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Early versus later extra physiotherapy compared with usual care to improve arm function after stroke

Submission date
09/08/2018

Recruitment status
No longer recruiting

Registration date
13/08/2018

Overall study status
Completed

Last Edited
13/08/2018

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many stroke survivors have difficulty using their arm or hand, which can affect them and their carers in many different ways. Many people need rehabilitation to improve arm function after a stroke. We already know that therapy that promotes using the affected arm in daily activities is most likely to help. A growing number of studies suggest that more therapy is needed to improve arm function after stroke than what is provided routinely. Stroke survivors, carers and health care professionals have indicated that further research on arm rehabilitation is a top priority.
More research is needed into the amount of extra arm therapy is required to make a difference, along with when is best to give this extra arm therapy. This study aims to look at the effectiveness of a new arm rehabilitation programme for people who have difficulties using their arm or hand after a recent stroke.

Who can participate?
Adults who have had a stroke in the previous 3 weeks and have difficulty using their arm and/or hand as a result of their stroke

What does the study involve?
All participants will receive the usual care and will be randomised into 3 groups:
1. Extra arm physiotherapy early after stroke (within 3 weeks after stroke) and usual care (early group)
2. Extra arm physiotherapy later after stroke (starting 3 months after stroke) and usual care (later group)
3. Usual care only (control group)
For all participants, the intervention will last for a total of 27 hours over 6 weeks. This will be 45 minutes per day, divided depending on each participant's tolerance (e.g. 15 minutes 3 times per day), 6 days per week over 6 weeks.

What are the possible benefits and risks of participating?
The possible benefit to participants is that those in the groups allocated to receive extra arm

physiotherapy may see more improvement in their arm/hand function as a result; however, this cannot be guaranteed. The only risks associated with this study are standard risks associated with arm physiotherapy. The extra amount of arm physiotherapy may lead to tiredness or soreness during or after therapy; however, this should only be short-lived.

Where is the study run from?
Glasgow Caledonian University and includes 5 sites across NHS Lanarkshire and NHS Greater Glasgow & Clyde in the UK, where participants will be recruited from.

When is the study starting and how long is it expected to run for?
July 2013 to August 2018

Who is funding the study?
The Charitable Trust of the Chartered Society of Physiotherapy (UK)

Who is the main contact?
Prof. Frederike van Wijck
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
3

Study information

Scientific Title
Early VERsus Later Augmented Physiotherapy compared with usual upper limb physiotherapy: an exploratory randomised controlled trial of arm function after stroke

Acronym

EVERLAP

Study objectives
The aim of this study is to test the feasibility of conducting a definitive three-arm randomised controlled trial of arm physiotherapy after stroke, and to determine its methodology, size and cost.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 5, 26/11/2014, 14/WS/1136

Primary study design
Interventional

Study design
Interventional multi-centre single-blinded three-armed exploratory randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke

Interventions
Participants will be randomly allocated into 3 groups. The Glasgow Clinical Trials Unit (UKCRC-registered, no. 16) provides a telephone randomisation service for this study. Participants are allocated to groups in equal numbers, minimised by baseline severity based on ARAT scores (severe: 0 ≤ ARAT ≤ 3; moderate: 4 ≤ ARAT ≤ 28; mild: 29 ≤ ARAT ≤ 56) 17. Randomisation takes place after baseline assessments, by telephone to an interactive voice response system to conceal future allocations. A minimisation schedule ensures equal allocation to each group within each stratum. At randomisation, each participant is allocated a unique participant code which is used to identify their study data. Participants' personal data are not used in any study documentation or study data.
All 3 groups will receive usual arm physiotherapy, and 2 of the 3 groups will receive additional, augmented arm physiotherapy delivered at different time points after stroke. The 3 groups will receive the following treatment:
1. The early group will receive early intervention treatment, in addition to usual arm physiotherapy. Participants in the early group will receive augmented arm physiotherapy, involving tailored strategies primarily aimed at improving functional activity of the affected arm and hand within 3 weeks after stroke. Therefore, these participants receive an extra 27 hours of physiotherapy over 6 weeks, with each session lasting for 45 minutes per day (divided depending on individual tolerance, e.g. 15 minutes, 3 times per day), 6 days per week, over a period of 6 weeks. To enhance self-management, research physiotherapists will provide participants with a choice of a home upper limb activity DVD, a workbook, or a novel mobile phone/tablet reminder service to remind participants to increase upper limb activity.
2. The later group will receive late intervention treatment, in addition to usual arm physiotherapy. Participants in the later group will receive the same treatment as the early group; however instead, they will receive this 3 months after their stroke.
3. The control group will receive usual arm physiotherapy only, which consists of routine

interventions delivered after a stroke, including those targeting positioning, sensory awareness, pain, hypertonia, and shoulder complications, along with function. Participants in the control group will not be offered the DVD/workbook/mobile phone reminder service
Participants in all 3 groups will be assessed at 4 timepoints - the baseline (3 weeks after stroke), 9 weeks, 16 weeks and at the follow-up (24 weeks). This includes assessments before and after the intervention for the early and later intervention groups. All 3 groups will be assessed at these same 4 timepoints to explore immediate and longer term intervention effects and compare recovery curves.

Intervention Type
Behavioural

Primary outcome(s)
Action Research Arm Test (ARAT)

Key secondary outcome(s)
Secondary outcome measures 1-12 will be assessed at the baseline (3 weeks after stroke), 9 weeks, 16 weeks and at the follow-up (24 weeks):
1. Arm activity in free-living conditions, assessed using body worn triaxial accelerometers
2. Self-reported arm activity, assessed using the 14-item Motor Activity Log (MAL 14)
3. Patient-selected goals and goal attainment, assessed using the Canadian Occupational Performance Measure (COPM)
4. Independence in activities of daily living, assessed using the Barthel Index of Activities of Daily Living
5. Motor performance, assessed during the Action Research Arm Test (ARAT):
5.1. Movement duration
5.2. Trunk movement
6. Grip strength, assessed using a Jamar dynamometer
7. Muscle strength, assessed using the arm section of Motricity Index
8. Mood, assessed using the Hospital Anxiety and Depression Scale (HADS)
9. Self-reported impairment, participation and health-related quality of life, assessed using the Stroke Impact Scale (SIS)
10. Self-reported health-related quality of life, assessed using the EuroQol-5D (EQ-5D)
11. Carer burden, assessed using Caregiver's Burden Scale
12. Resource impacts:
12.1. Capital (space and equipment)
12.2. Labour (physiotherapy whole time equivalents, employed in the usual and augmented arm physiotherapy)
12.3. Consumables
12.4. Private costs, assessed using a bespoke participant questionnaire
13. Acceptability, assessed through exit interviews with participants in the intervention groups (augmented arm physiotherapy groups) only at the end of the augmented arm physiotherapy intervention
14. Recruitment, retention and adherence rates, assessed by the number of patients approached, deemed eligible and recruited, the number of dropouts (including withdrawals) and the number of therapy sessions taken, recorded from the first approach about the study by clinical staff through to the follow-up (24 weeks)
15. Safety, assessed from the baseline through to the follow-up (24 weeks):
15.1. Participants will be asked at each visit about any adverse events since the previous visit.

Only those classed as serious will be recorded (e.g. events that result in permanent impairment, or in-patient hospitalisation), 15.2. Pain, assessed using a numeric pain rating scale (NPRS)
16. Resource impacts

Completion date
17/08/2018

Eligibility

Key inclusion criteria
1. Aged at least 18 years
2. Diagnosis of stroke, as confirmed by CT/MRI scans
3. Stoke-related upper limb impairment (score 0-56 on the Action Research Arm Test (ARAT))
4. Capable of undertaking the allocated physiotherapy intervention and adhering to the study protocol, as per judgement of the treating clinician
5. Able to provide informed consent to participate in the study
6. Living within the community services catchment area of a participating study centre

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Any factors likely to interfere with participation in the intervention, including:
1. Medically unstable
2. Severe cognitive/communication impairment (e.g. unable to follow a 2 step command)
3. Severe depression/anxiety
4. Other upper limb impairment:
4.1. Fixed contracture
4.2. Frozen shoulder
4.3. Severe arthritis
4.4. Upper limb pain that inhibits participation
5. Registered blind
6. Terminal cancer

Date of first enrolment
20/04/2016

Date of final enrolment

14/12/2017

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Monklands Hospital
Monkscourt Avenue
Airdrie
United Kingdom
ML6 0JS

Study participating centre
Hairmyres Hospital
Eaglesham Road
East Kilbride
United Kingdom
G75 8RG

Study participating centre
Wishaw General Hospital
50 Netherton Street
Wishaw
United Kingdom
ML2 0DP

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Western Infirmary
Dumbarton Road
Glasgow

United Kingdom
G11 6NT

Study participating centre
Glasgow Caledonian University
Cowcaddens Road
Glasgow
United Kingdom
G0 4BA

Sponsor information

Organisation
Glasgow Caledonian University

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Not defined

Funder Name
Chartered Society of Physiotherapy Charitable Trust

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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?
HRA research summary			28/06/2023	No	No