

# A pilot and feasibility study for a randomised controlled trial of 'Physio Direct' in primary health care

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<b>Registration date</b> 14/11/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/03/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

A pilot and feasibility study for a randomised controlled trial of 'Physio Direct' in primary health care

## **Study objectives**

Compared with usual physiotherapy care, a 'Physio Direct' service offering initial assessment and advice via telephone provides equivalent patient outcomes but with lower costs and shorter waiting times for patients.

Please note, this pilot study is complete and details of the main trial can be found at [www.controlled-trials.com/ISRCTN55666618](http://www.controlled-trials.com/ISRCTN55666618).

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethical approval obtained from Southmead Research Ethics Committee (REC no: 06/Q2002/47) on the 2nd August 2006.

## **Study design**

Pilot and feasibility study for a cluster randomised trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Musculoskeletal conditions requiring physiotherapy in primary healthcare

## **Interventions**

The unit of randomisation is the General Practice. The unit of analysis is the patient. The pilot study will involve developing the intervention, assessing rates of recruitment and retention, testing outcome measures and piloting research procedures.

### **Intervention Arm: 'Physio Direct'**

Patients referred for musculoskeletal physiotherapy and allocated to 'Physio Direct' will be invited to telephone the physiotherapy services for an initial assessment and advice at their convenience. A senior physiotherapist will assess the patient over the telephone and give appropriate education and advice. They may decide that a face-to-face consultation is necessary, on an urgent or routine basis. If the patient requires an urgent appointment they will organise this over the phone and routine appointments will be added to the 'Physio Direct' waiting list. A tailored advice leaflet sent the same day in the post will supplement this telephone assessment. Patients will be invited to phone back a few weeks later after they have undertaken the exercises or advice recommended, if they do not improve. When they phone back they will have another assessment and if a face-to-face consultation is required, their name will be added to the 'Physio Direct' waiting list. If at any time the patient feels they would prefer to see a physiotherapist face-to-face instead of receiving telephone advice, they will be seen in due course on the 'Physio Direct' waiting list.

### **Control Arm: 'Usual Care'**

Patients in the control arm will receive usual care that mirrors the current process for accessing

physiotherapy in primary health care in Bristol. When patients are referred by their GP their name will be placed on a 'usual care' waiting list. When they reach the top of the list they will be invited to telephone a physiotherapy department to book an appointment.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Designating primary and secondary outcomes is provisional since one aspect of this pilot study is to identify the best measures. Provisionally, the primary outcome is Measure Yourself Medical Outcome Profile (MYMOP2).

**Key secondary outcome(s)**

1. Patient health status (using Short Form health survey [SF-36] and EuroQoL instrument [EQ-5D]).
2. Patient perception of accessibility of care.
3. Patient perception of improvement in symptoms.
4. Patient satisfaction with care provided.
5. Time lost from work due to the health problems for which physiotherapy is indicated.
6. Patient preference for telephone or face-to-face assessment.
7. Waiting times for treatment, based on service data.
8. Did Not Attend (DNA) rates.

**Completion date**

01/09/2007

**Eligibility****Key inclusion criteria**

Adults consulting a General Practitioner (GP) in one of the general practices in the study and referred for musculoskeletal physiotherapy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Not Specified

**Key exclusion criteria**

1. Children (aged under 18 years)
2. Patients referred to physiotherapy by a hospital consultant

3. Patients requiring domiciliary physiotherapy (indicated by their GP)
4. Patients excluded by the referring GP or the senior physiotherapist, based on the referral form. This includes patients who appear unlikely to be able to complete a questionnaire in English. This is likely to include people with severe learning difficulties, dementia, or where the referral form indicated the patient would need an interpreter. Reasons for exclusion will be recorded
5. Patients excluded by a senior physiotherapist because their problem is too urgent to allow time for recruitment

**Date of first enrolment**

23/10/2006

**Date of final enrolment**

01/09/2007

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Academic Unit of Primary Health Care**

Bristol

United Kingdom

BS8 2AA

## **Sponsor information**

**Organisation**

University of Bristol (UK)

**ROR**

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

## **Funder(s)**

**Funder type**

Government

**Funder Name**

## Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration