ISRCTN13447832 https://doi.org/10.1186/ISRCTN13447832

Stroke Unit effect on Physical Activity

Submission date
16/03/2021

Recruitment status
No longer recruiting

Registration date
01/06/2021

Overall study status
Completed

Last Edited
01/07/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The most common cause of disability from stroke is motor impairment affecting around 80% of stroke survivors with up to 74% needing long-term support with basic daily activities. Patients spend more than 78% of their inpatient stay alone, inactive and sedentary. An increase in physical activity and the provision of self-directed therapy programmes are recommended to improve recovery.

Enriched environments are designed to allow patients to move around freely around the ward to access activities. They have been shown to increase physical activity and reduce the amount of time patients spend alone. Enriched environments also have the potential to support self-directed therapy practice.

A recent opportunity arose to design a new purpose-built stroke unit in Gateshead which will incorporate aspects of an enriched environment. Patients who are able and well enough, will be encouraged to spend the majority of their waking hours in a communal 'social' area and therapy garden. This will provide enhanced opportunities for mobility practice and semi-supervised therapy practice. It is anticipated that this will start to facilitate changes in the ward routines that more closely mirror routines at home. For example, patients getting up and dressed for breakfast at a table rather than having breakfast in bed.

This study aims to assess the impact of an enriched environment on physical activity and other outcomes in stroke rehabilitation patients.

Who can participate?
Consenting adult stroke patients who have been admitted to the stroke ward at the Queen Elizabeth Hospital in Gateshead in the previous 72 h

What does the study involve?
Patients will complete baseline assessments and asked to wear an accelerometer on their wrist to measure their physical activity levels for 3-7 days. Comparisons of daily activity levels will be made between patients treated on the old stroke ward and those on the new stroke unit. Further comparisons will be made between the two patient groups of functional independence and stroke impact will be made at the time of hospital discharge and 6 weeks after joining the study.

What are the possible benefits and risks of participating?
This is an evaluation of a new purpose-built stroke unit and its effect on physical activity. As such participants will be asked to provide data on outcomes and to have their physical activity levels monitored but will receive the same treatment as other patients on the ward. As such there will be no direct benefits or risks for those taking part in the study.

The safety of the new environment will be evaluated by examining the occurrence of all serious adverse events (SAEs) as well as all falls. Recording of any serious adverse events and falls will occur for the duration of a participant's involvement in the study at study assessments by asking participants the question the following question: "have there been any new medical problems since the last study assessment?". All SAEs will be reported to the Chief Investigator and trial sponsor within 24 hours. The main REC will be notified of related and unexpected SAEs within 15 days of the Chief Investigator becoming aware of the event.

Where is the study run from?
Queen Elizabeth Hospital (UK)

When is the study starting and how long is it expected to run for?
From November 2020 to December 2021

Who is funding the study?
The is being conducted as an evaluation of the newly designed stroke unit at Gateshead Health NHS Foundation Trust (UK) an no external funding has been incurred.

Who is the main contact?
Dr Ruth Da Silva, ruth.dasilva@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Ruth Da Silva

ORCID ID
http://orcid.org/0000-0002-8897-4090

Contact details
Queen Elizabeth Hospital
Queen Elizabeth Avenue
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX
+44 (0)191 4453903
ruth.dasilva@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
294935

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 294935

Study information

Scientific Title
Stroke Unit Effect on the Physical Activity Levels of patients on a non-hyperacute stroke unit

Acronym
SUPAL

Study objectives
To measure whether exposure to a purpose-built stroke unit is associated with changes in physical activity and other parameters in stroke rehabilitation patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/03/2021, West of Scotland Research Ethics Service 3 (Clinical Research and Development, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE; +44 (0)141 314 0211; WoSREC3@ggc.scot.nhs.uk), ref: 21/WS/0030

Study design
Single-centre prospective cohort observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
The activity levels of stroke patients treated on a new purpose-built stroke unit (designed as an 'enriched environment' to reduce sedentary behaviours and promote mobility) will be compared to those treated on the current acute medical ward. The study will take place before and after the advent of exposure to a new purpose-built unit.

Patients who are able to provide informed consent will be approached to take part in the study within 72 h of arriving on the ward. A member of the study team will provide them with a patient information sheet, discuss the study with them and offer them the opportunity to ask any questions before making a decision.

Once consented, baseline assessment will be carried out and patients will be provided with a wristband accelerometer programmed to start recording activity from midnight. This is to ensure that when analysing the accelerometer data complete days rather than partial days of data are available for comparison. Participants will wear the accelerometers for up to 7 days (a minimum of 3 days data is required for data to be included).

There will be no change to the care that participants receive during their stay on the ward. The pre-change participants will receive usual care in the existing acute medical ward. The post-change participants will receive usual care in a new purpose-built stroke unit.

Once a discharge date has been set, participants will be asked to complete the discharge assessment which should take approximately 30 min. In the event that a member of the study team is unavailable to complete the assessment before discharge, this will be carried out over the telephone within 2 days of discharge. A follow-up assessment will be carried out at 6 weeks after consent which will be carried out by a stroke nurse.

Intervention Type
Not Specified

Primary outcome measure
Physical activity measured using wrist-worn accelerometers between baseline and 3 to 7 days

Secondary outcome measures
1. Level of dependency measured using the modified Rankin Scale at discharge and 6 weeks
2. Ability to perform activities of daily living measured using the Barthel Index at discharge and 6 weeks
3. Quality of life and participation measured using the Stroke Impact Scale at discharge and 6 weeks

Overall study start date
18/11/2020

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Within 72 h of admission to the stroke ward
3. Patient able to provide informed consent to participate in the study
4. Living within the local community services catchment area

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Diagnosis which is likely to interfere with rehabilitation e.g. issues with infection control
2. Palliative treatment approach being provided

Date of first enrolment
17/03/2021

Date of final enrolment
17/03/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Avenue
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Gateshead Health NHS Foundation Trust

Sponsor details
Queen Elizabeth Avenue,
Sheriff Hill
Gateshead
England
United Kingdom
NE9 6SX
+44 (0)191 4452155
alison.harvey5@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.qegateshead.nhs.uk/

ROR
https://ror.org/01aye5y64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Gateshead Health NHS Foundation Trust

Results and Publications

Publication and dissemination plan
Planned participation in peer-reviewed journal

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request by email to Ruth Da Silva, ruth.dasilva@nhs.net. Only summary statistics will be

made available (for the purpose of publishing results) of patient characteristics; study outcome measures (Fatigue, Barthel Index, modified Rankin Scale, stroke impact scale and falls frequency). Individual participants' data will not be made available. All data will be anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No