived needs
4. The health outcomes and experiences of different groups of patients (those in different age groups and with different types of problems) when referred to PhysioDirect rather than usual care

Please note that as of 19/01/2010 the target number of participants in this record has been updated; the initial target number of participants was: 1875 patients in total (1250 and 625 patients in the PhysioDirect and usual care arms respectively).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added 17/02/2009: Southmead Research Ethics Committee (REC) gave approval on the 19th December 2008

## Study design

Multi-centre pragmatic individually randomised controlled trial. Nested qualitative research.

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Musculoskeletal diseases

## **Interventions**

### **Control:**

Usual care involves patients being referred by a GP to a physiotherapist. Patients then wait for an initial face-to-face physiotherapy assessment and then usually have follow-up appointments for several weeks or months.

### **Intervention:**

'PhysioDirect'. As soon as a referral for physiotherapy is received from the GP, the patient is invited to telephone a senior physiotherapist for initial assessment and advice. The physiotherapist will follow a computerised algorithm (as developed in Huntingdonshire) to assess the patient and record findings. In most cases, at the end of the consultation the physiotherapist will print a personalised tailored advice leaflet about exercises (based on 'Physiotools' software) and post it to the patient, inviting them to phone back to report progress after 2 to 4 weeks. At that point they can be given further advice or be booked for a face-to-face consultation if necessary. Alternatively, the initial phone call may establish that more urgent face-to-face care is needed, in which case this will be booked at the outset, or the assessment may establish that physiotherapy is unlikely to be effective and the patient can be given appropriate advice and discharged.

### **Treatment period:**

This will vary for individual patients. In Bristol, the mean number of consultations per patient with traditional physiotherapy is 2.9, over several weeks.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Current primary outcome measures as of 07/05/2009:

1. Clinical outcome at 6 months, measured using the physical component summary (PCS) measure from the 36-item short form health survey version 2 (SF-36v2)
2. Incremental cost-effectiveness will be measured in terms of Quality Adjusted Life Years (QALYs), assessed using the EQ5D measure and costs

Outcomes will be assessed at baseline, and 6 weeks and 6 months after randomisation.

Previous primary outcome measures amended in record as of 17/02/2009 (protocol amendment on the 21/11/2008):

1. Clinical outcome at 6 months, measured using the physical component summary (PCS) measure from the 36-item short form health survey version 2 (SF-36v2)
2. Incremental cost-effectiveness will be measured in terms of Quality Adjusted Life Years (QALYs), assessed using the SF-6D measure and costs

Outcomes will be assessed at baseline, and 6 weeks and 6 months after randomisation.

Initial information at the time of registration:

1. Clinical improvement at 6 months, measured using the physical component summary (PCS) measure from the 36-item short form health survey version 2 (SF-36v2) and the Measure Yourself Medical Outcome Profile (MYMOP questionnaire)
2. Incremental cost-effectiveness will be measured in terms of Quality Adjusted Life Years (QALYs), assessed using the SF-6D measure and costs

Outcomes will be assessed at baseline, and 6 weeks and 6 months after randomisation.

### **Secondary outcome measures**

Current secondary outcome measures as of 07/05/2009:

1. Costs
2. Quality of life (EQ5D)
3. The individual scales and the mental component summary measure from SF-36
4. Individual overall perception of improvement (seven point Likert scale from 'very much worse' to 'very much better')
5. Waiting times for treatment
6. Time lost from work and usual activities
7. Patient satisfaction with the care provided
8. Preference for telephone or face-to-face assessment
9. Clinical outcome using the Measure Yourself Medical Outcome Profile (MYMOP questionnaire)

Outcomes will be assessed at baseline, and 6 weeks and 6 months after randomisation.

Amended in record as of 17/02/2009 (protocol amendment on the 21/11/2008):

The following secondary outcome was added to this list:

10. Clinical outcome using the Measure Yourself Medical Outcome Profile (MYMOP questionnaire)

Initial information at the time of registration:

1. Costs
2. Quality of life (EQ5D)
3. The individual scales and the mental component summary measure from SF-36
4. Individual overall perception of improvement (seven point Likert scale from 'very much worse' to 'very much better')
5. Waiting times for treatment
6. Time lost from work and usual activities
7. Patients' perceptions of the accessibility of care
8. Satisfaction with care provided (based on CSQ8)
9. Preference for telephone or face-to-face assessment

Outcomes will be assessed at baseline, and 6 weeks and 6 months after randomisation.

### **Overall study start date**

15/09/2008

### **Completion date**

14/09/2011

## **Eligibility**

**Key inclusion criteria**

Current inclusion criteria as of 07/05/2009:

1. Adults (aged 18 years and over), either sex
2. Adults requiring musculoskeletal physiotherapy who are referred by General Practitioners (GPs), other members of the primary health care team, or who are self-referred

Previous inclusion criteria:

1. Adults (aged 18 years and over), either sex
2. Referred by General Practitioners (GPs) for physiotherapy

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

2143 patients in total (1429 and 714 patients in the PhysioDirect and usual care arms respectively)

**Key exclusion criteria**

Current exclusion criteria as of 07/05/2009:

1. Children (less than 18 years)
2. Patients referred to physiotherapy by a hospital consultant, emergency department or primary /secondary care interface service
3. Those needing domiciliary physiotherapy
4. Those needing post-operative physiotherapy
5. Those unable to communicate by telephone in English
6. Those needing physiotherapy for non-musculoskeletal problems

Previous exclusion criteria:

1. Children (less than 18 years)
2. Patients referred to physiotherapy by a hospital consultant
3. Those needing domiciliary physiotherapy
4. Those needing post-operative physiotherapy
5. Those unable to communicate by telephone in English

**Date of first enrolment**

15/09/2008

**Date of final enrolment**

14/09/2011

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Academic Unit of Primary Health Care

Bristol

United Kingdom

BS8 2PS

**Sponsor information****Organisation**

University of Bristol (UK)

**Sponsor details**

c/o Dr Birgit Whitman

Research Governance Manager

Research and Enterprise Development

Senate House

Tyndall Avenue

Bristol

England

United Kingdom

BS8 1TH

**Sponsor type**

University/education

**Website**

<http://www.bristol.ac.uk/>

**ROR**

<https://ror.org/0524sp257>

**Funder(s)****Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (UK) (ref: G0701575)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	03/08/2009		Yes	No
<a href="#">Results article</a>	results	29/01/2013		Yes	No
<a href="#">Other publications</a>	economic evaluation	03/10/2013		Yes	No
<a href="#">Results article</a>	results	30/01/2014		Yes	No