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A protocol for a systematic review of quantitative and qualitative studies of the unmet needs of informal carers of stroke survivors

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Abstract

Introduction: Stroke events deeply affect not only the stroke survivor but also the quality of life, and physical and psychological health of the family and friends who care for them. There is a need for further information about the unmet needs of these informal carers in order to develop support services and interventions. The primary objective of this review is to report and synthesise the research describing the unmet needs of carers of stroke survivors.

Methods and Analysis: A systematic review of quantitative and qualitative studies that report on the unmet needs of carers will be conducted. The following databases will be searched for relevant articles: MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Embase, Allied and Complementary Medicine Database (AMED), and Scopus. No publication date constraints will be applied. Studies will be limited to those published in English and conducted among humans. Eligible studies will report on the unmet needs of informal carers of stroke survivors, defined as family members, friends and other unpaid caregivers. Studies which focus on formal, clinical or medical caregivers will be excluded. A narrative synthesis of the main outcomes will be reported.

Ethics and Dissemination: This review will be submitted to a peer-reviewed journal. Our findings are expected to provide new insights into the unmet needs of stroke survivors' carers. Knowledge about the unmet needs of carers will inform the development and refinement of interventions and services to address these needs and better support carers of stroke survivors. The findings of this systematic review will be disseminated publicly and in peer-reviewed journals, and may be the topic of research presentations.

Trial registration number: CRD42017067391.

Strengths and limitations of this study

Strengths

- The inclusion of both qualitative and quantitative studies will provide more informative findings on the unmet needs of carers of stroke survivors.
- Our chosen method of analysing and synthesising qualitative and quantitative data has been tested and found effective for systematic reviews[1].
- The quality of the review will be strengthened by the input and involvement of multiple reviewers at each stage of the review

Limitations

- As there are few valid and reliable measures for assessing methodological rigor of qualitative research [2] and mixed-method assessment[3] there is a risk that flawed studies may bias the results of the systematic review.
- It is also possible that there are relevant non-English studies that will not be included in this review, therefore these findings may not be generalizable to non-English speaking populations in which there may be differing cultural unmet needs of carers of stroke survivors

INTRODUCTION

Rationale

As stroke survivors are often cognitively or physically disabled post-stroke, many require a carer to support them once discharged from acute care. Approximately 50% of people who have a stroke will require support from a carer[4], and the three most common areas that stroke survivors report needing assistance in are cognitive or emotional tasks, mobility and health care[5]. The Australian Survey of Disability, Ageing and Carers identified that 2.86 million Australians are informal carers, and 26,367 of these people have taken on the role of caregiver for someone with stroke as their main condition [6]. In England and Wales, it is estimated that 10% of the population are carers, with 60% of people becoming carers at some point[7 8]. In the United States, it is estimated that 4.35 million people are informal carers[9], and of those, 2.2 million are people who care for someone who has had a stroke[10 11]. These numbers are expected to increase with demographic changes worldwide[6 8 10], therefore it is becoming increasingly important to recognise the ongoing support needs of carers of stroke survivors.

There are a number of definitions of “carers” across stroke studies[12 13], generally they are referred to as informal, unpaid or primary carers, or as caregivers. Carers of stroke survivors may be family members, friends or other close individuals who provide physical or emotional support[13]. Informal carers (defined as people who provide unpaid care, support and/or assistance to someone in need of care) of stroke survivors are predominantly female spouses of the stroke survivor[14], and often take on a variety of complex tasks and roles, including physical, psychological, and daily living support with varying time commitments. The average time spent caring for someone with stroke has been reported to be 41 hours per week[6]. Furthermore, the replacement financial value of informal care across countries is staggering. If all hours of informal care were replaced with services purchased from formal care providers, the value would be $60.3 billion in Australia[6], £119 billion pounds in the United Kingdom[7] and $470 billion in the United States[15].

Caring for someone who has had a stroke can lead to issues and concerns for the carer, and these issues can also change over time[16]. For example, when carers must put aside their own needs to care for the stroke survivor, they can experience a sense of loss of autonomy[17]. Carers often report feeling underprepared to provide practical support following the patient's discharge from hospital, and also report feeling excluded from discharge and follow-up plans with health providers[17-19]. As a result, carers commonly experience a decline in their own physical and mental health, and a reduced quality of life[20-22]. As psychological distress is becoming increasingly common and health outcomes are declining in informal carers[23], there is a need to gain further understanding of the underlying mechanisms behind the unique unmet needs of informal carers of stroke survivors.

Unmet needs refer to a need that has not been satisfied yet. Carer needs often relate to inadequate information and resources, such as receiving information on stroke management and recovery, and/or how to contact a health care professional who could offer them psychological or emotional support[24 25]. Research suggests unmet needs result in adverse outcomes, such as increased burden, and depression and anxiety, for carers of those with disabilities and chronic illness[22 25-27]. Greenwood et al.[14] systematically reviewed qualitative studies investigating the challenges, satisfactions and coping strategies of carers of stroke survivors. The studies in the review described difficulties such as uncertainty, informational/training needs, and role and relationship changes of carers of stroke survivors. Unmet needs are an extremely important area of research, and it is becoming increasingly important to address these unmet needs to ensure the health and wellbeing of carers, and the people that they care for.

While there are interventions designed to address the unmet needs of carers of stroke survivors, research suggests the interventions require further evaluation, development and refinement to target these outcomes. A systematic review conducted by Eldred[28] investigating psychosocial interventions for carers of survivors of stroke found that interventions are failing to address carer depression, loneliness and stress, while there has been some success with interventions that use counselling and education to promote coping and adjustment to the carer role. In these studies, unmet psychological needs (such as depression) were directly reported by carers using validated measures of psychological health outcomes. These findings highlight the need to develop effective psychological interventions targeting the psychosocial functioning of carers of stroke survivors. A systematic review by Aldehaim et al.[29] focused on technology-based interventions for carers of stroke survivors. Only one study of the five studies eligible for review assessed carer preparedness for the caring role, a known unmet need identified by carers of stroke survivors[30-33]. That review emphasized the need for interventions to be provided to carers of stroke survivors as soon as possible as a strategy to address unmet needs. The limitations of interventions for carers of stroke survivors include: (1) not being delivered to carers after the stroke survivor is discharged home; (2) not providing appropriate interventions to the changing needs of carers through the stroke survivors' transition from home, to hospital and eventually the community; and (3) not targeting appropriate unmet needs outcomes for informal carers, including preparedness and psychosocial functioning, and unique unmet needs for carers of stroke survivors such as support with possible communication and mobility issues.

There are currently no systematic reviews examining the unmet needs of carers of stroke survivors in both qualitative and quantitative studies. Thus, this review aims to:

1) Define and identify the unmet needs of carers of stroke survivors
2) Define the variables associated with unmet needs of carers of stroke survivors

3) Report the prevalence of unmet needs identified in quantitative studies
4) Thematically analyse qualitative data to report meaningful patterns and themes of unmet needs of carers of stroke survivors
5) Synthesise quantitative and qualitative research on the unmet needs of carers of stroke survivors to guide the development of interventions and services to support carers of stroke survivors.

METHODS AND ANALYSES

Study Design

We will conduct a systematic review of studies reporting on unmet needs of informal carers of stroke survivors. These studies will be published in English and have no publication year limit. Qualitative and quantitative studies will be included and synthesised in this review. This systematic review protocol will conform with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P)[34 35] and will be reported in accordance with the (PRISMA) statement[36 37].

Study Registration

Based on the PRISMA-P guidelines[34], this systematic review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO) in July 2017: CRD42017067391.

Eligibility criteria

Types of studies

To be eligible for this systematic review, manuscripts must be published in a peer-reviewed journal and report primary data on the unmet needs self-reported by carers of stroke survivors. The needs of carers reported by others (such as the stroke survivors or by health professionals) will be excluded. English language qualitative, quantitative and mixed methods studies will be included. Intervention studies will be included if they report the baseline estimates of carers' unmet needs.

Participants

Carers of stroke survivors are defined as the spouse or partner, family members, friends or 'significant others' who provide unpaid physical, practical or emotional support to someone after their stroke event. Stroke survivors will be defined as an individual who has experienced a stroke event. Studies which report on mixed populations, such as reporting on carers' and stroke survivors' unmet needs, will be included in full text review to investigate if the carers of stroke survivors' data can be extracted separately. Studies will be included if carers provide information related to their unmet needs at any stage of caring for someone following a stroke. Manuscripts that only report on professional carers (doctors, nurses, healthcare providers and others) will be excluded.

Measures

Quantitative and qualitative studies that report any unmet needs of carers of stroke survivors will be included. Quantitative studies may include self-report surveys. Qualitative studies may include interviews and focus groups. We aim to (1) quantify the proportion of carers of stroke survivors reporting unmet needs in various domains and subcategories; (2) categorise carers of stroke survivors' unmet needs by domain; and (3) identify the main variables associated with reporting more unmet needs in carers of stroke survivors.

Unmet needs domains of carers of stroke survivors will be based on Lambert et al[38] which investigated the unmet needs of carers of adult cancer patients. These include unmet needs relating to changes in role and relationship(s), and informational unmet needs, such as preparedness in caring for someone with a chronic illness, and comprehensive knowledge of the condition. As carers of stroke survivors may also have unique needs that differ from being a carer of cancer survivors, other themes that emerge will also be analysed. These needs may include managing the loss of mobility[39], language[40] and mood/personality changes[41] as these changes are common following a stroke event.

Search Strategy

'Stroke' terms based on a Cochrane Review[42] will be developed. 'Needs' and 'Partners and Caregivers' terms will be based on a systematic review of unmet needs of partners and caregivers diagnosed with cancer[27]. In May 2017, a search strategy was developed on the MEDLINE database and then adapted for the other databases. This included medical subject headings (MeSH) and free-text terms using applicable controlled vocabulary. The following electronic databases will be searched: Medline, PsycINFO, EMBASE, Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus and Cochrane Database. Furthermore, the reference lists of included studies or identified relevant reviews will be searched. There will be no time limits on publications for the search strategy. Studies will be limited to those conducted among human subjects and published in English. Reference lists of included studies and relevant systematic reviews will be searched to identify additional studies for potential inclusion in this systematic review. The search terms for MEDLINE can be found in Appendix A.

Screening the studies

Search results will be entered into Endnote folders, and any duplicates will be removed. The online tool Covidence[43] will be used by reviewers to produce high-quality evidence for the systematic review. A flow diagram conforming to PRISMA guidelines[36] will report the selection process and reasons for exclusion. All titles of retrieved publications will be screened by one reviewer. Two reviewers will independently screen all abstracts, full text and data extraction. The two will meet to resolve any issues, and if a decision cannot be made, a third reviewer will be contacted to make the final decision.

Data extraction

Data will be extracted by one reviewer, tabled, and checked for accuracy by another reviewer. The two reviewers will discuss these findings and themes, and if a discrepancy exists and a consensus cannot be reached, a third reviewer will be contacted to make the final decision. Data extracted from the quantitative studies will be extracted and analysed. Data from the qualitative, quantitative and mixed-method studies will be integrated in a systematic way. Common data extracted from the articles will include: study aims, setting, sample characteristics, response rates, study methodology, data analysis, primary outcomes and the unmet needs domains identified. Data extraction tables will be based on Lambert et al.'s research of the unmet needs of carers of adults with cancer[38].

Quality appraisal

Qualitative Studies

The methodological quality of qualitative studies will be assessed using the Critical Appraisal Skills Programme (CASP)[44]. This quality assessment tool was cited by Aziz et al.[12] in the protocol for a systematic review in understanding stroke survivors' and informal carers' experiences of and need for primary care and community health services. The CASP tool is a 10-item tool that allows rapid evaluation of the credibility, transferability, dependability and conformability of the qualitative studies. Two reviewers will assess the methodological quality of all studies, and if an agreement cannot be reached, a third reviewer will make the final decision.

Quantitative studies

The methodological quality of quantitative studies will be assessed based on Greenwood et al[14] who performed a systematic review of the quantitative studies focused on factors influencing informal carers of stroke survivors. This quality assessment tool assesses six areas (1) statement of inclusion or exclusion criteria of carers; (2) clear hypotheses/hypothesis; (3) response rate reported or possible to calculate; (4) multivariate analysis/possible control for confounders; (5) full definition of carer provided (including spouse as the definition; and (6) timing of assessment similar for all participants. Studies are either scored "Yes" with a value of 1, or "No" with a value of 0. Scores are rated on a 6-point scale: a score of 6 indicates a maximum score, whereas a score 0 indicates a minimum score.

Mixed-method studies

The methodological quality of mixed-method studies will be assessed by using the CASP[44] on qualitative components, and the methodological assessment developed by Greenwood et al.[14] where appropriate regarding quantitative components.

Data analysis

Qualitative studies

Qualitative data will be thematically analysed using the qualitative research software NVivo[45]. Reviewers will develop descriptive themes through interpretation of the meaningful patterns in the qualitative research. Codes for unmet needs domains will be assigned to meaning within the text, and these codes will be compared between studies. Two reviewers will discuss these meanings, and a third reviewer will be consulted if an agreement cannot be reached.

Quantitative studies

The data analysis of quantitative studies in this review will be based on Lambert et al[38]. Results across quantitative studies will be pooled and the prevalence of unmet needs will be compiled. Unmet needs domains will be categorised and the factors associated within them will be examined. Where reported, the average number of unmet needs will be reported. To facilitate comparison across studies and where appropriate, averages will be standardised from 0 to 100. Comparable unmet needs will be combined and clustered into domains. Two reviewers will discuss these outcomes, and a third reviewer will be consulted if a decision cannot be reached.

Mixed-method studies

The data of mixed-method studies will be analyzed appropriately. Qualitative components will be analyzed using NVivo[45], and quantitative components will be based on the data analysis reported by Lambert et al[38].

DISCUSSION

Evidence from this systematic review of unmet needs of carers of stroke survivors will inform the development of interventions and services to address these needs. We will deliver evidence-based recommendations including consideration of the unmet needs of carers of stroke survivors in future research, and the refinement and development of interventions and services for this population. These recommendations may improve carer preparedness for their new caregiving role, and also assist in supporting carers across all time points of caring for a person who has survived a stroke. These improvements may subsequently improve the quality of life of carers by assisting carers to manage their own needs, mental and physical health, and increase their knowledge in providing physical, emotional and practical care for the stroke survivor. To our knowledge, this will be the first study to systematically synthesize qualitative and quantitative information regarding the unmet needs of carers of stroke survivors.

Strengths and limitations

The findings of this systematic review are dependent on the quality of original studies that will be reviewed. As there are few valid and reliable measures for assessing methodological rigor of qualitative research [2] and mixed-method assessment [3] there is a risk that flawed studies may bias the results of the systematic review. To minimise this, reviewers will independently review studies and communicate effectively if disagreements occur. It is also possible that there are relevant non-English studies that will not be included in this review. As such, these findings may not be generalizable to non-English speaking populations, in which there may be differing cultural unmet needs of carers of stroke survivors.

The quality of the review will be strengthened by the input and involvement of multiple reviewers at each stage of the review. Furthermore, the inclusion of both qualitative and quantitative studies will provide more informative findings on the unmet needs of carers of stroke survivors. Our chosen method of analysing and synthesising qualitative and quantitative data has been tested and found effective for systematic reviews [1]. The findings of this systematic review will be disseminated publicly and in peer-reviewed journals, and may be the topic of research presentations.

Amendments

If the protocol needs to be amended, the date of each amendment, the change and the rationale will be described in this section.

Contributorship Statement

AMJD is the guarantor of the review. AMJD, ALB, NS, AG, OW, AT, PM and BB assisted in writing the protocol. AMJD performed preliminary data searches, will perform data extraction, conduct quality assessments and draft the systematic review paper. All authors contributed to the design and conception of this review. All authors approved the protocol final manuscript and will offer critical revisions for the review manuscript.

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Competing interests

The authors declare that they have no competing interests.

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Appendix A. MEDLINE Search Strategy

No.	Search Item
1	(cva$ or stroke$ or poststroke$ or post-stroke$ or post stroke$ or transient isch?emic attack$ or TIA$ or ministroke$ or ministroke$ or mini stroke$).mp.
2	(cerebrovascular$ or cerebral vascular).tw.
3	(cerebral or cerebellar or brain$ or vertebrobasilar) adj5 (infarct$ or isch?emi$ or thrombo$ or apoplexy or emboli$).tw
4	(cerebral or intracerebral or intracranial or brain$ or cerebellar or subarachnoid) adj5 (accident$ or h?emorrhag$).tw
5	1 or 2 or 3 or 4
6	Need.mp.
7	Needs.mp.
8	6 or 7
9	Support person.mp.
10	Wife.mp.
11	Wives.mp.
12	Husband*.mp.
13	Close relative*.mp.
14	Next of kin*.mp.
15	Significant other*.mp.
16	Relative*.mp.
17	Caregiver*.mp.
18	Carer*.mp.
19	Famil*.mp.
20	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21	5 and 8 and 20
22	limit 21 to (english language and humans)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	9
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-3
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	16
Support:			
Sources	5a	Indicate sources of financial or other support for the review	16
Sponsor	5b	Provide name for the review funder and/or sponsor	16
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	6-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	8-9
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9-11
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	11
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits,	11 and 20

		such that it could be repeated	
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-14
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-14
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	10-11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12-14
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	12-14
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	15
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	12-14

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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A protocol for a systematic review of quantitative and qualitative studies of the unmet needs of informal carers of stroke survivors

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A protocol for a systematic review of quantitative and qualitative studies of the unmet needs of informal carers of stroke survivors

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Abstract

Introduction: Stroke events deeply affect not only the stroke survivor but also the quality of life, and physical and psychological health of the family and friends who care for them. There is a need for further information about the unmet needs of these informal carers in order to develop support services and interventions. The primary objective of this review is to report and synthesise the research describing the unmet needs of carers of stroke survivors.

Methods and Analysis: A systematic review of quantitative and qualitative studies that report on the unmet needs of carers will be conducted. The following databases will be searched for relevant articles: MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Embase, Allied and Complementary Medicine Database (AMED), and Scopus. No publication date constraints will be applied. Studies will be limited to those published in English and conducted among humans. Eligible studies will report on the unmet needs of informal carers of stroke survivors, defined as family members, friends and other unpaid caregivers. Studies which focus on formal, clinical or medical caregivers will be excluded. A narrative synthesis of the main outcomes will be reported.

Ethics and Dissemination: This review will be submitted to a peer-reviewed journal. Our findings are expected to provide new insights into the unmet needs of stroke survivors' carers. Knowledge about the unmet needs of carers will inform the development and refinement of interventions and services to address these needs and better support carers of stroke survivors. The findings of this systematic review will be disseminated publicly and in peer-reviewed journals, and may be the topic of research presentations.

Trial registration number: CRD42017067391.

Strengths and limitations of this study

Strengths

- The inclusion of both qualitative and quantitative studies will provide more informative findings on the unmet needs of carers of stroke survivors.
- Our chosen method of analysing and synthesising qualitative and quantitative data has been tested and found effective for systematic reviews.
- The quality of the review will be strengthened by the input and involvement of multiple reviewers at each stage of the review

Limitations

- As there are few valid and reliable measures for assessing methodological rigor of qualitative research and mixed-method assessment there is a risk that flawed studies may bias the results of the systematic review.
- It is also possible that there are relevant non-English studies that will not be included in this review, therefore these findings may not be generalizable to non-English speaking populations in which there may be differing cultural unmet needs of carers of stroke survivors

INTRODUCTION

Rationale

As stroke survivors are often cognitively or physically disabled post-stroke, many require a carer to support them once discharged from acute care. Approximately 50% of people who have a stroke will require support from a carer[1], and the three most common areas that stroke survivors report needing assistance in are cognitive or emotional tasks, mobility and health care[2]. The Australian Survey of Disability, Ageing and Carers identified that 2.86 million Australians are informal carers, and 26,367 of these people have taken on the role of caregiver for someone with stroke as their main condition [3]. In England and Wales, it is estimated that 10% of the population are carers, with 60% of people becoming carers at some point[4 5]. In the United States, it is estimated that 4.35 million people are informal carers[6], and of those, 2.2 million are people who care for someone who has had a stroke[7 8]. These numbers are expected to increase with demographic changes worldwide[3 5 7], therefore it is becoming increasingly important to recognise the ongoing support needs of carers of stroke survivors.

There are a number of definitions of “carers” across stroke studies[9 10], generally they are referred to as informal, unpaid or primary carers, or as caregivers. Carers of stroke survivors may be family members, friends or other close individuals who provide physical or emotional support[10]. Informal carers (defined as people who provide unpaid care, support and/or assistance to someone in need of care) of stroke survivors are predominantly female spouses of the stroke survivor[11], and often take on a variety of complex tasks and roles, including physical, psychological, and daily living support with varying time commitments. The average time spent caring for someone with stroke has been reported to be 41 hours per week[3]. Furthermore, the replacement financial value of informal care across countries is staggering. If all hours of informal care were replaced with services purchased from formal care providers, the value would be $60.3 billion in Australia[3], £119 billion pounds in the United Kingdom[4] and $470 billion in the United States[12].

Caring for someone who has had a stroke can lead to issues and concerns for the carer, and these issues can also change over time[13]. For example, when carers must put aside their own needs to care for the stroke survivor, they can experience a sense of loss of autonomy[14]. Carers often report feeling underprepared to provide practical support following the patient's discharge from hospital, and also report feeling excluded from discharge and follow-up plans with health providers[14-16]. As a result, carers commonly experience a decline in their own physical and mental health, and a reduced quality of life[17-19]. As psychological distress is becoming increasingly common and health outcomes are declining in informal carers[20], there is a need to gain further understanding of the underlying mechanisms behind the unique unmet needs of informal carers of stroke survivors.

Unmet needs refer to a need that has not been satisfied yet. Carer needs often relate to inadequate information and resources, such as receiving information on stroke management and recovery, and/or how to contact a health care professional who could offer them psychological or emotional support[21 22]. Research suggests unmet needs result in adverse outcomes, such as increased burden, and depression and anxiety, for carers of those with disabilities and chronic illness[19 22-24]. Greenwood et al.[11] systematically reviewed qualitative studies investigating the challenges, satisfactions and coping strategies of carers of stroke survivors. The studies in the review described difficulties such as uncertainty, informational/training needs, and role and relationship changes of carers of stroke survivors. Unmet needs are an extremely important area of research, and it is becoming increasingly important to address these unmet needs to ensure the health and wellbeing of carers, and the people that they care for.

While there are interventions designed to address the unmet needs of carers of stroke survivors, research suggests the interventions require further evaluation, development and refinement to target these outcomes. A systematic review conducted by Eldred[25] investigating psychosocial interventions for carers of survivors of stroke found that interventions are failing to address carer depression, loneliness and stress, while there has been some success with interventions that use counselling and education to promote coping and adjustment to the carer role. In these studies, unmet psychological needs (such as depression) were directly reported by carers using validated measures of psychological health outcomes. These findings highlight the need to develop effective psychological interventions targeting the psychosocial functioning of carers of stroke survivors. A systematic review by Aldehaim et al.[26] focused on technology-based interventions for carers of stroke survivors. Only one study of the five studies eligible for review assessed carer preparedness for the caring role, a known unmet need identified by carers of stroke survivors[27-30]. That review emphasized the need for interventions to be provided to carers of stroke survivors as soon as possible as a strategy to address unmet needs. The limitations of interventions for carers of stroke survivors include: (1) not being delivered to carers after the stroke survivor is discharged home; (2) not providing appropriate interventions to the changing needs of carers through the stroke survivors' transition from home, to hospital and eventually the community; and (3) not targeting appropriate unmet needs outcomes for informal carers, including preparedness and psychosocial functioning, and unique unmet needs for carers of stroke survivors such as support with possible communication and mobility issues.

There are currently no systematic reviews examining the unmet needs of carers of stroke survivors in both qualitative and quantitative studies. Thus, this review aims to:

1) Define and identify the unmet needs of carers of stroke survivors
2) Define the variables associated with unmet needs of carers of stroke survivors

3) Report the prevalence of unmet needs identified in quantitative studies
4) Thematically analyse qualitative data to report meaningful patterns and themes of unmet needs of carers of stroke survivors
5) Synthesise quantitative and qualitative research on the unmet needs of carers of stroke survivors to guide the development of interventions and services to support carers of stroke survivors.

METHODS AND ANALYSES

Study Design

We will conduct a systematic review of studies reporting on unmet needs of informal carers of stroke survivors. These studies will be published in English and have no publication year limit. Qualitative and quantitative studies will be included and synthesised in this review. This systematic review protocol will conform with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P)[31 32] and will be reported in accordance with the (PRISMA) statement[33 34].

Study Registration

Based on the PRISMA-P guidelines[31], this systematic review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO) in July 2017: CRD42017067391.

Eligibility criteria

Types of studies

To be eligible for this systematic review, manuscripts must be published in a peer-reviewed journal and report primary data on the unmet needs self-reported by carers of stroke survivors. The needs of carers reported by others (such as the stroke survivors or by health professionals) will be excluded. English language qualitative, quantitative and mixed methods studies will be included. Intervention studies will be included if they report the baseline estimates of carers' unmet needs.

Participants

Carers of stroke survivors are defined as the spouse or partner, family members, friends or 'significant others' who provide unpaid physical, practical or emotional support to someone after their stroke event. Stroke survivors will be defined as an individual who has experienced a stroke event. Studies which report on mixed populations, such as reporting on carers' and stroke survivors' unmet needs, will be included in full text review to investigate if the carers of stroke survivors' data can be extracted separately. Studies will be included if carers provide information related to their unmet needs at any stage of caring for someone following a stroke. Manuscripts that only report on professional carers (doctors, nurses, healthcare providers and others) will be excluded.

Measures

Quantitative and qualitative studies that report any unmet needs of carers of stroke survivors will be included. Quantitative studies may include self-report surveys. Qualitative studies may include interviews and focus groups. We aim to (1) quantify the proportion of carers of stroke survivors reporting unmet needs in various domains and subcategories; (2) categorise carers of stroke survivors' unmet needs by domain; and (3) identify the main variables associated with reporting more unmet needs in carers of stroke survivors.

Unmet needs domains of carers of stroke survivors will be based on Lambert et al[35] which investigated the unmet needs of carers of adult cancer patients. These include unmet needs relating to changes in role and relationship(s), and informational unmet needs, such as preparedness in caring for someone with a chronic illness, and comprehensive knowledge of the condition. As carers of stroke survivors may also have unique needs that differ from being a carer of cancer survivors, other themes that emerge will also be analysed. These needs may include managing the loss of mobility[36], language[37] and mood/personality changes[38] as these changes are common following a stroke event.

Search Strategy

'Stroke' terms based on a Cochrane Review[39] will be developed. 'Needs' and 'Partners and Caregivers' terms will be based on a systematic review of unmet needs of partners and caregivers diagnosed with cancer[24]. In May 2017, a search strategy was developed on the MEDLINE database and then adapted for the other databases. This included medical subject headings (MeSH) and free-text terms using applicable controlled vocabulary. The following electronic databases will be searched: Medline, PsycINFO, EMBASE, Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Scopus and Cochrane Database. Furthermore, the reference lists of included studies or identified relevant reviews will be searched. There will be no time limits on publications for the search strategy. Studies will be limited to those conducted among human subjects and published in English. Reference lists of included studies and relevant systematic reviews will be searched to identify additional studies for potential inclusion in this systematic review. The search terms for MEDLINE can be found in Supplementary Appendix A.

Screening the studies

Search results will be entered into Endnote folders, and any duplicates will be removed. The online tool Covidence[40] will be used by reviewers to produce high-quality evidence for the systematic review. A flow diagram conforming to PRISMA guidelines[33] will report the selection process and reasons for exclusion. All titles of retrieved publications will be screened by one reviewer. Two reviewers will independently screen all abstracts, full text and data extraction. The two will meet to resolve any issues, and if a decision cannot be made, a third reviewer will be contacted to make the final decision.

Data extraction

Data will be extracted by one reviewer, tabled, and checked for accuracy by another reviewer. The two reviewers will discuss these findings and themes, and if a discrepancy exists and a consensus cannot be reached, a third reviewer will be contacted to make the final decision. Data extracted from the quantitative studies will be extracted and analysed. Data from the qualitative, quantitative and mixed-method studies will be integrated in a systematic way. Common data extracted from the articles will include: study aims, setting, sample characteristics, response rates, study methodology, data analysis, primary outcomes and the unmet needs domains identified. Data extraction tables will be based on Lambert et al.'s research of the unmet needs of carers of adults with cancer[35].

Quality appraisal

Qualitative Studies

The methodological quality of qualitative studies will be assessed using the Critical Appraisal Skills Programme (CASP)[41]. This quality assessment tool was cited by Aziz et al.[9] in the protocol for a systematic review in understanding stroke survivors' and informal carers' experiences of and need for primary care and community health services. The CASP tool is a 10-item tool that allows rapid evaluation of the credibility, transferability, dependability and conformability of the qualitative studies. Two reviewers will assess the methodological quality of all studies, and if an agreement cannot be reached, a third reviewer will make the final decision.

Quantitative studies

The methodological quality of quantitative studies will be assessed based on Greenwood et al[11] who performed a systematic review of the quantitative studies focused on factors influencing informal carers of stroke survivors. This quality assessment tool assesses six areas (1) statement of inclusion or exclusion criteria of carers; (2) clear hypotheses/hypothesis; (3) response rate reported or possible to calculate; (4) multivariate analysis/possible control for confounders; (5) full definition of carer provided (including spouse as the definition; and (6) timing of assessment similar for all participants. Studies are either scored “Yes” with a value of 1, or “No” with a value of 0. Scores are rated on a 6-point scale: a score of 6 indicates a maximum score, whereas a score 0 indicates a minimum score.

Mixed-method studies

The methodological quality of mixed-method studies will be assessed by using the CASP[41] on qualitative components, and the methodological assessment developed by Greenwood et al.[11] where appropriate regarding quantitative components.

Data analysis

Qualitative studies

Qualitative data will be thematically analysed using the qualitative research software NVivo[42]. Reviewers will develop descriptive themes through interpretation of the meaningful patterns in the qualitative research. Codes for unmet needs domains will be assigned to meaning within the text, and these codes will be compared between studies. Two reviewers will discuss these meanings, and a third reviewer will be consulted if an agreement cannot be reached.

Quantitative studies

The data analysis of quantitative studies in this review will be based on Lambert et al[35]. Results across quantitative studies will be pooled and the prevalence of unmet needs will be compiled. Unmet needs domains will be categorised and the factors associated within them will be examined. Where reported, the average number of unmet needs will be reported. To facilitate comparison across studies and where appropriate, averages will be standardised from 0 to 100. Comparable unmet needs will be combined and clustered into domains. Two reviewers will discuss these outcomes, and a third reviewer will be consulted if a decision cannot be reached.

Mixed-method studies

The data of mixed-method studies will be analyzed appropriately. Qualitative components will be analyzed using NVivo[42], and quantitative components will be based on the data analysis reported by Lambert et al[35].

DISCUSSION

Evidence from this systematic review of unmet needs of carers of stroke survivors will inform the development of interventions and services to address these needs. We will deliver evidence-based recommendations including consideration of the unmet needs of carers of stroke survivors in future research, and the refinement and development of interventions and services for this population. These recommendations may improve carer preparedness for their new caregiving role, and also assist in supporting carers across all time points of caring for a person who has survived a stroke. These improvements may subsequently improve the quality of life of carers by assisting carers to manage their own needs, mental and physical health, and increase their knowledge in providing physical, emotional and practical care for the stroke survivor. To our knowledge, this will be the first study to systematically synthesize qualitative and quantitative information regarding the unmet needs of carers of stroke survivors.

Strengths and limitations

The findings of this systematic review are dependent on the quality of original studies that will be reviewed. As there are few valid and reliable measures for assessing methodological rigor of qualitative research [43] and mixed-method assessment [44] there is a risk that flawed studies may bias the results of the systematic review. To minimise this, reviewers will independently review studies and communicate effectively if disagreements occur. It is also possible that there are relevant non-English studies that will not be included in this review. As such, these findings may not be generalizable to non-English speaking populations, in which there may be differing cultural unmet needs of carers of stroke survivors.

The quality of the review will be strengthened by the input and involvement of multiple reviewers at each stage of the review. Furthermore, the inclusion of both qualitative and quantitative studies will provide more informative findings on the unmet needs of carers of stroke survivors. Our chosen method of analysing and synthesising qualitative and quantitative data has been tested and found effective for systematic reviews [45]. The findings of this systematic review will be disseminated publicly and in peer-reviewed journals, and may be the topic of research presentations.

Amendments

If the protocol needs to be amended, the date of each amendment, the change and the rationale will be described in this section.

Contributorship Statement

AMJD is the guarantor of the review. AMJD, ALB, NS, AG, OW, AT, PM and BB assisted in writing the protocol. AMJD performed preliminary data searches, will perform data extraction, conduct quality assessments and draft the systematic review paper. All authors contributed to the design and conception of this review. All authors approved the protocol final manuscript and will offer critical revisions for the review manuscript.

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Competing interests

The authors declare that they have no competing interests.

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Supplementary Appendix A. MEDLINE Search Strategy

No.	Search Item
1	(cva$ or stroke$ or poststroke$ or post-stroke$ or post stroke$ or transient isch?emic attack$ or TIA$ or ministroke$ or ministroke$ or mini stroke$).mp.
2	(cerebrovascular$ or cerebral vascular).tw.
3	(cerebral or cerebellar or brain$ or vertebrobasilar) adj5 (infarct$ or isch?emi$ or thrombo$ or apoplexy or emboli$).tw
4	(cerebral or intracerebral or intracranial or brain$ or cerebellar or subarachnoid) adj5 (accident$ or h?emorrhag$).tw
5	1 or 2 or 3 or 4
6	Need.mp.
7	Needs.mp.
8	6 or 7
9	Support person.mp.
10	Wife.mp.
11	Wives.mp.
12	Husband*.mp.
13	Close relative*.mp.
14	Next of kin*.mp.
15	Significant other*.mp.
16	Relative*.mp.
17	Caregiver*.mp.
18	Carer*.mp.
19	Famil*.mp.
20	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21	5 and 8 and 20
22	limit 21 to (english language and humans)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	9
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-3
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	16
Support:			
Sources	5a	Indicate sources of financial or other support for the review	16
Sponsor	5b	Provide name for the review funder and/or sponsor	16
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	6-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	8-9
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	9-11
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	11
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits,	11 and 20

		such that it could be repeated	
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-14
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-14
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	10-11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12-14
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	12-14
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	15
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	12-14

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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