

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

Submission date 02/11/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 14/11/2006	Overall study status Completed	☐ Protocol
Last Edited 16/03/2020	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

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.

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.

Primary study design

Interventional

Study design

Pilot and feasibility study for a cluster randomised trial

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

Avon Primary Care Research Collaborative (APCRC) Project Grant (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration