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

Submission date
30/09/2008

Recruitment status
No longer recruiting

Registration date
26/11/2008

Overall study status
Completed

Last Edited
14/02/2014

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G0701575

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Academic Unit of Primary Health Care
Bristol
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Sponsor information

Organisation

University of Bristol (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

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?
Results article	results	29/01/2013		Yes	No
Results article	results	30/01/2014		Yes	No
Protocol article	protocol	03/08/2009		Yes	No
Other publications	economic evaluation	03/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes