STUDY PROTOCOL



Effectiveness of interventions to support the transition REVISED

home after acute stroke: a protocol for a systematic review

[version 2; peer review: 2 approved]

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Abstract

Background

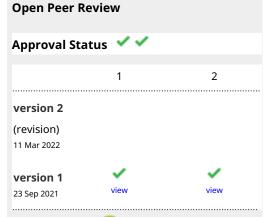
Despite advances in the quality of acute stroke management, there are gaps in knowledge about effective support interventions to better manage the transition of care to home for patients with this complex condition. The goal of this systematic review is to explore the literature around support interventions available for patients as they navigate from acute hospital, rehabilitation or early supported discharge (ESD) services to independent living at home; and to establish if, in comparison with usual care or other comparative active interventions, support services offered to patients as they transition from acute hospital, inpatient rehabilitation/ESD to home, can achieve better patient and / or process outcomes.

Protocol

In June 2021, we will carry out, on electronic peer-reviewed databases, a comprehensive literature search based on a pre-defined search strategy, developed and conducted in collaboration with an Information Specialist. In an effort to identify all published trials we will perform citation tracking of included studies, check reference lists of relevant articles, review grey literature, and extend our search to google scholar.

We will include randomised controlled trials (including cluster and quasi-randomisation) recruiting stroke patients transitioning to home, to receive either usual care or any support intervention designed to improve outcomes after stroke.

The primary clinical outcome will be functional status. Two review



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Any reports and responses or comments on the article can be found at the end of the article.

authors will scrutinise trials, categorise them on their eligibility, and extract data. We will analyse the results for all trials and perform meta-analyses where possible. We will assess risk of bias for the included trials and use GRADE to assess the quality of the body of evidence.

Patient and public involvement (PPI) engaged in the development of the research questions, and will participate in co-design of a strategy for dissemination of findings.

Conclusions: The findings from this review will be used to identify knowledge gaps to direct future research.

Keywords

Stroke, Transition, Systematic review, Intervention

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REVISED Amendments from Version 1

In response to reviewer feedback a number of changes have been made to the protocol.

- Functional status is further defined as per the activities component in the ICF Framework i.e. the execution of a task or action by an individual, and the difficulties an individual may have in performing tasks of daily living (e.g. washing, dressing, walking around the house, preparing a meal).
- Additional information is provided to deal with cluster randomisation and judging if outcomes can be pooled i.e. data will be pooled if the elements being pooled together are homogeneous with respect to the parameters being estimated. Authors will identify any cluster-randomised trials in the review and explicitly state that they will conduct sensitivity analyses to investigate the robustness of meta-analysis findings based on their inclusion.
- Peer reviewers highlighted the need to build our knowledge in relation to the mechanisms that drive successful support interventions. The authors agree and they will extract all available detail in relation to the background and expertise of the facilitators, the methods used to deliver key intervention strategies, and the components of usual care within each study.
- In response to concerns how authors will manage the breadth of inclusion criteria in synthesis, the authors agree that where possible, sub-group analysis according to patient or trial characteristics will be conducted.
- Following reviewer and PPI feedback, additional secondary outcomes will include patient satisfaction with care, and caregiver outcomes such as burden, quality of life, and mood.
- Affiliations for three authors have been amended from RCSI to RCSI University of Medicine and Health Sciences.
- Searches will take place in June 2021. It was acknowledged in the initial publication that searching would take place before the protocol would be published (August 2021).

Any further responses from the reviewers can be found at the end of the article

Introduction

Stroke is one of the leading causes of death and disability worldwide¹. While incidence, prevalence, mortality, and disability-adjusted life-years rates are in decline, "the overall stroke burden in terms of absolute number of people affected by, or who remained disabled from, stroke has increased across the globe in both men and women of all ages"². Costs of stroke are rising, partly due to an ageing population, and the economic burden of stroke across Europe is currently estimated at 60 billion³.

Rehabilitation interventions such as early supported discharge (ESD) reduce hospital lengths of stay and costs in stroke care, while improving outcomes such as physical, cognitive and psychosocial function⁴. However, patients recovering from acute stroke have complex needs and face significant challenges in self-management of hospital to home transitions⁵. The American Geriatrics Society defines transitions of care as: "a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different

locations or different levels of care"⁶. Interventions at transitions of care are recognised as key to care coordination, impacting on quality of care and adverse events⁷.

Stroke survivors, caregivers and healthcare professionals identify a focus on minimising stroke-related impairments, adjusting to life after stroke, and receiving information and guidance in relation to the long-term consequences of stroke and secondary stroke prevention, as research priorities⁸. Stroke survivors require signposting in order to navigate the healthcare system, and information and support in relation to healthy living, fatigue management, maintaining physical activity, managing stress and psychological issues, return to work and driving^{9–11}.

There is an opportunity for "support" interventions, provided when individuals are discharged from hospital or inpatient rehabilitation to home, to improve continuity and quality of care, improve functional outcomes, reduce healthcare utilisation, and improve patient and carer experience¹², but there are gaps in knowledge about effective "support" interventions to better manage transitions for this complex health condition. A systematic review by Prvu Bettger et al., 2012, of the benefits or harms of interventions at transitions of care after hospitalisation for stroke or myocardial infarction, showed low-to-moderate strength evidence of effectiveness of hospital-initiated transitional care, but insufficient evidence for education, community-based models of support, and chronic disease management models of care for patients with stroke or myocardial infarction¹³. Wang et al., 2017, sought to identify the type of interventions at transitions of care to effectively reduce mortality and improve activities of daily living (ADLs) in stroke patients, categorising supports at transitions of care into hospital-initiated support, home-visiting programmes, telephone support, primary education, and out-patient setting support. Their meta-analysis showed that only home-visiting programmes reduced mortality rates (Risk Ratio (RR)=0.46; 95% Confidence Interval (CI): 0.28-0.74), and impacted positively on patient ADLs (RR=0.56; 95% CI: 0.31-0.81) after stroke, compared with usual care¹⁴.

Given the time since the most recent review¹⁴, the subsequent publication of a number of transitions of care intervention studies^{15,16}, and policy plans to shift the way in which health and social care services are delivered¹⁷, we determined a systematic review of effectiveness of "support" interventions provided at transitions of care after stroke to be feasible.

An evidence synthesis will aid in identifying the key "support" elements that promote successful hospital-home transitions for stroke survivors and their families/caregivers. The aim of this protocol is to describe the methods we will employ to synthesise the best available evidence in relation to the effectiveness of support interventions provided at transitions of care after stroke on clinical and process outcomes.

Protocol

Design: We will conduct a systematic review of randomised controlled trials (including cluster and quasi-randomisation)

exploring the effectiveness of supports provided at transitions of care (moving between acute hospital/inpatient rehabilitation and home) after stroke. This protocol has been prepared in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol (PRISMA-P) statement and checklist^{18,19}, and it is registered in PROSPERO.

Stage 1: Identifying the research question

The PICOTS (population, intervention, comparison, outcomes, types of study design, setting) acronym has been applied to clarify the research question.

• Population

Adult stroke survivors (18 years of age or older) discharged from acute hospitalisation, inpatient rehabilitation to home. Studies that include TIA or subarachnoid haemorrhage will be accepted if > 80% of the participants have had an ischaemic stroke.

• Intervention(s)

"Support" intervention will be defined as an intervention specifically designed to help facilitate stroke survivors to self-manage their care after discharge from acute hospitalisation or inpatient rehabilitation to home e.g. individualised discharge plan, patient booklet, stroke passport etc. Interventions can take place before or after discharge, or include bridging interventions i.e. components that span settings (e.g. home visit from the acute setting). We will exclude an evidence synthesis of ESD interventions from the acute setting as this has been completed^{4,20}. However, studies that explore interventions to bridge the transition to the community following ESD will be included.

• Comparator(s), Control

Usual care or other active interventions e.g. individualised discharge plan and patient booklet versus patient booklet.

• Outcomes

The primary outcome of interest is functional status, classified as per the activities component in the ICF Framework. All validated outcomes of functional status will be considered e.g. Functional Independence Measure (FIM); Barthel Index (BI).

Secondary outcomes will include clinical (physical and psychological), process (emergency department visits, rehospitalisation, mortality) and caregiver (e.g. burden, quality of life, mood) outcomes assessed within one year of hospital discharge.

Adverse events, expected (e.g. scheduled medical or surgical procedures) and unexpected (e.g. recurrent stroke, seizure, falls), will also be examined.

Stage 2: Identifying relevant studies

Randomised controlled trials (including cluster and quasirandomisation) will be included. Studies included in quasirandomisation will be limited to those that have a "strong" design, as determined by a checklist of design features²¹, which can estimate cause and effect with minimal risk of bias. A systematic review of the literature will be conducted, with three groups of keywords related to "stroke", "transition", and "care setting". One reviewer (GOC) will complete a comprehensive search of electronic databases (Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, CINAHL, Cochrane Library, APA PsychInfo and SCOPUS), based on a pre-defined search strategy, developed and conducted in collaboration with an Information Specialist (PM). The search will initially be conducted in MEDLINE via OVID, and we will then adapt this strategy to other databases. Databases will be searched from inception, with no language limitation. The reference list of articles that meet the inclusion criteria after full-text review will be hand-searched to identify additional articles. We will include a search of grey literature, and extend the search to Google Scholar. We will attempt to contact authors of published abstracts to request full-text versions of studies and/or study data. The full search strategy, with MESH and Keywords can be found in Table 1.

Stage 3: Study selection

All articles will be imported into Endnote X9 bibliographic software, and where possible duplicates will be deleted. The primary researcher (GOC) will carry out an initial scan to judge and exclude clearly irrelevant literature. Two reviewers (GOC and RG) will independently review the remaining titles and abstracts from transitional care trials obtained in the literature search and compare them to the inclusion/exclusion criteria. They will meet to reach consensus about full text inclusion. If either one of the reviewers deems that an article could fulfil the inclusion criteria, then the article will be included for full text screening. Two reviewers (GOC and RG) will read each article to confirm eligibility using the same agreement structure as for abstract screening.

Stage 4: Charting the data

Characteristics of the intervention such as

- 1. Study design,
- 2. Funding source,
- 3. Setting,
- 4. Geographic location,
- 5. Participant characteristics (age, sex, race, ethnicity, severity of stroke, communication status, support system and urban/rural),
- 6. Intervention characteristics (transitional care component details, theory, comparator details, outcome results including adverse events, and time to follow up),
- 7. Facilitator characteristics (profession, expertise)
- 8. Risk of Bias,

will be extracted by one reviewer (GOC) into evidence tables using Rayyan systematic review screening software. The data abstraction will be reviewed by a second reviewer (FH) for accuracy. Disagreements will be resolved by consensus. All studies included will be critically appraised by two independent reviewers (GOC and FH) applying The Cochrane tool Table 1. Search Strategy for Ovid Medline, COCHRANE LIBRARY and CENTRAL REGISTRY OF CLINICAL TRIALS on Wiley, EMBASE on Elsevier.com, CINAHL on Ebscohost, APA PsychINFO on Ebscohost and SCOPUS on Elsevier.com. What is the effectiveness of support interventions provided at transitions of care after stroke on clinical and process outcomes?

	Ovid MEDLINE(R)
1	Stroke.mp. OR exp Stroke/ OR (Post stroke).mp. OR poststroke.mp. OR Stroke rehabilitation.mp. OR exp Stroke Rehabilitation/ OR Cerebro-vascular accident.mp. OR (Cerebro vascular).mp. OR CVA.mp. OR exp cerebrovascular disease/ OR (cerebrovascular adj1 disease).mp.
2	subarachnoid hemorrhage.mp. or Subarachnoid Hemorrhage/
3	1 NOT 2
4	(Continuity adj3 patient adj3 care).mp. OR exp Continuity of Patient Care/ OR (patient adj2 discharge).mp. or exp Patient Discharge/ OR (discharge adj1 plan*).mp.
5	(Transition* adj2 care).mp. OR exp Transitional Care/ OR (Patient adj2 transition*).mp. OR (Patient adj2 handoff).mp. OR (Patient adj2 transfer).mp. OR exp Patient Transfer/
6	Exp Patient Navigation/ OR (Patient adj2 Navigation).mp. OR *Case Management/ OR (Posthospital OR Post hospital OR Post discharge).mp.
7	4 OR 5 OR 6
9	Exp Home Care Services/ OR (home adj3 care).tw. OR Exp Home Care Services, Hospital-Based/ OR Exp Home Nursing/ OR Exp Primary Health Care/ OR (primary adj2 care).mp. OR (domiciliary adj 1 care).mp. OR (Community adj2 based adj2 support\$) OR Exp Community Health Services/ OR (community adj1 care).mp.
10	3 AND 7 AND 9
	COCHRANE LIBRARY and CENTRAL REGISTRY OF CLINICAL TRIALS on Wiley
1	Mesh Descriptor: [stroke] explode all trees OR MeSH descriptor: [Cerebrovascular Disorders] explode all trees OR Mesh Descriptor: [Stroke Rehabilitation] explode all trees OR stroke:ti,ab OR poststroke:ti,ab
2	subarachnoid NEAR/1 hemorrhage:ti,ab,kw
3	#1 NOT #2
4	Patient NEAR/1 care:ti,ab,kw OR patient NEAR/2 discharge:ti,ab,kw OR discharge NEAR/1 plan:ti,ab,kw OR Transition NEAR/2 care: ti,ab,kw OR transitional NEAR/1 care OR Patient NEAR/1 transition:ti,ab,kw OR patient NEAR/1 handoff:ti,ab,kw OR Patient NEAR/1 transfer:ti,ab,kw
5	Mesh Descriptor:[Patient Discharge] explode all trees
6	#4 OR #5
7	Mesh Descriptor: [Primary Health Care] explode all trees
8	Home NEAR/1 care:ti,ab,kw OR Domiciliary NEAR/1 care:ti,ab,kw
9	#7 OR #8
	#9 = Cochrane Systematic Reviews
	#9 = Central Registry of Clinical Trials
	EMBASE on Elsevier.com
1	stroke:ti,ab,kw OR Stroke/exp OR 'Post stroke':ti,ab,kw OR poststroke:ti,ab,kw OR 'Stroke rehabilitation':ti,ab,kw OR 'acute ischemic stroke'/exp OR 'cerebrovascular accident'/exp OR 'Cerebrovascular accident':ti,ab,kw OR CVA:ti,ab,kw OR 'cerebrovascular disease': ti,ab,kw
2	'subarachnoid hemorrhage':ti,ab OR 'Subarachnoid Hemorrhage'/exp
3	#1 NOT #2
4	'Continuity patient care':ti,ab,kw OR 'patient discharge':ti,ab,kw OR 'hospital discharge'/exp OR discharge:ti,ab,kw OR 'discharge plan*':ti,ab,kw
5	'Transition* care':ti,ab,kw OR 'Transitional Care'/exp OR 'Patient transition*':ti,ab,kw OR 'Patient handoff':ti,ab,kw OR 'Patient transfer': ti,ab,kw

EMBASE on Elsevier.com stroke:ti,ab,kw OR Stroke/exp OR 'Post stroke':ti,ab,kw OR poststroke:ti,ab,kw OR 'Stroke rehabilitation':ti,ab,kw OR 'acute ischemic stroke'/exp OR 'cerebrovascular accident'/exp OR 'Cerebrovascular accident':ti,ab,kw OR CVA:ti,ab,kw OR 'cerebrovascular disease': ti,ab,kw 'Patient Navigation':ti,ab,kw OR 'Case Management':ti,ab,kw OR (Posthospital OR 'Post hospital'):ti,ab,kw 4 OR 5 OR 6 'Home Care'/exp OR 'home care':ti,ab,kw OR 'Home Nursing':ti,ab,kw OR 'Primary Health Care'/exp OR 'primary care':ti,ab,kw OR 'domiciliary care':ti,ab,kw OR 'Community based support\$':ti,ab,kw OR 'community care':ti,ab,de,kw 3 AND 7 AND 9

CINAHL on Ebscohost

1 (MH "Stroke+") OR (MH "Cerebral Hemorrhage+") OR TI stroke OR AB stroke OR "stroke rehabilitation" OR TX cerebrovascular N1 accident\$ OR cerebral N1 hemorrhage

2 subarachnoid N1 hemorrhage

3 S1 NOT S2

- 4 (MH "Continuity of Patient Care+") OR (MH "Patient Discharge") OR "patient discharge" OR (MH "Transfer, Discharge") OR (MH "Discharge Planning")
- 5 (MH "Transitional Care") OR "transitional care" OR "Patient transition* OR (Patient handoff" OR "Patient transfer" OR "patient navigation"

7 4 OR 5

- 8 (MH "Home Health Care") OR "home care" OR "domiciliary care" OR (MM "Primary Health Care") OR (primary N2 care) OR (MH "Community Health Nursing+")
- 9 3 AND 7 AND 8

APA PsychINFO on Ebscohost

1 TX stroke OR TX 'Cerebrovascular Accidents'

2 TX 'subarachnoid hemorrhage'

3 S1 NOT S2

4 TX continuity N3 care OR MM "Continuum of Care" OR TX patient N2 discharge OR DE "Hospital Discharge" OR DE "Discharge Planning" OR TX (Transition* N2 care) OR TX Patient* N2 transition OR TX 'Patient handoff' OR TX 'Patient transfer' OR TX Patient N2 navigation OR TX post N1 discharge

- 5 TX home N1 care OR MM "Home Care" OR TX domiciliarly N1 care OR MM "Primary Health Care" OR TI Primary N3 care OR AB Primary N3 care
- 6 3 AND 4 AND 5

SCOPUS on Elsevier.com

1 TITLE-ABS-KEY (("stroke") OR ("poststroke") OR ("cerebrovascular accident") OR ("Stroke rehabilitation") OR ("Cerebrovascular accident"))

2 TITLE-ABS-KEY ("subarachnoid hemorrhage")

3 #1 AND NOT #2

4 TITLE-ABS-KEY("continuity of care" OR "patient discharge" OR "hospital discharge" OR "discharge plan" OR "discharge planing" OR "post discharge" OR "Transitional care" OR "Patient transition" OR "patient handoff" OR "Patient transfer" OR "patient navigation")

5 TITLE-ABS-KEY("home care" OR "Home Nursing" OR "Primary Health Care" OR "primary care" OR "domiciliary care")

6 3 AND 4 AND 5

for assessing risk of bias version 2 (RoB 2) in randomised trials²². The RoB2 tool covers 5 Domains and risk of bias is categorised as "low risk of bias", "some concerns" or "high risk of bias". Disagreements will be resolved through discussions, and if necessary by consulting a third reviewer (RG). Studies will not be excluded based on risk of bias but we will include this assessment in rating the strength of evidence.

GRADE (Grading of Recommendations, Assessment, Development and Evaluations) provides an explicit framework for rating the quality of evidence in systematic reviews²³. The overall certainty in the evidence, based on our confidence that the estimate of effects are correct, will be assessed for each outcome identified across studies using GRADE's four categories (high, moderate, low, or very low)²⁴.

Stage 5: Collating, summarising, and reporting the results

Data will be extracted separately for the meta-analysis. For each study, data on the outcomes will be extracted post-intervention and at follow-up time points. For our primary outcome of functional status, data extraction will comprise mean and standard deviation values, across the intervention and control groups as well as the number in each group at baseline. Pooled mean differences (MD) and 95% confidence intervals (CI) will be calculated to determine treatment effect. Pooled risk ratios and 95% CI for dichotomous outcomes will be calculated. If the scale for each continuous outcome varies across the studies, we will calculate a standardised mean difference (SMD) and 95% CI based on end-of-study results. If studies report changed values and the baseline value is not available, we will use this data in meta-analyses but plan sensitivity analyses to investigate the effect of using these data. We will analyse the incidence of adverse events as dichotomous variables.

Meta-analysis will be performed using Review Manager 5 (RevMan5, Cochrane)²⁵. We will determine heterogeneity using visual inspection of the forest plots and the I² statistic. In the first instance, we will assume homogeneity across out studies and we will complete our meta-analysis using a fixed effects model and 95% CI. If the I² reveals > 50%, which may be indicative of substantial clinical heterogeneity (different interventions) or methodological heterogeneity (variation in risk of bias across studies), then we will compute using a random effect model and 95% confidence intervals. For heterogeneity present after meta-analysis, subgroup analysis will be carried out for potential sources of heterogeneity²⁶.

Where statistical pooling is not possible, the findings will be presented in table and narrative form.

• Missing outcome data

The extent of missing outcome data will be recorded on our risk of bias table.

Where the reporting of an outcome in a particular study is unclear, incomplete, or missing we will attempt to contact the study's authors to obtain the data. If we are unsuccessful in obtaining the data, we will not include that study in the meta-analysis of that outcome.

If an included study has missing data (e.g. reports means but not standard deviations for follow-up data) we will attempt to contact the study's authors to obtain the data. If we are unsuccessful, then we will take logical steps to enter an assumed value, by estimating a standard deviation based on a reported standard error, estimating a follow-up standard deviation based on a baseline value, using the median as a proxy for the mean, and using a multiple of 0.75 times the interquartile range or 0.25 times the range as a proxy for the standard deviation values²⁷. We will undertake a sensitivity analysis to investigate the effect of entering assumed values.

• Sensitivity analysis

Selection bias: We will exclude studies with evidence of selection bias (bias in randomisation or allocation concealment processes)

Missing outcome data: we will re-analyse the data, excluding trials with inadequate or unclear methods of dealing with missing outcome data.

Quality/risk of bias: we will re-analyse the data, excluding trials deemed to be at high risk of bias.

Quasi-randomised trials: we will reanalyse to determine how data from studies with quasi-randomisation influence the treatment effect.

Cluster-randomised trials: we will reanalyse to determine how data from cluster-randomisation influence the treatment effect.

• Subgroup analyses

We will attempt to conduct sub-group analyses according to patient (e.g. age, gender) or trial characteristics (e.g. recruitment setting, duration of intervention, choice of comparison intervention, length of follow-up, presence of caregiver).

Stage 6: Patient and public involvement (PPI)

The ACTIVE framework²⁸ and GRIPP2-SF²⁹ will help describe and report PPI in the systematic review. Engaging PPI partners will ensure that the systematic review is relevant and meaningful to people affected by stroke, and to people using the review to inform health policy or practice. A "top-and-tail" approach²⁹ will be used to involve the same group of people at the start (stages 1 to 3: framing the question and planning the review) and end (stages 10 to 12: interpretation, publication and dissemination of findings) of the review. A PPI Champion (Stroke survivor (MF)) will contribute as a core member of the review team, while an advisory

network comprising stakeholders representing key groups in stroke (patients and their family members, carers, healthcare professionals, advocacy groups) will be formed. Recruitment to the advisory network will take place throughout the review, and different individuals will have varying levels of involvement, and at different stages.

Ethical considerations

The systematic review consists of reviewing and collecting data from publicly available materials, and therefore does not require ethics approval.

The systematic review constitutes the first step in a multi-phased research project aimed at improving and supporting transitions of care after stroke by understanding the long-term needs of stroke survivors; and by identifying the effectiveness of, and preferences, for supports provided at transitions of care.

The results from this systematic review will guide and be combined with data from later phases of the research, including an observational study and qualitative interviews and focus groups with stroke survivors and healthcare professionals, and a co-design process.

Ethics approval will be sought for these later stages of the research.

Dissemination

Upon completion, the findings of the systematic review will be published in a peer-reviewed open-source journal; presented at national and international conferences; and shared with researchers, clinicians, stroke survivors and families through organisations for people with stroke. We will provide recommendations for practice and research. PPI will engage in the development of the dissemination strategy, and assist in summarising the research is a clear and accessible format.

Study Status

The study protocol has been registered on PROSPERO (CRD42021237397).

At the time of publication of this protocol, the database searches will have been completed and screening initiated.

Tracked and dated amendments

Any amendments to this protocol, including the dates of the amendments and justifications, will be documented and presented in a table in the systematic review publication.

Conclusions

Given the challenges experienced by stroke survivors during the transition from acute stroke services to home, there is an urgent need to better understand what interventions are effective in supporting this transition. This systematic review will broadly and systematically explore the totality of evidence around support types provided at hospital to home transitions after stroke. Findings will be used to identify knowledge gaps to direct future research and provide a foundation for developing research priorities.

Data availability

Underlying data No data are associated with this article.

Reporting guidelines

Zenodo PRISMA-P checklist for "Effectiveness of interventions to support the transition home after acute stroke: A protocol for a systematic review". https://doi.org/10.5281/zenodo. 5145362³⁰

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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Stage 1: identifying the research question

- Regarding "comparators, control", the information of what "usual care" entails is often quite sparse. If available, we recommend the authors to include what "usual care" implied in the separate studies. This would strengthen the quality of the review and help readers interpret the findings.
- The primary outcome chosen is functional status, which is broad and unspecific. Could the authors please define and outline what will be included in functionals status?

Additional plausible secondary outcomes that would be of interest for outcomes of interventions to support transitions to home are patient satisfaction with care, specifically with the transition to home, measures on mood or wellbeing both on the part of the patient but also of caregivers, as well as their perceived care giver burden.

Stage 3: Study selection

- If available, it might be of interest to consider extracting the characteristics of professionals involved in the intervention. (Professions, competence, experience)
- The systematic review aims to explore the effectiveness of support interventions provided at transitions of care after stroke. However, the mechanism that drive such interventions successfully remains to a large extent unknown. Hence, if available, it would be of interest to extract suggested mechanisms and facilitators.

Stage 5: Collating, summarising, and reporting the results

• The inclusion criteria of different interventions are quite broad i.e., both different components and in different contexts, which will make the synthesising evidence challenging. How will this be handled in the analysis?

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others? $\ensuremath{\mathsf{Yes}}$

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Sebastian Lindblom PhD: Neurorehabilitation, integrated care and care transitions

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 01 Mar 2022

Geraldine O'Callaghan, Royal College of Surgeons in Ireland, Dublin 2, Ireland

On behalf of all the protocol authors I would like to acknowledge the feedback that you have provided for our protocol – 'Effectiveness of interventions to support the transition home after acute stroke; a protocol for a systematic review'. We are extremely grateful to you for giving of your time and expertise, and hope the attached responses address your concerns and comments.

1. Stage 1: identifying the research question. Regarding "comparators, control", the information of what "usual care" entails is often quite sparse. If available, we recommend the authors to include what "usual care" implied in the separate studies. This would strengthen the quality of the review and help readers interpret the findings.

The authors agree that it is important to extract the available information on what denotes "usual care" in each study and we will do so in our systematic review.

2. The primary outcome chosen is functional status, which is broad and unspecific. Could the authors please define and outline what will be included in functional status? Functional status will be classified as per the activities component in the ICF Framework, i.e. the execution of a task or action by an individual, and the difficulties an individual may have in performing tasks of daily living (e.g. washing, dressing, walking around the house, preparing a meal).

3. Additional plausible secondary outcomes that would be of interest for outcomes of

interventions to support transitions to home are patient satisfaction with care, specifically with the transition to home, measures on mood or wellbeing both on the part of the patient but also of caregivers, as well as their perceived care giver burden. All clinical outcomes including satisfaction with stroke care will be considered, as will caregiver outcomes of mood, quality of life, caregiver burden, and other outcomes included by the study researchers.

4. Stage 3: Study selection. If available, it might be of interest to consider extracting the characteristics of professionals involved in the intervention. (Professions, competence, experience). The systematic review aims to explore the effectiveness of support interventions provided at transitions of care after stroke. However, the mechanism that drive such interventions successfully remains to a large extent unknown. Hence, if available, it would be of interest to extract suggested mechanisms and facilitators.

The authors agree that increasing our knowledge in relation to the mechanisms that drive successful support interventions is important. To this end, we will extract all available details in relation to the background and expertise of the facilitators in each study, and the methods used to deliver key strategies within each intervention.

5. Stage 5: Collating, summarising, and reporting the results. The inclusion criteria of different interventions are quite broad i.e., both different components and in different contexts, which will make the synthesising evidence challenging. How will this be handled in the analysis?

Where possible, sub-group analysis according to patient (e.g. age, gender) or trial characteristics (e.g. recruitment setting, duration of intervention, length of follow-up, presence of caregiver) will be conducted. This will address the breadth of the inclusion criteria and allow the authors to explore differences in response to an intervention.

Competing Interests: No competing interests were disclosed.

Reviewer Report 19 October 2021

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This is an important protocol for a systematic review of RCTs, cluster-RCTs and quasi randomized clinical trials investigating the effectiveness of types of supports provided at transitions of care. The Protocol is registered following PROSPERO and in line with statements of PRISMA.

The systematic review is straightforward however I have some minor concerns.

- 1. Defining outcome functional status is broad and with that not clear. I suggest to further classify this following ICF in subdomains related with basic ADLs, extended ADLs, mobility.
- 2. Second outcomes: I suggest to include caregivers QoL including mood as well.
- 3. Stage 4 is clear. Indeed wise to use Rayyan software for search as well.
- 4. With respect to pooling of data. Please clarify the condition when pooling will be applied. How are the authors dealing with cluster randomized clinical trials in their pooling? When do the authors judge if the outcome (eg basic ADLs) can be pooled?

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others? $\ensuremath{\mathsf{Yes}}$

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Stroke, behavioral Recovery, Neurorehabilitation, Systematic Reviews.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 01 Mar 2022

Geraldine O'Callaghan, Royal College of Surgeons in Ireland, Dublin 2, Ireland

On behalf of all the protocol authors, I would like to acknowledge the feedback that you have provided for our protocol – 'Effectiveness of interventions to support the transition home after acute stroke; a protocol for a systematic review'. We are extremely grateful to you for giving of your time and expertise and hope the attached responses address your concerns and comments.

1. Defining outcome functional status is broad and with that not clear. I suggest to further classify this following ICF in subdomains related with basic ADLs, extended ADLs, mobility.

Functional status will be classified as per the activities component in the ICF Framework, i.e. the execution of a task or action by an individual, and the difficulties an individual may have in performing tasks of daily living (e.g. washing, dressing, walking around the house, preparing a meal).

2. Secondary outcomes: I suggest to include caregiver's QoL including mood as well. The authors acknowledge that caring for stroke patients is challenging and may influence several subjective and objective aspects of the caregivers' life. In response to peer reviewer and patient and public involvement feedback, caregiver outcomes (e.g. QOL, mood, burden) will be included as measures of effectiveness of supports provided at the transition from hospital to home.

3. **Stage 4 is clear. Indeed wise to use Rayyan software for search as well.** Rayyan identify a number of shortfalls in its software capabilities i.e. RIS exports from a number of databases fail to import successfully into Rayyan, while duplicate detection, resolution, and reporting is still under development. For this reason, the authors will export all search results into Endnote, de-duplicate in Endnote, and then export the remaining results to Rayyan for screening.

4. With respect to pooling of data. Please clarify the condition when pooling will be applied. How are the authors dealing with cluster randomized clinical trials in their pooling? When do the authors judge if the outcome (e.g. basic ADLs) can be pooled. Data will be pooled if the elements being pooled together are homogeneous, with respect to the parameters being estimated. Specifically, this means that, if there is similarity in terms of intervention variances then study data can be pooled i.e. if the interventions components and follow up time points are similar, and the same or comparable tool is used to measure the outcome (e.g. Barthel Index for ADLs), then it is fine to pool the data. The authors will identify any cluster-randomised trials in the review and explicitly state that they will conduct sensitivity analyses to investigate the robustness of meta-analysis findings based on their inclusion.

Competing Interests: No competing interests were disclosed.