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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

Registration date
14/11/2006

Overall study status
Completed

Last Edited
16/03/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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 measure
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).

Secondary outcome measures
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.

Overall study start date
23/10/2006

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

Age group
Adult

Sex
Not Specified

Target number of participants
124 (provisionally aiming to include 62 patients in each arm)

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
England

United Kingdom

Study participating centre
Academic Unit of Primary Health Care
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Sponsor information

Organisation
University of Bristol (UK)

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Sponsor type
University/education

Website
http://www.bristol.ac.uk/research

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

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

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